Beyond Enterprise Liability in DES Cases—*Sindell*

I. Introduction

Throughout the development of tort law, the concept of causation has occupied differing levels of significance as a justification for the assessment of liability. Theories of liability have developed which have gradually expanded the continuum of possible relationships in which causation can be established.[1] In 1980, the California Supreme Court in *Sindell v. Abbott Laboratories*[2] further extended the realm of potential causal relationships. The plaintiff in *Sindell* was allegedly injured by a drug ingested by her mother and, being unable to identify the manufacturer of the drug, brought suit against several of the manufacturers.[3] Each defendant was held liable under a market share liability theory.[4] In so holding, the California Supreme Court rejected the more traditional theories of tort liability and moved one step forward on the spectrum of causal relationships.

The purpose of this Note is to explain the market share theory of liability and to discuss its potential effects on similar parties in future litigation.

II. Historical Backgrounds of *DES*

Between the years 1947 and 1971, diethylstilbestrol (DES) was manufactured and marketed by the drug industry for the purpose of preventing miscarriages in pregnant women.[5] Diethylstilbestrol, a synthetic compound of the female hormone estrogen,[6] was first authorized on an experimental basis and with the requirement of a warning on the label by the Food and Drug Administration for prevention of miscarriages in 1947.[7] In 1952, the Food and Drug Ad-

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[1] *See generally* Hall v. E.I. DuPont de Nemours & Co., 345 F. Supp. 353 (E.D.N.Y. 1972); Henningsen v. Bloomfield Motors, Inc., 32 N.J. 358, 161 A.2d 69 (1960); Klemme, *The Enterprise Liability Theory of Torts*, 47 U. Colo. L. Rev. 153 (1976).

[2] 26 Cal. 3d 588, 607 P.2d 924, 163 Cal. Rptr. 132, *cert. denied*, 101 S.Ct. 268 (1980).

[3] *Id.* at 593, 607 P.2d at 925, 163 Cal. Rptr. at 133.

[4] *Id.* at 612, 607 P.2d at 937, 163 Cal. Rptr. at 145.

[5] *E.g.*, *id.* at 593, 607 P.2d at 925, 163 Cal. Rptr. at 133; Comment, *DES and a Proposed Theory of Enterprise Liability*, 46 Fordham L. Rev. 963, 963-64 (1978) [hereinafter cited as Fordham Comment].

[6] *E.g.*, 26 Cal. 3d at 593, 607 P.2d at 925, 163 Cal. Rptr. at 133; Affidavit of Don Carlos Hines, M.D., at 3, Payton v. Abbott Labs., No. 76-1514-S (D. Mass., questions certified Jan. 15, 1981); Affidavit of A. Brian Little, M.D., at 4, Payton v. Abbott Labs., No. 76-1514-S (D. Mass., questions certified Jan. 15, 1981).

[7] 26 Cal. 3d at 593, 607 P.2d at 925, 163 Cal. Rptr. at 133.

ministration (FDA) considered DES no longer to be a "new drug,"[8] thus removing the inference that the drug was "not generally recognized as . . . safe"[9] and allowing additional producers to manufacture the drug without conducting further testing of the drug's safety.[10] In 1971, however, because of a possible connection between the ingestion of DES by pregnant women and cancerous or precancerous conditions in the daughters of these women, the FDA required drug companies to delete pregnancy uses from their product literature and labeling and to add specific warnings against the administration of estrogens to pregnant women.[11] The form of cancer linked to DES use is adenocarcinoma which manifests itself after a minimum latent period of ten to twelve years and which causes cancerous vaginal and cervical growths in women.[12]

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[8]Petition for Rehearing at 28 n.10, Sindell v. Abbott Labs., 85 Cal. App. 3d 1, 149 Cal. Rptr. 138 (1978) [hereinafter cited as *Sindell*, Petition for Rehearing].

[9]21 U.S.C. § 321(p)(1) (1976).

[10]*Sindell*, Petition for Rehearing, *supra* note 8, at 16. It is extremely difficult to determine how many drug companies actually manufactured DES or a similar generic compound. In an interview with an attorney for a drug company which has been a defendant in several DES cases, however, one list of 294 drug companies was presented. The companies were believed to have manufactured or distributed five milligrams or larger dosages of DES and related congeners at some time within a span of approximately 30 years from the early 1940's to the early 1970's.

In another DES case, Payton v. Abbott Labs., No. 76-1514-S (D. Mass., questions certified Jan. 15, 1981), the affidavit of one doctor includes a list of 83 companies which had effective New Drug Applications to market DES or its congeners in 1952, a list of 118 companies which had manufactured or distributed DES or its congeners in 1952, and a list of 118 trade names for DES and its congeners. Affidavit of Jerome M. Maas, M.D., Exhibits A, B, & C, Payton v. Abbott Labs., No. 76-1514-S (D. Mass., questions certified Jan. 15, 1981).

[11]U.S. FOOD AND DRUG ADMINISTRATION, DEP'T OF HEALTH, EDUCATION, AND WELFARE, DRUG BULL., DIETHYLSTILBESTROL CONTRAINDICATED IN PREGNANCY (Nov. 1971).

[12]The leading publication is Herbst, Ulfelder and Poskanzer, *Adenocarcinoma of the Vagina*, 284 NEW ENGLAND J. OF MED. 878 (1971). The Herbst Report, however, does not show a definite causal relation between DES ingestion and adenocarcinoma in the daughters, but rather only a statistical association. Further, Dr. Herbst later reported that there are probably other factors associated with the occurrence of adenocarcinoma other than DES ingestion by the mother. Interview, *DES Update*, 30 CA-A CANCER J. FOR CLINICIANS 326, 331 (Nov./Dec. 1980).

Another condition in offspring associated with the use of DES is adenosis, a nonmalignant presence of glandular tissue in the vagina. Affidavit of Ann Brace Barnes, M.D., at 5, Payton v. Abbott Labs., No. 76-1514-S (D. Mass., questions certified Jan. 15, 1981). There is evidence establishing that adenosis is not transformed into cancer and that the condition in many instances disappears spontaneously. *See, e.g.*, Ng, Reagan, Nadji, & Greenberg, *Natural History of Vaginal Adenosis in Women Exposed to Diethylstilbestrol* in Utero, 18 J. OF REPRODUCTIVE MED. 1 (1977).

Affidavits of nine distinguished physicians in *Payton v. Abbott Labs.* show that prior to the Herbst Registry in 1971 no publication was available showing any association between DES use in pregnant women and cancer in their offspring.

The litigation arising from suits brought by the injured daughters against the drug manufacturers has presented the courts with some difficult and significant issues. Because of the time span between the manufacturing, purchasing, and ingestion of the DES and the resulting injury, many women are unable to trace the drug back to its specific manufacturer.[13] Class actions against groups of the chemical corporations which manufactured DES are the result.[14]

In March of 1980, the first DES case to reach a state supreme court was decided. The case, *Sindell v. Abbott Laboratories*,[15] was a consolidation of two class actions brought against eleven drug companies as representatives of drug manufacturers which sold DES after 1941.[16] The plaintiff class represented by Sindell, the first named plaintiff, consisted of "girls and women who [were] residents of California and who [had] been exposed to DES before birth and who may or may not [have known] that fact or the dangers to which they [had been] exposed."[17] The plaintiff class represented by Rogers, the other named plaintiff, was substantially the same as that represented by Sindell,[18] but the court stated that the discussion in its opinion would apply to Rogers only if she did not succeed in establishing that one specific defendant had manufactured the DES taken by her mother.[19] Reversing the superior courts,[20] the California Supreme Court held that each defendant would be liable for the proportion of the judgment represented by its share of the DES market unless it proved that it could not have been the manufacturer of the drug which caused the plaintiff's injuries.[21]

By the time the case reached the California Supreme Court, several causes of action were alleged in the complaint. Under the first cause of action, the plaintiffs claimed that the defendants were "jointly and individually negligent in that they manufactured,

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[13]*E.g.*, Gray v. United States, 445 F. Supp. 337 (S.D. Tex. 1978); Sindell v. Abbott Labs., 26 Cal. 3d 588, 607 P.2d 924, 163 Cal. Rptr. 132, *cert. denied*, 101 S.Ct. 268 (1980); McCreery v. Eli Lilly & Co., 87 Cal. App. 3d 77, 150 Cal. Rptr. 730 (1978); Abel v. Eli Lilly & Co., 94 Mich. App. 59, 289 N.W.2d 20 (1979); Bichler v. Eli Lilly & Co., No. 15600-1974 (Sup. Ct. N.Y. 1979).

[14]*E.g.*, Gray v. United States, 445 F. Supp. 337 (S.D. Tex. 1978); Sindell v. Abbott Labs., 26 Cal. 3d 588, 607 P.2d 924, 163 Cal. Rptr. 132, *cert. denied*, 101 S.Ct. 268 (1980); McCreery v. Eli Lilly & Co., 87 Cal. App. 3d 77, 150 Cal. Rptr. 730 (1978); Abel v. Eli Lilly & Co., 94 Mich. App. 59, 289 N.W.2d 20 (1979); Bichler v. Eli Lilly & Co., No. 15600-1974 (Sup. Ct. N.Y. 1979).

[15]26 Cal. 3d 588, 607 P.2d 924, 163 Cal. Rptr. 132, *cert. denied*, 101 S.Ct. 268 (1980).

[16]*Id.* at 593 n.1, 607 P.2d at 925 n.1, 163 Cal. Rptr. at 133 n.1.

[17]*Id.*

[18]*Id.* at 596, 607 P.2d at 927, 163 Cal. Rptr. at 135.

[19]*Id.* at 597, 607 P.2d at 927, 163 Cal. Rptr. at 135.

[20]*Id.* at 613, 607 P.2d at 938, 163 Cal. Rptr. at 146.

[21]*Id.* at 612, 607 P.2d at 937, 163 Cal. Rptr. at 145.

marketed, and promoted DES as a safe and efficacious drug to prevent miscarriage, without adequate testing or warning, and without monitoring or reporting its effects."[22] A second cause of action alleged that the defendants were jointly liable because they collaborated in marketing and testing the drugs and because they adhered to an industry-wide safety standard.[23] Other causes of action included strict liability, conspiracy, and violation of express and implied warranties.[24] The common factor in all of these causes of action was the allegation that each defendant acted in concert with the other defendants on the basis of express and implied agreements and in reliance on the testing and marketing methods of the other defendants.[25] The plaintiff sought $1 million in compensatory damages and $10 million in punitive damages for herself, and equitable relief for her class in the form of an order forcing the defendants to warn of the danger of DES and to establish free clinics in California to perform tests to establish the presence of the disease.[26]

III. A Rejection of Traditional Theories

The novelty and importance of *Sindell* arises from the court's rejection of the traditional theories of tort liability in preference to a "market share" theory.[27] Before analyzing the possible effects that this new liability theory may have on similar parties in future litigation, a brief explanation of the more traditional theories is needed.[28] The court in *Sindell*, before adopting its own basis for allowing liability under the allegations of the plaintiff's complaint, discussed two more traditional theories.

The first of these is often called the alternative liability theory and is exemplified by *Summers v. Tice*.[29] The rule established in *Summers* applies when a party cannot identify which of two or more defendants caused an injury. The burden of proof of causation may then shift to the defendants to show that they were not responsible for the harm. In *Summers*, also decided by the California Supreme Court, the plaintiff had been injured when two hunters negligently shot in his direction,[30] and, as in *Sindell*, the plaintiff was unable to

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[22]*Id.* at 595, 607 P.2d at 926, 163 Cal. Rptr. at 134.

[23]*Id.*

[24]*Id.*

[25]*Id.*

[26]*Id.*

[27]*Id.* at 598, 607 P.2d at 928, 163 Cal. Rptr. at 136.

[28]For a more detailed explanation of the theories rejected by the *Sindell* court and of their applicability to DES cases, see FORDHAM Comment, *supra* note 5.

[29]33 Cal. 2d 80, 199 P.2d 1 (1948).

[30]*Id.* at 81, 199 P.2d at 2.

identify which of the defendants actually fired the injury-causing shot.[31] Both defendants were held jointly and severally liable.[32] In *Sindell*, the court stated that its reasoning in *Summers* had been based on the negligence of both defendants to the plaintiff and on the unfairness of forcing the plaintiff to isolate the defendant whose shot actually injured him.[33] Deciding that under these circumstances the defendant was in a better position to offer evidence to determine whether he or another defendant caused the injury, the *Sindell* court stated, "In these circumstance [*Summers*], we held, the burden of proof shifted to the defendants, 'each to absolve himself if he can.' "[34]

The *Sindell* court explained that the logic in *Summers* had been drawn from cases such as *Ybarra v. Spangard*,[35] in which the doctrine of res ipsa loquitur was used to imply an inference of negligence which the defendants were required to rebut.[36] In *Ybarra*, the plaintiff allegedly suffered an injury while he was unconscious during the course of surgery,[37] and again the court found that the plaintiff need not identify which defendant was responsible for the injury when the plaintiff was in no position to attain such knowledge.[38]

The defendants in *Sindell* argued that they did not have greater access than did the plaintiff to information regarding the cause of injury, but rather that the converse was true and that the *Summers* doctrine could therefore not be applied.[39] Although the language of both *Ybarra* and *Summers* implies the superior ability of the defendants to identify the specific instrumentality which injured the plaintiff, the *Sindell* court held that under *Summers* greater access by the defendants to information regarding the cause of injury was not a prerequisite to shifting the burden of proof of causation from the plaintiff to the defendant.[40] The alternative liability theory developed in *Summers*, however, was nonetheless rejected in *Sindell*.[41]

The fatal defect of the theory was the impossibility of joining all of the defendants in *Sindell*.[42] In *Summers*, there had been only two

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[31] *Id.*

[32] *Id.* at 84, 199 P.2d at 5.

[33] 26 Cal. 3d at 599, 607 P.2d at 928, 163 Cal. Rptr. at 136.

[34] *Id.* (quoting Summers v. Tice, 33 Cal. 2d at 86, 199 P.2d at 4).

[35] 25 Cal. 2d 486, 154 P.2d 687 (1944).

[36] 26 Cal. 3d at 599, 607 P.2d at 928-29, 163 Cal. Rptr. at 137.

[37] 25 Cal. 2d at 487, 154 P.2d at 688.

[38] *Id.* at 488, 154 P.2d at 690-91.

[39] *Sindell*, Petition for Rehearing, *supra* note 8, at 33-35.

[40] 26 Cal. 3d at 602, 607 P.2d at 930, 163 Cal. Rptr. at 138.

[41] *Id.*

[42] *Id.* at 602, 607 P.2d at 930-31, 163 Cal. Rptr. at 138-39.

people who were or could have been responsible for the plaintiff's injuries, and both were defendants in the lawsuit. In *Sindell*, however, there were approximately 200 drug companies which could have manufactured the drug taken by the plaintiff's mother,[43] and only five of the companies remained as defendants in the appeal.[44] The court noted that the existing *Summers* rule as embodied in the Restatement (Second) of Torts allowed the burden of proof to shift to the defendants only if the plaintiff could demonstrate that all of the defendants acted tortiously and that the harm resulted from the conduct of one of them.[45] The rule could not, therefore, fairly be applied in *Sindell* because "there [was] no rational basis upon which to infer that any defendant in this action caused plaintiff's injuries, nor even a reasonable possibility that they were responsible."[46]

The second traditional theory, the concert of action theory, applies when the defendants act pursuant to a common design to injure the plaintiff. While no express agreement among the defendants is required under this theory, at least a tacit understanding is necessary.[47] This theory of liability was also rejected in *Sindell*.[48] In defining the elements necessary to allow a recovery under concert of action, the *Sindell* court quoted section 876 of the Restatement (Second) of Torts which provides:

> For harm resulting to a third person from the tortious conduct of another, one is subject to liability if he (a) does a tortious act in concert with the other or pursuant to a common design with him, or (b) knows that the other's conduct constitutes a breach of duty and gives substantial assistance or encouragement to the other so to conduct himself, or (c) gives substantial assistance to the other in accomplishing a tortious result and his own conduct, separately considered, constitutes a breach of duty to the third person.[49]

The allegations of the complaint which charged the defendants with failure to adequately test the drug, failure to warn of its dangers, and reliance on the testing and marketing methods of the other

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[43]*Id.* at 602-03, 607 P.2d at 931, 163 Cal. Rptr. at 139.

[44]*Id.* at 596, 607 P.2d at 926, 163 Cal. Rptr. at 134. While the original complaint was against 11 drug companies, the action had been dismissed or the appeal abandoned as to the other six defendants. *Id.* at 597 n.4, 607 P.2d at 927 n.4, 163 Cal. Rptr. at 135 n.4.

[45]*Id.* at 603 n.16, 607 P.2d at 931 n.16, 163 Cal. Rptr. at 139 n.16 (construing RESTATEMENT (SECOND) OF TORTS § 433B, Comment g at 446 (1965)).

[46]26 Cal. 3d at 603, 607 P.2d at 931, 163 Cal. Rptr. at 139.

[47]W. PROSSER, HANDBOOK OF THE LAW OF TORTS § 46, at 292 (4th ed. 1971).

[48]26 Cal. 3d at 605, 607 P.2d at 932, 163 Cal. Rptr. at 140.

[49]RESTATEMENT (SECOND) OF TORTS § 876 (1965), *quoted in* 26 Cal. 3d at 604, 607 P.2d at 932, 163 Cal. Rptr. at 140.

defendants were found insufficient to satisfy the necessary elements.[50] The court emphasized that using the experience and methods of others is a common practice in industry and that it would be unfair to find that the defendants acted in concert merely by their use of the same drug with different trade names when the formula for DES is a "scientific constant . . . and any manufacturer producing the drug must . . . utilize the formula set forth in [the United States Pharmacopoeia]. (21 U.S.C. § 351, subd. (b).)"[51]

Having rejected the two traditional theories of tort liability, the court next considered the third theory under which the plaintiff tried to recover—enterprise liability. Although generally considered to be less traditional than the alternative liability theory and the concert of action theory, enterprise liability has gained recognition as a valid theory of tort liability.[52] Enterprise liability has been defined as "the notion that losses should be borne by the doer, the enterprise, rather than distributed on the basis of fault,"[53] and thus by its definition, enterprise liability differs from the traditional tort theories based on fault.[54] This industry-wide liability theory, however, was also rejected in *Sindell*.[55] The court set forth the following reasons explaining the inapplicability of enterprise liability to the

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[50]26 Cal. 3d at 605, 607 P.2d at 932, 163 Cal. Rptr. at 140.

[51]*Id.* at 605, 607 P.2d at 933, 163 Cal. Rptr. at 142.

[52]The *Sindell* court stated that enterprise liability was "suggested in" Hall v. E.I. DuPont de Nemours & Co., 345 F. Supp. 353 (E.D.N.Y. 1972). 26 Cal. 3d at 607, 607 P.2d at 933-34, 163 Cal. Rptr. at 141-42. *Hall* was an action brought by 13 children injured by the explosions of blasting caps in 12 separate incidents in 10 different states. 345 F. Supp. at 359. In a footnote by the *Sindell* court, the choice of the phrase "was suggested" is explained as reflecing the court's uncertainty of the validity of *Hall* as authority because of a severance and transference of the plaintiffs' claims to federal court with resulting judgments based on grounds unrelated to industry-wide liability. 26 Cal. 3d at 607 n.22, 607 P.2d at 934 n.22, 163 Cal. Rptr. at 142 n.22.

However, regardless of the authoritative value of *Hall*, enterprise liability did not magically appear from one case. For excellent discussions of the development of enterprise liability, see Calabresi, *Some Thoughts on Risk Distribution and the Law of Torts*, 70 YALE L. J. 499, 500-07 (1961) [hereinafter cited as Calabresi, *Risk Distribution*] and Klemme, *supra* note 1, at 176-78.

[53]Calabresi, *Risk Distribution*, *supra* note 52, at 500.

[54]Courts have found the principles of enterprise liability inherent in cases of respondeat superior, workmen's compensation, dangerous activities, and nondelegable duties. *Hall*, 345 F. Supp. at 376-77. In these situations an employer is held vicariously liable, not because of fault but because the risks involved are broadly incidental to the enterprise undertaken. 2 F. HARPER & F. JAMES, THE LAW OF TORTS § 26.7, at 1376 (1956). The loss falls on the manufacturer rather than on the consumer because of the responsibility which the manufacturer owes to the community. *See* W. PROSSER, *supra* note 47, § 71, at 471.

Whether this responsibility extends beyond the individual manufacturer to the industrial entity is necessarily based on a public policy decision of where the risk of loss best be laid. 345 F. Supp. at 378.

[55]26 Cal. 3d at 609, 607 P.2d at 935, 163 Cal. Rptr. at 143.

Sindell fact situation: (1) the large number of manufacturers of DES; (2) the lack of allegations of any trade association to which the defendants had delegated any safety functions and which would, therefore, have evidenced a joint controlling of the risk; and (3) the close regulation of testing and manufacturing of drugs by the FDA.[56]

If the court had been confined to these three theories of liability, the plaintiff's complaint in *Sindell* would not have stated a sufficient cause of action.[57] The *Sindell* court, however, reversed the lower court's judgment sustaining the defendant's demurrers and, by combining aspects of alternative liability and enterprise liability, developed a fourth theory of liability. This hybrid theory would hold each defendant liable for the proportion of the judgment represented by its share of the DES market, absent any proof by an individual defendant that it could not have manufactured the injury-causing drug.[58]

IV. Causation Under the Market Share Liability Theory

To understand the implications of the market share theory, it must be realized that the problem presented by the DES cases is mainly one of causation. The solution reached by the court in *Sindell* attempts to reconcile the inability of innocent plaintiffs similar to Sindell to recover from anyone other than the manufacturer[59] with

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[56]*Id.* These three factors point out the differences between *Hall* and *Sindell*. In *Hall*, the court placed emphasis on the relatively small number of manufacturers in the blasting cap industry, 345 F. Supp. at 378, (as opposed to 200 manufacturers of DES); the defendants in *Hall* had delegated safety functions to a trade association, 345 F. Supp. at 367; and the blasting cap industry was not strictly regulated by an agency such as the FDA.

[57]26 Cal. 3d at 610, 607 P.2d at 936, 163 Cal. Rptr. at 144. Other DES cases which disagree with the *Sindell* court's finding of an insufficient cause of action under the three theories of liability will be discussed later. *See* note 89 *infra* and accompanying text.

[58]26 Cal. 3d at 612, 607 P.2d at 937, 163 Cal. Rptr. at 145.

[59]Bichler v. Eli Lilly & Co., No. 15600-1974 (Sup. Ct. N.Y. 1979) is another DES case which illustrates the difficulty of a plaintiff similarly situated to Sindell in bringing a suit against someone other than the manufacturer of the drug. The plaintiff, a woman who had taken DES during pregnancy, brought an action against a manufacturer, the doctor who prescribed the drug, and a hospital. In a second action, she also brought charges against the pharmacist who provided her with the drug. Bichler v. Willing, Index No. 7799/75. On an appeal from a denial of the pharmacist's motion for summary judgment, the claim against the pharmacist alleging negligence, strict liability, and breach of warranty was dismissed. Bichler v. Willing, 58 A.D.2d 331, 397 N.Y.S.2d 57 (1977), *appeal dismissed*, (May 12, 1978).

The claim against the hospital was heard by a medical malpractice board which unanimously found for the hospital, and the claim against the hospital was discontinued. Brief of Defendant at 6, Bichler v. Eli Lilly & Co., No. 15600-1974 (Sup. Ct. N.Y. 1979). After the case against the doctor was dismissed, only the manufacturer remained as a defendant in the final case.

the questionable justice of holding the manufacturer liable when there has been no proof of causation showing their drug to have been ingested by the plaintiff's mother. Reiterating its rejection of an unmodified *Summers* rationale, the *Sindell* court recognized that if the chance that any particular defendant produced the injury-causing drug were measured, there would be a significant possibility, perhaps even a probability, that none of the five companies named as defendants had manufactured the drug and that one of the other 200 companies not named as defendants had actually produced the injury-causing drug. The company which actually "caused" the injury would thus escape liability.[60] The court, however, chose to approach the issue of causation from a different perspective and held that it would be "reasonable . . . to measure the likelihood that any of the defendants supplied the product which allegedly injured plaintiff by the percentage which the DES sold by each of them for the purpose of preventing miscarriage bears to the entire production of the drug sold by all for that purpose."[61] This view of causation would make each manufacturer's liability "approximate its responsibility for the injuries caused by its own products."[62] The court explained this rationale as follows:

> "[I]f X Manufacturer sold one-fifth of all the DES prescribed for pregnancy and identification could be made in all cases, X would be the sole defendant in approximately one-fifth of all cases and liable for all the damages in those cases. Under alternative liability, X would be joined in all cases in which identification could not be made, but liable for only one-fifth of the total damages in these cases. X would pay the same amount either way. Although the correlation is not, in practice, perfect . . . , it is close enough so that defendants' objections on the ground of fairness lose their value."[63]

Thus, the court's analysis of causation is taken from alternative liability, but has expanded the *Summers* rule to include an entire industry, as in enterprise liability, in the range of those who may be held liable, even though all manufacturers are not joined as defendants. In discussing enterprise liability, the *Sindell* court relied heavily on a law review comment[64] which suggested the application of enterprise liability to DES cases. Although the court refused to apply this doctrine as set forth in the comment and relied mainly on a

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[60]26 Cal. 3d at 611, 607 P.2d at 936-37, 163 Cal. Rptr. at 144-45.

[61]*Id.* at 611-12, 607 P.2d at 937, 163 Cal. Rptr. at 145.

[62]*Id.* at 612, 607 P.2d at 937, 163 Cal. Rptr. at 145.

[63]*Id.* at 612 n.28, 607 P.2d at 937 n.28, 163 Cal. Rptr. at 145 n.28.

[64]FORDHAM Comment, *supra* note 5.

modification of the *Summers* rule, there are parallels between enterprise liability and market share liability which strongly suggest a very close correlation between the two theories.

One such parallel is the philosophy upon which the theories are based. The justification for enterprise liability, placing the losses caused to a society upon the industry which caused them, was perhaps most competently stated by Guido Calabresi, and Calabresi's justification was perhaps most coherently paraphrased by Howard Klemme.[65] Klemme stated that:

> [R]ecognizing at any one point in time that the total resources available to a society are limited, the "best" way for the members of a community to decide collectively how they want those limited resources to be used and distributed in order to satisfy most efficiently the greatest possible number of the members' individual wants and desires is through an open, competitive market system. The various competing uses to which the community's limited resources might be allocated in order to satisfy the maximum possible individual wants and desires will accordingly be determined through operation of the laws of supply and demand.[66]

Enterprise liability uses the marketplace as a tool not only for the original allocation of resources but also for the distribution of losses on a resource allocation theory. The loss distribution theory based on resource allocation requires two things: (1) that the cost of injuries should be borne by the activities which caused them, because the injury, regardless of fault, is a cost of such activity; and (2) that among the several societal groups participating in an enterprise, the loss should be borne by the group most likely to cause the burden to be reflected in the price of the product sold by the enterprise.[67] This reasoning differs from the rationale behind the more traditional fault theory. Under a fault theory, damages were awarded when it was determined that the defendant's activity was of less value than the resources his activity destroyed.[68] In either case, the loss to society is not replaced by a distribution of the loss to the plaintiff or to the defendant;[69] the distinction between the theories arises from the different motives behind the loss distribution.

Sindell contains language suggesting aspects of both fault and

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[65]Klemme is a professor of law at the University of Colorado.

[66]Klemme, *supra* note 1, at 158-59 (footnote omitted) (citing Calabresi, *Risk Distribution*, *supra* note 52, at 500-06).

[67]Calabresi, *Risk Distribution*, *supra* note 52, at 505.

[68]Klemme, *supra* note 1, at 176.

[69]*Id.* at 161.

enterprise liability but relies mainly on the principle established in *Summers*, that "as between an innocent plaintiff and negligent defendants, the latter should bear the cost of the injury."[70] The court stated that under its market share liability theory, the defendant would be held liable for approximately the same amount of losses as were actually caused by its production of DES.[71] This logic implies a fault concept; each defendant was allegedly at fault for a certain percentage of the injuries caused by the use of DES, and each manufacturer will pay this percentage. However, the court also stated that "from a broader policy standpoint,"[72] the defendants are better able to bear the cost of the injury resulting from the use of DES. Citing Justice Traynor in *Escola v. Coca Cola Bottling Co.*,[73] the court proposed that through insurance and distribution of the loss among the public as a cost of doing business, the manufacturer was better able to bear the loss.[74] This reasoning is the resource allocation and risk distribution rationale of enterprise liability, yet the court combined it with the rationale behind fault liability by attempting to hold each defendant liable for only the part of a judgment which corresponds to the percentage of all injury-causing DES production attributable to that defendant.

A second issue on which market share liability combines a fault theory of liability with enterprise liability is the degree of deterrence which a judgment allowed under each theory would produce. Proponents and opponents of enterprise liability recognize that under enterprise liability a certain degree of deterrence, or prevention of similar future losses, would normally be achieved because one of the criteria for attaching liability in enterprise liability is a consideration of whether a finding of liability would effectively increase safety incentives.[75] Opponents of enterprise liability and similar theories, however, stress that the major focus of enterprise liability is not on prevention of future losses but rather on a more appropriate application of funds available for injury compensation.[76]

Under the fault theory, it has been suggested that a system evolved which protected the integrity of an original contract between members of a society and, only incidentally, compensated the

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[70]26 Cal. 3d at 610-11, 607 P.2d at 936, 163 Cal. Rptr. at 144.

[71]*See* notes 62 & 63 *supra* and accompanying text.

[72]26 Cal. 3d at 611, 607 P.2d at 936, 163 Cal. Rptr. at 144.

[73]24 Cal. 2d 453, 462, 150 P.2d 436, 441 (1944).

[74]26 Cal. 3d at 611, 607 P.2d at 936, 163 Cal. Rptr. at 144.

[75]*See, e.g.*, Campbell, *Enterprise Liability—An Adjustment of Priorities*, 10 FORUM 1231, 1234-35 (1975); Klemme, *supra* note 1, at 176-82; O'Connell, *Expanding No-Fault Beyond Auto Insurance: Some Proposals*, 59 VA. L. REV. 749, 777-78 (1973).

[76]Campbell, *supra* note 75, at 1234-35.

victims of accidents.[77] Because no deterrence would be effected if liability was attached to a litigant for injuries which could not have been avoided, the system developed by the latter part of the nineteenth century into one which attached liability on the basis of fault.[78] Presumably, the compensation of victims, as opposed to deterrence, has now become the desired result of the system.[79] Enterprise liability, therefore, is just one more step in the evolution of the system. The emphasis has shifted from a fault limitation on liability to the best application of funds available for injury compensation.

The court in *Sindell* raised the issue of deterrence and summarily dismissed it by stating, "[t]he manufacturer is in the best position to discover and guard against defects in its products and to warn of harmful effects; thus, holding it liable for defects and failure to warn of harmful effects will provide an incentive to product safety."[80] The deterrence aspect of the court's decision focuses primarily on the superior knowledge of the defendant, or at least on the potential for superior knowledge.[81] While this emphasis appears to revert to a more traditional concept of deterrence than the compensatory aspect of enterprise liability deterrence, the court looked to the ability of the manufacturer to distribute the loss and thus again seemed to combine a fault theory with an enterprise liability theory.[82]

The court in *Sindell* found this *Summers*-type deterrence particularly applicable in a case involving medication where "the consumer is virtually helpless to protect himself" from the harm caused by a drug.[83] There are, however, many aspects of loss distribution and loss prevention in DES cases and in the application of a market share liability theory to DES litigation which are brought out in discussions of enterprise liability and which appear to indicate some startling results if the theory is widely accepted. The effects of the application of a market share theory cannot be ignored regardless of a court's nominative choice in placing the jusification for the market share liability on traditional fault theories, enterprise liability, or a new theory. It is the effect, not the choice of policy behind it, which may prove either beneficial or deleterious.

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[77]*Id.* at 1233.

[78]*Id.* at 1234 (citing Fischer, *Products Liability—The Meaning of Defect*, 39 Mo. L. Rev. 339 (1974)).

[79]Campbell, *supra* note 75, at 1234.

[80]26 Cal. 3d at 611, 607 P.2d at 936, 163 Cal. Rptr. at 144.

[81]This "superior knowledge" should not be confused with the knowledge of which manufacturer produced the injury-causing drug discussed at notes 37-40 *supra* and accompanying text.

[82]26 Cal. 3d at 611, 607 P.2d at 936, 163 Cal. Rptr. at 144.

[83]*Id.*

V. Possible Effects of the Acceptance of the Market Share Theory in *DES* Cases

A. Effects on Procedure

One area in which an acceptance of the market share liability doctrine might have a significant effect is procedure. There are at least two ways in which a plaintiff may benefit procedurally from an acceptance of the market share theory—one involving summary judgment and one involving class actions. The validity of the complaints in many DES cases has been resolved on a defendant's motion for summary judgment.[84] Although the exact requirements which must be met to withstand a defendant's motion for summary judgment may vary from state to state, it is generally true, as evidenced by the Federal Rules of Civil Procedure, that if a complaint states a genuine issue as to any material fact, the motion for summary judgment must be denied.[85]

If a market share liability theory is not accepted by courts, then plaintiffs injured by their mothers' use of DES will continue to be faced with the difficult task of deciding which theory of liability should be used as a basis for their complaints. While at first it may seem that this is the same decision which is presented to the plaintiffs in any lawsuit, it must be emphasized that because courts may find that DES cases do not fit neatly into any of the existing theories of tort liability,[86] the choice of theories by DES plaintiffs may be more critical than is the normal decision.[87] If, for example, a plaintiff brings an action under a strict liability or negligence theory, believing these theories to be most applicable, but the court feels that concert of action should have been pleaded to state a sufficient cause of action, a defendant's motion for summary judgment

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[84]*E.g.*, Sindell v. Abbott Labs., 26 Cal. 3d 588, 607 P.2d 924, 163 Cal. Rptr. 132 (1980), *cert. denied*, 101 S. Ct. 286 (1980); McCreery v. Eli Lilly & Co., 87 Cal. App. 3d 77, 150 Cal. Rptr. 730 (1978); Abel v. Eli Lilly & Co., 94 Mich. App. 59, 289 N.W.2d 20 (1979).

[85]Fed. R. Civ. P. 56(c).

[86]The confusion concerning the application of traditional liability theories to DES complaints is evidenced by the resolution of *Sindell* by the California courts. The superior courts dismissed the complaints. The appellate court reversed the lower courts and allowed the complaints under either concert of action or alternative liability, Sindell v. Abbott Labs., 85 Cal. App. 3d 1, 149 Cal. Rptr. 138 (1978). The California Supreme Court rejected all of the traditional theories. 26 Cal. 3d at 610, 607 P.2d at 936, 163 Cal. Rptr. at 144.

[87]An argument exists that DES cases do indeed fit into existing theories of tort liability but fit into the pigeonhole called "plaintiff's losers." Because some courts have allowed DES actions to be brought under existing theories, the "loser" category may be inapplicable. *See generally* Abel v. Eli Lilly & Co., 94 Mich. App. 59, 289 N.W.2d 20 (1979).

may be granted based on a mistake in pleading.[88] A DES plaintiff must therefore plead every possible cause of action under which liability may be attached in order to avoid an unfavorable summary judgment. Although it may always seem to be the best policy to bring any tort suit under all possible causes of action, DES plaintiffs are disadvantaged because the defendant's actions in manufacturing DES do not fit within any of the traditional categories of liability.[89] Because the categorization of a defendant's actions into an existing theory is unclear, the plaintiff would benefit more from a chance to argue the correlation between the facts and a theory of liability than would a plaintiff in a case involving a more standardized fact/liability theory situation. A motion for summary judgment would deny the plaintiff this opportunity. Market share liability would provide the plaintiff with a cause of action on which to base her complaint without any guessing or mistakes in pleading.

A second procedural advantage of the market share liability theory gained by a plaintiff in a DES case is an increased likelihood of a class action. The main issue under market share liability, as under enterprise liability,[90] would be whether the entire drug industry had produced and marketed a dangerous and defective drug. The economies in answering this question once in a class action instead of many times in separate law suits by individual plaintiffs are obvious; conservation of judicial time and avoidance of inconsistent verdicts would be achieved.[91] To achieve these advantages, however, the plaintiff class would have to be carefully limited. Because a

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[88]This example is very similar to the result in McCreery v. Eli Lilly & Co., 87 Cal. App. 3d 77, 150 Cal. Rptr. 730 (1978). The plaintiff in *McCreery* did bring the action under strict liability and negligence theories without alleging concert of action until appeal, and the defendant's motion for summary judgment was granted. Although the court did not state that if the plaintiffs had brought the original action under concert of action, the motion would have been denied, there is language which implies at least the possibility of this result. *Id.* at 84-85, 150 Cal. Rptr. at 735.

[89]*But see* Abel v. Eli Lilly & Co., 94 Mich. App. 59, 289 N.W.2d 20 (1979). The Michigan Court of Appeals in *Abel* reversed the lower court's grant of the defendant's motion for summary judgment and held that the plaintiffs had sufficiently stated a cause of action. *Id.* at 66, 289 N.W.2d at 27.

The court specifically stated that it was not adopting a new theory of liability (including enterprise liability as a new theory) and that the only obstacle to the plaintiffs was to prove that they had suffered a certain amount of injury caused by the defendants. The apportionment of the damages was left to the defendants. *Id.* The court noted that precedent showed that the identification of the manufacturer which produced the DES taken by the plaintiff's mother was too heavy a burden to place on the plaintiff. *Id.*

[90]For a discussion of the effect of enterprise liability on DES class actions, *see* FORDHAM Comment, *supra* note 5, at 968-70 n.22.

[91]Appellant's Reply Brief at 27-28, Sindell v. Abbott Labs., 149 Cal. Rptr. 138 (1978) [hereinafter cited as *Sindell*, Reply Brief].

defendant company under market share liability could prove that it was not liable by presenting evidence proving that it did not manufacture DES at the time it was ingested by the plaintiff's mother or in the location where the plaintiff's mother received the drug,[92] conservation of judicial time and fair results would be achieved only if the plaintiff class consisted of women whose mothers had used DES in the same general time period and in the same geographical area.[93]

Further, it appears that the class action would "stand or fall with the question of joint liability of the defendant drug manufacturers."[94] In cases such as *Sindell*, where not only damages for the named plaintiffs are sought, but also equitable relief for the class through clinics established by the defendant,[95] it seems unlikely that if the plaintiff could identify one specific manufacturer, this defendant manufacturer would be burdened with the costs of establishing statewide clinics when the entire DES manufacturing industry had followed the same FDA standards and had used the same testing and marketing methods.[96] If, however, the whole industry was found to be at fault, the entire industry would presumably be responsible for performing whatever remedial action needed to be taken.[97] Thus, market share liability would be advantageous to plaintiffs by allowing them to join in one action, making the action more economically feasible to all plaintiffs, and providing relief to those plaintiffs not named but nonetheless injured, as well as by encouraging a more remedial solution as opposed to only a compensatory one.

Although the terms compensatory and remedial may seem almost synonymous in tort cases, the differentiation betweeen the words may be more than semantic.[98] If the building of clinics by defendant manufacturers is viewed as remedial, meaning that the women who will benefit from the clinics will be women who know they have been injured by the production of DES and also those women who will use the very clinics established by the defendants to determine whether they have been injured by the drug, then there appears to be more than mere compensation. The defendant

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[92]*See* note 21 *supra* and accompanying text.

[93]This was not the case in *Sindell* where the plaintiff Sindell's mother ingested the drug in Florida, and plaintiff Roger's mother took the drug in Illinois. *Sindell*, Petition for Rehearing, *supra* note 8, at 42. Had the plaintiff class been limited to plaintiffs from the same geographical area, some of the unfairness suggested by the defendants in holding them liable for a drug which may have been manufactured by a company not subject to the California court's jurisdiction would be eliminated.

[94]*Sindell*, Reply Brief, *supra* note 91, at 28.

[95]*See* note 26 *supra* and accompanying text.

[96]*Sindell*, Reply Brief, *supra* note 91, at 28.

[97]*Id.*

[98]*See generally id.* at 27.

companies will in effect be paying the costs of seeking out unknown "plaintiffs," women who may not even know themselves that they have been injured. Compensation, on the other hand, may be used to refer to the reduction of societal costs resulting from accidents.[99] Compensation in this sense connotes an attempt to reduce social dislocations resulting from an accident by "compensating" an individual for personal injury or property loss resulting from some action by another which caused the accident.[100] "The purpose of [assessing] such liability is to insure that the costs of injuries resulting from defective products are borne by the manufacturers that put such products on the market rather than by the injured persons who are powerless to protect themselves."[101]

It must be remembered, however, that any loss to society will not be totally compensated, if total compensation means elimination of the loss, by placing the burden of compensation on either the plaintiff, the defendant, or anyone else.[102] A loss is just that, and the questions become who is best equipped to bear the loss and how the social dislocation of the loss can be most effectively reduced.[103]

Because the solution sought by the plaintiffs in *Sindell* asks not only for compensation for the victims known to be injured but also for remedial action for all those who may have been injured, the issue of causation becomes even more relevant. Once again, the use of the marketplace as a tool for distribution of the loss and for deterrence enters into the discussion.[104] Deterrence, the reduction of the number and severity of accidents, can be achieved by collective deterrence,[105] market deterrence,[106] or a mixed system.[107] Each type

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[99]Note, *Class Action in a Products Liability Context: The Predomination Requirement and Cause-in-Fact*, 7 HOFSTRA L. REV. 859, 867 n.48 (1979) [hereinafter cited as HOFSTRA Note] (citing G. CALABRESI, THE COSTS OF ACCIDENTS 26-27 (1970)).

[100]HOFSTRA Note, *supra* note 99, at 867.

[101]Greenman v. Yuba Power Prods., Inc., 59 Cal. 2d 57, 63, 377 P.2d 897, 901, 27 Cal. Rptr. 697, 701 (1963).

[102]*See* note 69 *supra* and accompanying text.

[103]In deciding whether the consumer or the producer should bear the loss, Calabresi stated:

> Traditional tort law, even apart from the special defenses accorded to remote contractors, put the risk of loss on the victim *unless* some rather special circumstances, like injurer fault (strictly construed), existed. Today, in product liability, the risk is initially placed on the producer and remains there unless complex circumstances, more powerful than user fault, justify a shift in riskbearing from producer to user.

Calabresi, *Product Liability: Curse or Bulwark of Free Enterprise*, 27 CLEV. ST. L. REV. 313, 319 (1978) (footnote omitted). For a justification of this loss allocation, *see id.* at 319-23.

[104]*See* notes 65 & 66 *supra* and accompanying text, and note 111 *infra* and accompanying text.

[105]*See generally* G. CALABRESI, THE COSTS OF ACCIDENTS 95-113 (1970).

[106]*See generally id.* at 68-94.

[107]*See generally id.* at 113-29.

of deterrence reflects an attempt to "creat[e] incentives so that people will avoid those future injuries worth avoiding and thus achieve an optimal trade-off between safety and injury in a world where safety is not a free good, and hence injury is not a total bad."[108] Collective deterrence leaves the trade-offs to society's collective determination of which activities are to be permitted, while market deterrence allows the market to make the determination.[109] It is market deterrence which may be strengthened by allowing class actions in DES cases.

For market deterrence to be effective, the price of a particular product or activity must accurately reflect its total injury costs. Only then will the market indicate whether people are willing to pay the true cost of a product or activity or whether its cost is too high for the value placed upon it by society.[110] Permitting class actions may increase the effectiveness of market deterrence in DES cases by enabling more legitimate plaintiffs to bring claims against the drug industry through less expensive class procedures than would otherwise be possible. The price of manufacturing DES would therefore more accurately reflect the true cost of the activity. However, the issue of causation plays a vital role in the effectiveness of market deterrence. To achieve proper allocation of injury costs to a particular activity, the activity must be the cause of the injury. If there is no causal relationship between the activity and the injury, there can be no correlative trade-off between safety and injury reflected in the market price of the activity.[111]

As stated previously, the main issue in DES cases revolves around a determination of who should carry the burden of proof of causation.[112] It has been suggested that causation in the case of a defective drug is particularly compatible with class actions in that "the degree to which a contracted disease was caused by a defective drug—as opposed to other factors having nothing to do with the defective drug, *e.g.*, other drugs or poor diet—may be impossible to determine on an individual basis."[113] It was further proposed that the study of many persons over an extended period of time might provide a reliable conclusion that in each given case there would be a high degree of probability that the injury was caused by the defective drug, and that if so, individual proof of causation would be im-

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[108]Calabresi, *Concerning Cause and the Law of Torts: An Essay for Harry Kalven, Jr.*, 43 U. CHI. L. REV. 69, 77 (1975) (footnote omitted).

[109]HOFSTRA Note, *supra* note 99, at 868 (citing Calabresi, *supra* note 108, at 84).

[110]Because the value placed on an activity is done ultimately by a society and not by the market, an element of collective deterrence is present in market deterrence.

[111]HOFSTRA Note, *supra* note 99, at 878.

[112]*See* notes 59-63 *supra* and accompanying text.

[113]HOFSTRA Note, *supra* note 99, at 880 (footnote omitted).

possible for the plaintiff, and the injury cost would not be allocated to the activity.[114] Thus, class actions would be more effective than individual lawsuits.

The class action may therefore seem to provide a means for a more realistic and efficient allocation of injury costs to the proper activity. However, this very difficulty confronted by individual plaintiffs in meeting the burden of proof of causation, relied on as a basis for the greater efficiency of class actions, raises the antithetical argument. For this allocation of injury costs to the defendant drug manufacturers to be proper, the defendants' activity must indeed be the cause of the injury. If there are intervening factors, having nothing to do with the nature of the drug, which make it difficult to determine the degree to which a disease was caused by the drug, then the causal link between the drug and the disease appears questionable. If the defendants' activity is not the cause of the injury, then the taxing of the manufacturers with the injury costs will cause the pricing system in the drug industry to reflect a cost which should not be placed upon it, and the market system will be distorted. The issue of causation in DES cases must therefore be closely scrutinized before the accident costs of women allegedly injured by the drug are allocated to the entire industry.

B. Effects Limited by Causation

A more detailed understanding of the use of DES may help clarify the issue of causation. Before synthetic estrogens were available, natural estrogen was used to increase the level of this hormone in pregnant women to help prevent spontaneous and habitual abortion.[115] In 1947, when the synthetic estrogen compound DES became available for use as a miscarriage preventive, doctors began to

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[114] *Id.* at 880-81. Even if the burden of proof of causation could be met by an individual plaintiff, a more accurate determination of cause might be achieved by statistical proof based on a multitude of cases. *Id.* at 881.

[115] The use of estrogen to prevent miscarriages was explained as follows. The female body produces estrogen throughout life but at fluctuating levels. During pregnancy, the levels of both estrogen and progesterone begin to rise and increase continuously until a peak is reached shortly before delivery. The levels of both hormones drop precipitously immediately prior to delivery, whether delivery takes place at term or prematurely. Experimental evidence showed that the production of progestorone was dependent upon estrogen and could be regulated by estrogen administration. Estrogen could, therefore, be used to help prolong pregnancies which showed symptoms of spontaneous abortions. Affidavit of George Van Siclen Smith, M.D., at 4-6, Payton v. Abbott Labs., No. 76-1514-S (D. Mass., questions certified Jan. 15, 1981). Dr. Smith is a graduate of Harvard College and Harvard Medical School, was head of the Department of Gynecology at Harvard Medical School for 20 years, was a founding member of the American College of Obstetricians and Gynecologists, and published six papers on cancer of the female genital organs. *Id.* at 1-3.

substitute the synthetic estrogen for the natural hormone in their treatment of these women, because the synthetic compound was much less expensive than natural estrogen and because of the ease with which it could be administered orally.[116] Stilbestrol, acting as an estrogen, has three effects on the pregnant woman: an increase in the circulation of the blood to the uterus, an increase in circulating estrogen, and a significant increase in the production of the natural hormone progesterone.[117]

While the fact that DES was used in women with symptoms of habitual or threatened abortion[118] tends to show that these women had problem pregnancies without any use of drugs, it has not been suggested that habitual or threatened abortion is linked causally with any form of adenosis or adenocarcinoma. Statistics, however, do indicate that many babies born of mothers who used DES would not have lived were it not for the treatment of the mothers.[119] This evidence, however, no matter how strongly it promotes the social value of DES, does not weaken the causal relationship between DES and adenocarcinoma or adenosis in the offspring. Statistics which do weaken this link are found in a comparison of the number of children with adenocarcinoma or adenosis who were daughters of women who used DES with the number of children with the diseases who were daughters of women who did not use DES. At least one study has shown the following:

> Although doctors prescribed synthetic estrogens for millions of pregnant women between the late 1940's and 1971, only 389 reported cases of clear cell adenocarcinoma have been reported in the offspring of *all* women born in the entire world during that period. Some have a drug history and some do not, but the physical appearance of the disease is the same in both groups.[120]

The studies showing no causal relation between DES and adenocarcinoma as well as those studies which do show such a relationship are not clear, concrete evidence.[121] The fact is that the ques-

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[116]Affidavit of A. Brien Little, M.D., at 4-5, Payton v. Abbott Labs., No. 76-1514-S (D. Mass., questions certified Jan. 15, 1981).

[117]*Id.*

[118]Each case would need to be examined to determine if the doctor properly prescribed estrogen. Affidavit of Ralph M. Richart, M.D., at 6-7, Payton v. Abbott Labs., No. 76-1514-S (D. Mass., questions certified Jan. 15, 1981).

[119]Affidavit of George Van Siclen Smith, M.D., at 8, Payton v. Abbott Labs., No. 76-1514-S (D. Mass., questions certified Jan. 15, 1981).

[120]Affidavit of Ralph M. Richart, M.D., at 4, Payton v. Abbott Labs., No. 76-1514-S (D. Mass., questions certified Jan. 15, 1981).

[121]The almost polar differences in the interpretations of statistical studies of DES victims are apparent from a comparison of Dixon, *Female Hormones: Hazardous*

tion of causation remains just that—a question, and even the report which first associated DES use in pregnant women with cancerous or precancerous conditions in their daughters showed only a statistical association and not a definite cause and effect relationship.[122]

The causation between DES use and adenocarcinoma in the offspring is only one of two causal connections which may be required to be shown by the plaintiff. The second causal connection is the relationship between a particular defendant and the injury to the plaintiff from DES manufactured by that particular defendant. While it is the second causal relation which is shifted from the plaintiffs to the defendants under market share liability, the first causal relation also has a significant effect on the efficacy of class actions in DES cases. Because the statistical association between maternal DES use and adenocarcinoma is not definite, other factors become significant in the case of each individual plaintiff. For example, the complete medical history of the mother, father, siblings, and other relatives, including a detailed family history of cancer, is of great relevance in determining whether the ingestion of DES by the plaintiff's mother bears any causal relation to the disease in the offspring.[123] Because the proof of this cause and effect relationship is so individualized, the support given to class actions in drug cases[124] may prove to be misplaced. While class actions would allow a study of more persons than a lawsuit with an individual plaintiff, the burden of proof of causation in the relationship between the injury and DES in general, without regard to a shifting of the burden of proof of identification of the specific manufacturer, would still need to be met on an individual basis if the industry is to be held liable only or injuries it actually caused. Only if the industry is held liable for the costs of accidents it actually caused will the market reflect a proper price determination.[125]

The second area of causation, that is, between a DES plaintiff's injury and a specific manufacturer, should be shifted to the defendants only after the first area of causation—between the plaintiff's injury and DES in general—has been proved. It is in this second area of causation that the *Sindell* court deviated from traditional tort theories. The market share liability theory of causation, which holds

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Panacea, 12 TRIAL MAGAZINE 21 (Oct. 1976); White, *Pregnancy Complicating Diabetes*, 7 AM. J. MED. 609 (1949) and White, *Pregnancy Complicating Diabetes*, 128 J.A.M.A. 181 (1945).

[122]*See* note 12 *supra* and accompanying text.

[123]Affidavit of Ralph M. Richart, M.D., at 6, Payton v. Abbott Labs., No. 76-1514-S (D. Mass., questions certified Jan. 15, 1981).

[124]*See* note 113 *supra* and accompanying text.

[125]*See* notes 65 & 70 *supra* and accompanying text.

each defendant to have "caused" a percentage of the injury to each specific plaintiff equal to each defendant's share of the DES market, differs from the *Summers* theory in that not all of those manufacturers who may have produced the DES ingested by the plaintiff's mother are joined as defendants,[126] and from enterprise liability in that, according to the court in *Sindell*, one manufacturer would not be responsible for the products of any or all other manufacturers, but rather would be responsible only for the damages caused by its own production of DES.[127]

Opponents of a market share liability theory have argued that allowing a cause of action in which the burden of proof of this second area of causation is shifted to the defendant is a rejection of years of tort law.[128] The applicable principles of causation in traditional tort law as stated by Dean Prosser require that, "[a]n essential element of the plaintiff's cause of action for negligence, or for that matter for any other tort, is that there be some reasonable connection between the act or omission of the defendant and the damage which the plaintiff has suffered."[129] In the context of products liability, the causation requirement has been established as follows:

> It is clear that any holding that a producer, manufacturer, seller, or a person in a similar position, is liable for injury caused by a particular product, must necessarily be predicated upon proof that the product in question was one for whose condition the defendant was in some way responsible. Thus, for example, if recovery is sought from a manufacturer, it must be shown that he actually was the manufacturer of the product which caused the injury.[130]

Although market share liability may present an extension of existing principles of causation, the expansion has a base in principles which have already been accepted such as de-emphasis on privity[131] and strict liability as applied to manufacturers without an express warranty.[132] Market share liability may, therefore, not represent a complete deviation from the more widely accepted theories of causation.

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[126]*See* notes 41-2 & 44 *supra* and accompanying text.

[127]26 Cal. 3d at 613, 607 P.2d at 938, 163 Cal. Rptr. at 146.

[128]This is the reasoning used in the *Sindell* dissent. 26 Cal. 3d at 614-16, 607 P.2d at 938-40, 163 Cal. Rptr. at 146-48 (dissenting opinion).

[129]W. PROSSER, *supra* note 47, § 41, at 236.

[130]1 F. HURSH & F. BAILEY, AMERICAN LAW OF PRODUCTS LIABILITY § 1:41, at 125 (2d ed. 1974), *cited in Sindell*, 26 Cal. 3d at 614, 607 P.2d at 938, 163 Cal. Rptr. at 146 (dissenting opinion).

[131]*See* Henningsen v. Bloomfield Motors, Inc., 32 N.J. 358, 161 A.2d 69 (1960).

[132]Greenman v. Yuba Power Prods., Inc., 59 Cal. 2d 57, 377 P.2d 897, 27 Cal. Rptr. 697 (1963).

Opponents of market share liability also argue that because there is no matching between plaintiffs and defendants, that is, because there is no direct cause-in-fact relation between a specific plaintiff and a particular defendant, the plaintiffs are free to "pick and choose their targets."[133] Two reasons can be given why it is unfair to target defendants: (1) because they are large companies and a plaintiff may feel there is a better chance of a higher recovery from such "deep pocket" defendants, or (2) merely because the defendant manufacturers happen to be the ones easily recognized by the plaintiff as possible manufacturers again with no proof that the manufacturers produced the injury-causing drug.[134] However, under the majority's rationale in *Sindell*, each defendant would be liable for approximately the percentage of damage for which its production of DES was responsible.[135] Thus, theoretically, even if larger manufacturers are chosen as target defendants, they will still be held liable only for the percentage of damage resulting from their production of DES.

While it may be true that "a defendant's wealth is an unreliable indicator of fault, and should play no part, at least consciously, in the legal analysis of the problem,"[136] the possible overburdening of larger manufacturers with injury costs of DES may help to offset another argument raised by opponents of market share liability.

C. Effects on the Drug Industry

This second complaint of market share liability consists of a fear that a small pharmaceutical company could be charged with liability for more than its actual market share[137] and thus the potential liability of the company could then easily exceed its total sales. Presumably, the smaller company would not be able to obtain insurance and would be driven out of business.[138] If larger companies are generally chosen as target defendants, therefore, this chilling effect on smaller companies may be lessened. Problems, however, do remain. Opponents of market share liability argue that even if the target com-

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[133]26 Cal. 3d at 616, 607 P.2d at 939, 163 Cal. Rptr. at 147 (dissenting opinion).

[134]Again, this problem was suggested by the dissent in *Sindell*. 26 Cal. 3d at 618, 607 P.2d at 941, 163 Cal. Rptr. at 149.

[135]*See* note 93 *supra* and accompanying text.

[136]26 Cal. 3d at 618, 607 P.2d at 941, 163 Cal. Rptr. at 149 (dissenting opinion). For a justification of deep pocket liability, see Calabresi, *Risk Distribution*, *supra* note 52, at 527-28.

[137]Although the defendants argue that they may be held liable for the entire industry's output, their potential liability would approximate only their own percentage of the total production of DES under the market share liability theory proposed by the *Sindell* court.

[138]*Sindell*, Petition for Rehearing, *supra* note 8, at 14-17.

pany "could absorb the initial loss of a liability judgment caused by a competitor's product, it could not recoup that loss by raising the price of its own product."[139]

The defendants explain that because some drug manufacturers would not be named as target defendants, they would not be forced to bear any of the injury costs of the drug and could thus continue producing and selling DES at the regular price, while companies named as defendants would be forced to raise their prices to absorb the loss, thus making their products noncompetitive.[140] The reasoning follows that two evils would be produced: (1) "[T]he federal program of generating increased price competition by encouraging new producers or existing drugs would be seriously impeded;"[141] and (2) "the smaller companies would be driven out of the generic prescription drug business."[142]

The defendants reason that smaller companies which entered the DES market after DES was declared to be no longer a new drug and which could not afford to do the testing required of a new drug[143] would not be willing to accept potential liability for all drugs manufactured by the original manufacturers who did perform the testing.[144] These smaller companies would therefore not enter the market, resulting in fewer producers of common generic drugs and a consequent increase in the prices of all drugs due to a lack of price competition.[145] Further, if a company may be held liable for a competitor's product, the defendants argue, the unpredictability of the loss would force insurance prices to such a high level that smaller companies would not be able to afford insurance at all.[146] Without insurance, investment capital would be extremely difficult to attract, and even with the necessary investment capital, a smaller company gambling on not being chosen as a target defendant would be ruined if the gamble were lost.[147]

Although authorities were cited to support these propositions,[148] the detrimental results predicted by the defendant drug manufacturers basically remain theoretical "ifs." There is no way of knowing the actual results of an acceptance of market share liability in DES cases, and while the defendants' fears certainly have merit, there

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[139]*Id.* at 14.
[140]*Id.* at 14-15.
[141]*Id.* at 15.
[142]*Id.* at 17.
[143]*See* note 10 *supra* and accompanying text.
[144]*Sindell*, Petition for Rehearing, *supra* note 8, at 15-17.
[145]*Id.*
[146]*Id.*
[147]*Id.* at 17.
[148]*See id.* at 11-17.

are other factors which, theoretically, might offset their fears. For example, although defendants assert that some DES manufacturers, not chosen as target defendants, will escape liability and will be able to continue manufacturing DES at regular prices, it must be remembered that a market share liability theory as proposed in *Sindell* would require a "substantial" share of the entire DES market to be represented by the chosen defendants.[149] Thus, it would not be only a few manufacturers who were forced to increase their prices; rather the manufacturers not chosen as defendants would constitute the minority.

It seems very unlikely that all of the market represented by the chosen defendants, being a substantial share of the market, would suddenly shift to those companies not selected as defendants. Particularly, if it is the larger companies which will be singled out as defendants, as the defendants fear, it seems that the smaller nondefendant companies would not be able to suddenly shift gears to handle such an increased market. Carrying this line of reasoning further, if some of the market which had belonged to the larger manufacturers is shifted to the smaller companies, it appears that over a period of time, as the percentage of market owned by each manufacturer became more equalized, the manufacturers which had originally been smaller manufacturers and which had not been defendants, would now be just as attractive to plaintiffs as the other companies. As these companies increased their percentage of the market, the percentage of the market, the percentage of liability belonging to each company would increase proportionately. The result might very well be a more price-competitive drug industry.

The defendants' fears may also be mitigated when a few other basic economic considerations are applied. For example, if the target defendants are price leaders within the industry or if they are able to spread their losses over the costs of other products, the allocation to these manufacturers of accident costs from DES production may be less burdensome.[150] The degree of competition present in the industry may also play a different role in the effect of placing accident costs on the manufacturer than the defendants anticipate.

In competitive industries, an industry-wide liability would result in the following:

> substantial secondary loss spreading through wages and prices; this is true at least when accident costs vary with output or with the use of some specific resource in production. The added cost—if it is significant enough to mat-

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[149]26 Cal. 3d at 612, 607 P.2d at 937, 163 Cal. Rptr. at 145.

[150]*See generally* Calabresi, *Risk Distribution*, *supra* note 52, at 519-27.

> ter—results in (a) decreased output and higher prices, and (b) lower payments to, and decreased use of, those resources giving rise to the extra cost, assuming that these can be identified.[151]

In an industry involving substantial control over price and output, including monopolies, oligopolies, and price-leader industries, some of the added cost would be borne permanently by the industry in the form of decreased profits.[152] An industry-wide liability theory applied in such an industry, however, "would be unlikely to create a chronically sick industry or to concentrate losses through the elimination of firms."[153] Further, decreased profits can often be spread through decreased dividends if there are numerous firm owners.[154]

The drug industry has been considered a relatively oligopolistic industry.[155] The introduction of generic drugs in recent years, however, has allowed a greater number of capital inferior manufacturers to enter the market and to increase the price competition.[156] Therefore, because of the combined aspects of competitive and oligopolistic industries present in the drug industry, the results of a market share theory of liability may not be as extreme as the defendants fear.

Moreover, insurance may not be as difficult for smaller companies to acquire as the defendants would suggest. Even though a manufacturer will be held liable under market share liability for the results of testing performed by other manufacturers, its liability will be proportionate to its percentage of the market. The potential amount of monetary liability, therefore, is not as great as that of a larger company, and it seems logical that insurance costs for larger and smaller companies would reflect this variance in potential liability. As one further theoretical proposition, it could be argued that even if it were proportionately more difficult for a smaller manufacturer of DES to purchase insurance, this higher degree of difficulty is the same as that faced by smaller companies in any industry. If it

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[151]Calabresi, *Risk Distribution*, *supra* note 52, at 519.

[152]*Id.* at 524.

[153]*Id.*

[154]*Id.* at 526.

[155]FORDHAM Comment, *supra* note 5, at 977-78.

[156]This increased price competition arising from the use of multiple-source drugs was recognized by the Department of Health, Education, and Welfare in its 1974 discussion and adoption of maximum allowable cost regulations applicable to these multiple-source drugs. *See* 39 Fed. Reg. 40302, 40302-03 (1974); Limitations on Payment Reimbursement for Drugs, 45 C.F.R. § 19.5 (1979). *Maximum Allowable Costs for Drugs*, Office of the Secretary, Dep't of Health, Education & Welfare (July 25, 1975), *cited in Sindell*, Petition for Rehearing, *supra* note 8, at 27.

is accepted that a smaller company has less ability to spread its costs than does a larger company, then it is true for any small company in any industry, not specifically DES manufacturers.

D. Effects on Future Litigants

The issues discussed above, no matter how great their merit, remain only theoretical propositions. It would be difficult indeed for a court to determine whether the market share liability theory should be accepted based on future effects on the drug industry. There are, however, problems which arise from the market share liability theory as proposed in *Sindell* which could be more easily resolved. The requirement that a "substantial" share of the market must be represented by the aggregate of the defendants is not defined.[157] The *Sindell* court cited the Fordham Comment[158] which suggested that 75% to 80% of the market be represented, but the *Sindell* court stated, "we hold only that a substantial percentage is required."[159] No further guidelines are offered.

The percentage required before a cause of action may be allowed is important in two ways: (1) to help establish a causal relationship, and (2) to ensure that each defendant is only liable for approximately his market share of the judgment. The percentage requirement is important in establishing a causal relationship because the higher the percentage of the total market represented by the defendants, the greater the chance that one of the defendants actually caused the injury. For example, if 99% of the total market is represented by the defendants, there is only a 1% chance of the true defendant escaping liability. If only 70% of the market is represented, there is a 30% chance that the injury-causing drug manufacturer will not be joined as a defendant. Representation of a greater percentage of the total market does not establish causation between any one particular defendant and the injured plaintiff. The chance, however, that *one* of the defendants actually caused the injury does increase with the higher percentage requirement of the total market, thus diminishing the chance that the injury-causing manufacturer will escape liability. Because it is the entire concept of liability, and not just an apportionment of damages, which is based on a market share theory,[160] it would seem important to reach as high a percentage of the total market as feasible to ensure as much of a causal relation as possible.

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[157]*See* 26 Cal. 3d at 612, 617, 607 P.2d at 937, 940, 163 Cal. Rptr. at 145, 148.

[158]*See* note 5 *supra*.

[159]26 Cal. 3d at 612, 607 P.2d at 937, 163 Cal. Rptr. at 145.

[160]*See id.* at 612, 617, 607 P.2d at 937, 940, 163 Cal. Rptr. at 145, 148.

The percentage required to constitute a substantial percentage of the market also becomes important as a result of the court's language used in defining the liability of each defendant. The court stated, "[e]ach defendant will be held liable for the proportion of the judgment presented by its share of that market . . . ."[161] This language is susceptible to two interpretations. An example may be the easiest way to explain the two possible interpretations. If 80% of the market is represented by the aggregate shares of the defendants, and if Defendant X owned 20% of the market, then under one interpretation X may be held liable for 20% of the judgment. Under this interpretation, 20% of the judgment would be left unsatisfied because 20% of the market would not be represented. Using a second interpretation, the court would say that 80% of the market would be responsible for 100% of the judgment, and using proportions, X would be liable for 25% of the judgment. Under this second analysis, the entire judgment would be allocated among the defendants, but each defendant would be held liable for a percentage of the judgment which is greater than the percentage of the market which he occupied.

Language used by the *Sindell* court, both in the majority and dissenting opinions, suggests that the second interpretation was intended.[162] Therefore, the higher the percentage of the market required to constitute a substantial share, the greater the correlation between each defendant's share of the market and its share of the judgment. Applying the reasoning of the court that each defendant "caused" a percentage of the total DES caused injuries equal to its percentage of the market, a very high correlation between the two percentages should be required.

One other question arises from the fact that only a substantial share of the manufacturers is required for a cause of action. In *Sindell*, the superior court stated that the defendants had "ignored" bringing in other manufacturers as cross-defendants.[163] Serious practical problems, however, are presented for defendants who attempt by cross-claims to bring in other manufacturers. For example, in *Rogers*, the class action consolidated with *Sindell*, the plaintiff's mother took the drug in Illinois, while in *Sindell*, the drug was prescribed and taken in Florida.[164] Some of the companies that sold DES in those states may not have sold DES in California, and may, therefore, not be subject to the jurisdiction of the California

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[161]*Id.* at 612, 607 P.2d at 937, 163 Cal. Rptr. at 145.

[162]*Id.* at 612-13, 617, 607 P.2d at 937, 940, 163 Cal. Rptr. at 145, 148.

[163]*Sindell*, Petition for Rehearing, *supra* note 8, at 42 (citing slip opinion at 29).

[164]*Sindell*, Petition for Rehearing, *supra* note 8, at 42.

courts.[165] The defendants would be hard pressed to join these other manufacturers. Also, a named defendant, if he could not even show that it was not the producer of the injury-causing drug, would certainly have a difficult task in showing enough causation relating to another manufacturer's product to bring that manufacturer in as a defendant by a cross-claim.[166] One might wonder whether a court would allow the same *Summers* theory of proof of causation among defendants as it has for the plaintiff.

E. Effects Peculiar to the Drug Industry

There are other problems associated with market share liability which are more burdensome to manufacturers of prescription drugs than to the defendants in a *Summers* fact situation. These problems are based on at least two factors: (1) the large role played by the FDA in the production of the product, and (2) the social value of encouraging research and production of prescription drugs.

Prescription drugs are subject to intense scrutiny by the FDA.[167] Prescription drugs are not sold directly to the public. Rather, they are dispensed only after a doctor has examined, analyzed, and evaluated a patient.[168] Moreover, a manufacturer of a prescription drug must give an adequate warning to the physician, not to the patient, of the risks of a drug.[169] Beyond its role in categorizing drugs as "new drugs," the FDA also often dictates the language of the warnings based on information submitted by the various manufacturers, data collected from independent clinical researchers, and risks revealed by its own review of the medical literature.[170] Prescription drug cases, therefore, differ greatly from the situation found in *Summers*. The actions of the hunters in *Summers* were not regulated by any governmental agency, and the negligence of the hunters was much more attributable to their own actions and judgments than is that of a manufacturer of a prescription drug who follows FDA requirements.[171] The injuries caused by DES are,

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[165]*See* 26 Cal. 3d at 617, 607 P.2d at 940, 163 Cal. Rptr. at 148 (Richardson, J., dissenting); *Sindell*, Petition for Rehearing, *supra* note 8, at 42-43.

[166]*Sindell*, Petition for Rehearing, *supra* note 8, at 43.

[167]*See* 21 U.S.C. §§ 351-360 (1976 & Supp. III 1979).

[168]*Id.*

[169]Carmichael v. Reitz, 17 Cal. App. 3d 958, 989, 95 Cal. Rptr. 381, 400 (1971). In addition, the risks that are well known to the medical profession need not be included in the warnings. RESTATEMENT (SECOND) OF TORTS § 402A, Comment j (1965).

[170]Comment, *Package Inserts for Prescription Drugs as Evidence in Medical Malpractice Suits*, 44 U. CHI. L. REV. 398, 410 n.56, 413 (1977). *See, e.g.*, Chambers v. G. D. Searle & Co., 441 F. Supp. 377, 383 (D. Md. 1975); FDA Applicability of Drug Efficacy Study Implementation, 21 C.F.R. § 310.6 (1980).

[171]This reasoning applies, of course, only if the manufacturers have indeed complied with all of the FDA standards.

therefore, perhaps not "obviously the result of *some one's* negligence,"[172] and more specifically, not the result of the defendant's negligence. The reliance placed on FDA standards by the drug manufacturers removes a DES case one step further from the reasoning in *Summers* that as between an innocent plaintiff and negligent defendants, the latter should bear the cost of the injury.[173]

The second factor, the social utility of prescription drugs, also differentiates DES cases from *Summers*. The social utility connected with hunting must certainly balance out less than that associated with researching and manufacturing prescription drugs. This weighing is embodied in the Restatement (Second) of Torts § 402A which states:

> 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, . . . 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 strictly liable 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.[174]

Moreover, as the dissent in *Sindell* reasoned:

> "The social and economic benefits from mobilizing the industry's resources in the war against disease and in reducing the costs of medical care are potentially enormous. The development of new drugs in the last three decades has already resulted in great social benefits. The potential gains from further advances remain large. To risk such gains is unwise. Our major objective should be to encourage a continued high level of industry investment in pharmaceutical R & D [research and development]."[175]

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[172]Ybarra v. Spangard, 25 Cal. 2d 486, 487, 154 P.2d 687, 689 (1944) (emphasis added).

[173]33 Cal. 2d at 84, 199 P.2d at 5.

[174]RESTATEMENT (SECOND) OF TORTS § 402A, Comment k (1965).

[175]26 Cal. 3d at 619, 607 P.2d at 941-42, 163 Cal. Rptr. at 149 (quoting McCreery v. Eli Lilly & Co., 87 Cal. App. 3d 77, 86-87, 150 Cal. Rptr. 730, 736 (1978) (quoting D. SCHWARTZMAN, THE EXPECTED RETURN FROM PHARMACEUTICAL RESEARCH: SOURCES OF NEW DRUGS AND THE PROFITABILITY OF R & D INVESTMENT 54 (1975).

The research and production of new drugs can be threatened by the imposition of regulations and rules of liability on prescription drug manufacturers.[176]

While the effects of these two factors would be present under any theory which places liability on the manufacturer, it becomes particularly important to be cautious in placing liability on a drug manufacturer for alleged injuries caused by a competitor's product. This caution is especially important when the causal link between DES and the plaintiff's injuries is so tenuous.

Other factors may enter into a court's acceptance or rejection of a market share liability theory.[177] However, in the final analysis the determination may simply be based upon a judicial balancing of the interests of an innocent plaintiff against the interests of a drug manufacturer who may be held liable for the injurious effects of a competitor's product which appear a generation after the product was manufactured.

VI. CONCLUSION

The potential effects of the court's opinion in *Sindell*, both beneficial and detrimental, remain to be seen. Courts in other states may choose not to apply the California court's market share liability theory in DES cases, thus eliminating much of the controversy surrounding *Sindell*. Conversely, it may be that California, following in the tradition of *Greenman v. Yuba Power Products, Inc.*[178] and *Ybarra v. Spangard*,[179] will once again be the leading jurisdiction, pro-

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[176]W. PROSSER, *supra* note 47, § 99, at 661. One example of the deleterious effect an expansion of liability to prescription drug manufacturers may have is shown in the context of vaccines. Dr. David Sencer, then Assistant Surgeon General, indicated in January 1976, that "[m]anufacturer liability for vaccine-associated disability, regularly assigned by courts, threatens a predictable vaccine supply . . . and diminishes the chances of significant independent manufacturer-sponsored research and development of new biologics." *Hearings Before the Subcomm. on Health of the Comm. on Labor and Public Welfare*, 94th Cong. 2d Sess. 119 (Sept. 23, 1976) (Statement of Dr. David Sencer).

Further, amendments to the Food, Drug and Cosmetic Act that inhibited the introduction of new drugs by requiring more extensive proof of efficacy have cost the public more than $300 million and thousands of lives as a result of a reduced availability of those new drugs. S. PELTZMAN, REGULATION OF PHARMACEUTICAL INNOVATION: THE 1962 AMENDMENTS 1-3 (1974).

[177]One factor may arise from statutes of limitation in various states. In California a personal injury claim generally accrues, and the period of limitation commences when the wrongful act takes place. However, an exception exists when the pathological effect occurs without perceptible trauma, and the statute of limitations then begins to run only when the person knows or, by the exercise of reasonable diligence should have known, of the injury. Warrington v. Charles Pfizer & Co., 274 Cal. App. 2d 564 (1969); CAL. CIV. PROC. CODE § 29 (West 1954).

[178]59 Cal. 2d 57, 377 P.2d 897, 27 Cal. Rptr. 697 (1963).

[179]25 Cal. 2d 486, 154 P.2d 687 (1945).

viding precedent which courts throughout the United States will follow.

Because the theory proposed in *Sindell* may become widely accepted, the decision and its possible effects should be analyzed carefully by the legal profession. This analysis is essential because of the tenuous causal relation between DES and adenocarcinoma and because shifting the burden of proof of causation from the plaintiff to the defendant, when neither party can identify the manufacturer of the injury-causing drug, may effect more than a mitigation of an insurmountable burden on the plaintiff. It may be burdening the defendant with a presumption of guilt which may in itself be insurmountable. If the California court's step forward on the spectrum of causal relationships[180] is to avoid becoming two steps backward, the market share liability theory should be applied cautiously in DES cases.

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[180]*See* note 1 *supra* and accompanying text.