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THE DES LABYRINTH

HARLAN S. ABRAHAMS*

AND

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The temptation seems to be constant to find certainty where it does not exist rather than to accept the existence of uncertainty and choose how to act in the face of it.¹

I. INTRODUCTION

DES plaintiffs² face an array of complex hurdles. Even before considering legal action, they encounter life-threatening

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We also wish to thank our student assistant, Ms. Tracy Borge, for her valuable research endeavors and her willingness to serve as our sounding board.

1. Lindgren, *Social Theory and Judicial Choice: Damages and Federal Statutes*, 28 BUFFALO L. REV. 741, 752 (1979).

2. "Diethylstilbestrol (DES) is a man-made estrogen, first approved by the Federal Drug Administration (FDA) in 1947 for use in complications during pregnancy—specifically, to prevent miscarriages." Comment, *DES and a Proposed Theory of Enterprise Liability*, 46 FORDHAM L. REV. 963 (1978) [hereinafter FORDHAM Comment] (written by Naomi Sheiner, this article is the seminal legal discussion of products liability issues arising from the use of DES). The drug is associated with the development of abnormalities among the users' offspring, both male and female, most notably clear cell adenocarcinoma among "DES daughters." See *id.* at 964-65. Our analysis of the legal issues arising from this association is premised on our belief that DES plaintiffs are entitled to redress for their suffering from an industry that negligently marketed a nonefficacious, dangerous drug without adequate testing. See notes 134-208 and accompanying text *infra*. Although the analysis in this article is limited to the effects of DES on females exposed to it *in utero*, evidence suggests that the drug also caused abnormalities in males exposed *in utero*. Robboy, Prat & Welch, *Vaginal Cervical Pathology Associated with Prenatal Exposure to Diethylstilbestrol*, in ESTROGENS AND CANCERS 173 (Silverberg & Majors, eds. 1978).

situations and alien medical procedures.³ Imagine a young woman, nineteen years old, who seeks medical attention because of abnormal bleeding during her menstrual cycle. A review of her medical history discloses a background of menstrual problems commencing with the onset of puberty. The subsequent medical examination by her gynecologist reveals adenosis⁴ in the vaginal tract.

Recognizing an association between adenosis and fetal exposure to DES, the young woman's gynecologist seeks information from her mother concerning the mother's drug history during pregnancy. The mother recalls taking DES from the second month of pregnancy until the birth of her daughter. Armed with this information, the young woman is referred to a gynecologist-oncologist at a nearby research hospital. A biopsy is performed, and the diagnosis is clear cell adenocarcinoma in the vaginal tract. A hysterectomy and a vaginectomy⁵ are performed.

After a ten-day stay in the hospital following the surgery, the young woman discovers numerous complications caused by the surgery: lack of bladder control, increased susceptibility to bladder infections, and pain during sexual intercourse. Moreover, she becomes increasingly depressed over her inability to bear children, anxious about her frequent postsurgery examinations, and fearful that her cancer might recur. In frustration, she finally consults an attorney. She has just entered the DES labyrinth.

Confronting the DES plaintiff are piles of legal and medical literature,⁶ a maze of novel problems of proof, and many paths

3. See J. BICHLER, *DES DAUGHTER* chs. 2-5 (1981).

4. See notes 22-35 and accompanying text *infra*.

5. A vaginectomy is an excision of the vagina or a segment thereof. *STEDMAN'S MEDICAL DICTIONARY* 1526 (4th unabridged ed. 1976).

6. For legal literature, see, e.g., *FORDHAM Comment, supra* note 2; *Comment, Beyond Enterprise Liability in DES Cases—Sindell*, 14 *IND. L. REV.* 695 (1981); *Comment, Manufacturers' Liability Based on a Market Share Theory: Sindell v. Abbott Laboratories*, 16 *TULSA L.J.* 286 (1980); *Comment, Diethylstilbestrol: Extension of Federal Class Action Procedures to Generic Drug Litigation*, 14 *U.S.F. L. REV.* 461 (1980); *Note*, 4 *AM. J. TRIAL ADVOC.* 492 (1980); *Note*, 12 *J. MAR. L. REV.* 201 (1980); *Note*, 49 *U. CIN. L. REV.* 926 (1980); *Note*, 49 *UMKC L. REV.* 245 (1981); *Note*, 42 *U. PITT. L. REV.* 669 (1981); *Note*, 59 *WASH. U.L.Q.* 571 (1981). For medical literature, see, e.g., *Dunn & Green, Cysts of the Epididymis, Cancer of the Cervix, Granular Cell Myoblastoma, and Other Lesions After Estrogen Injection in Newborn Mice*, 31 *J. NAT'L CANCER INST.* 425 (1963); *Fu, Robboy & Prat, Nuclear DNA Study of Vaginal and Cervical Squamous Cell Abnormalities in DES Exposed Progeny*, 52 *J. OBST. & GYN.* 129 (1978); *Greenwald, Bar-*

through that maze. The legal literature tends to focus narrowly on one or two of the novel issues without depicting the range of problems characterizing DES litigation. This article instead portrays the complexity of the maze. Rather than dwelling on isolated components of the legal process, we trace the path taken by the plaintiff from beginning to end. In no other way can the complexity of the DES labyrinth be appreciated.

The DES plaintiff sees stretching before her the numerous routes she may take. Each represents a distinct theory of recovery: negligence, strict liability, failure to warn, misrepresentation, and breach of warranty.⁷ The theories are interrelated; the paths cross frequently.⁸ Each has recognizable branches; negligence, for example, has been "charged in the design, testing, investigation, experimenting with, manufacturing, packaging, marketing, distributing, inspecting, promoting and labeling of the drugs."⁹ We select one branch—negligent failure to test adequately—and follow it, knowing that each of the other theories raises important issues¹⁰ and that each theory should be alleged

low, Nasca & Burnett, *Vaginal Cancer After Maternal Treatment with Synthetic Estrogens*, 285 N. ENG. J. MED. 878 (1971); Herbst, Ulfelder & Poskanzer, *Adenocarcinoma of the Vagina*, 284 N. ENG. J. MED. 878 (1971); McLachlon, Newbold & Bullock, *Long-Term Effects on the Female Mouse Genital Tract Associated with Prenatal Exposure to Diethylstilbestrol*, 40 CANCER RESEARCH 3988 (1980); Poskanzer & Herbst, *Epidemiology of Vaginal Adenosis and Adenocarcinoma Associated with Exposure to Stilbestrol in Utero*, 39 CANCER 1892 (1977); Ulfelder, *The Stilbestrol-Adenosis-Carcinoma Syndrome*, 38 CANCER 426 (1976).

7. See, e.g., *Abel v. Eli Lilly & Co.*, 94 Mich. App. 59, 66-67, 289 N.W.2d 20, 22 (1980); *Ferrigno v. Eli Lilly & Co.*, 175 N.J. Super. 551, 560, 420 A.2d 1305, 1309 (1980).

8. For example, to establish a breach of implied warranty in Michigan, the plaintiff must show "a defect in the product." *Abel*, 94 Mich. App. at 70, 289 N.W.2d at 24. Proof of a product defect is similarly crucial to a strict liability claim in California. See Note, 42 U. PRR. L. REV. 669, 679-85 (1981).

9. *Ferrigno*, 175 N.J. Super. at 560, 420 A.2d at 1309.

10. Two particularly interesting issues that do not arise in the failure to test context are the potential for basing a claim on overpromotion of DES and the relationship between the lack of efficacy of DES and the exceptions to the strict liability standards of RESTATEMENT (SECOND) OF TORTS § 402A (1965). In connection with the overpromotion issue, compare *Stevens v. Parke, Davis & Co.*, 9 Cal. 3d 51, 507 P.2d 653, 107 Cal. Rptr. 45 (1973) (overpromotion of the antibiotic Chloromycetin held to be a proper basis for claim) and Note, 10 GA. ST. B.J. 450 (1974); with FORDHAM Comment, *supra* note 2, at 964 n.4.

In connection with the relationship between efficacy and § 402A, note that RESTATEMENT (SECOND) OF TORTS § 402A, Comment k (1965), entitled "Unavoidably Unsafe Products" and written with particular focus on new and experimental drugs, essentially creates an exception from strict liability for such drugs and reintroduces "rules of negligence embodying the longstanding concepts of a lack of due care and foreseeability of

by plaintiff's counsel. We select negligent failure to test because the substantive evidence on that issue is especially compelling:

[S]erious questions had . . . been presented, some prior to FDA approval and others prior to use by plaintiff's mother, concerning the drug's potential carcinogenic effect and its efficacy for accidents of pregnancy.

. . . It was well known, before FDA approval was sought, that substances given a pregnant woman would pass through the placenta into the fetus. It was also well known that there were available tests on mice which, if conducted, would have demonstrated within six months the danger of cancer developing in the fetus after it had reached maturity. In fact, three prominent Chicago physiologists had administered DES to rats and mice in 1939 and concluded that the hormone crossed the placenta and had malforming action on the fetus. In 1938, Dr. Charles Dodd, one of the British researchers responsible for synthesizing DES, had published a paper with respect to his findings in relation to DES. In his summary of conclusions, Dr. Dodd stated that DES could actually cause miscarriages or abortions, not save them. In the late '40's, one of the studies cited in Lilly's supplemental application specifically questioned:

. . . .

2. Is diethylstilbestrol in such large doses carcinogenic, and as such unsafe to give even to pregnant women?

3. Can diethylstilbestrol in any way affect the glandular balance of the child in utero, particularly the male child?

. . . . *These reservations, however, were not noted on the application.* Several other studies appearing in the period 1950-

the risk." *Ferrigno*, 175 N.J. Super. at 576, 420 A.2d at 1318. Given the evidence, which was available before DES was marketed to pregnant women, that the drug was never effective in preventing miscarriages, see Parts II.C. & II.E. *infra*, plaintiffs have asserted that if they can demonstrate such a lack of efficacy, the provisions of Comment k, which presuppose "an apparently useful and desirable product," do not apply, and the general rules governing strict liability control the case. See *Ferrigno*, 175 N.J. Super. at 575-77, 420 A.2d at 1317-19; Keeton, *Products Liability—Drugs & Cosmetics*, 25 VAND. L. REV. 131, 135, 141-43 (1972); FORDHAM Comment, *supra* note 2, at 972 n.25, 967-68 n.18. The court in *Ferrigno* agreed with the plaintiff's assertion: "Did it reasonably appear to be efficacious at the time it was manufactured, marketed, and distributed? . . . In my view, if it did not, comment k rules will not apply and the established rules of strict liability defined in the machine cases will." 175 N.J. Super. at 577, 420 A.2d at 1319. Resolution of this issue carries implications far beyond the DES context; it also provides another example of how the paths representing different theories of recovery—here negligence and strict liability—intersect. See note 8 and accompanying text *supra*.

53 questioned the efficacy of DES for complications of pregnancy. There was, therefore, in existence . . . [before DES was marketed], not only doubts as to efficacy but also scientific criticism of the lack of proper control in those studies which had advocated use of DES. *Despite these reservations, it is undisputed that none of the companies producing or marketing DES had performed any tests on the drug's effect on the fetus itself, either in humans or in animals, although DES was specifically aimed at the placenta and fetus.*¹¹

Yet few plaintiffs reach the issue of breaching the standard of care. Before that problem is encountered, the plaintiff must demonstrate a duty to her while she was a fetus;¹² she must convince the court that the applicable statute of limitation did not begin running until the manifestation of her injury in adolescence;¹³ and she must negotiate the cause-in-fact impasse: who manufactured those pills her mother took nearly twenty years ago?¹⁴ Even after negotiating the substantive negligence standard,¹⁵ the plaintiff must prove legal causation through statistical correlation rather than observable cause-and-effect,¹⁶ since today no one knows what actually causes cancer generally, let alone the rare form of clear cell carcinoma afflicting DES daughters.¹⁷ Finally, she must prove her damages—the dollar worth of her lost capacity to bear children,¹⁸ the value of her postsurgery traumas,¹⁹ and the cost of the time bomb possibly awaiting her during menopause.²⁰

11. *Bichler v. Eli Lilly & Co.*, 79 A.D.2d 317, ___, 436 N.Y.S.2d 625, 629-30 (1981) (emphasis added).

12. See Part II.A. *infra*.

13. See *id.*

14. See Part II.B. *infra*.

15. See Part II.C. *infra*.

16. See Part II.D. *infra*.

17. See *id.*; FORDHAM Comment, *supra* note 2, at 964-65 n.5.

18. Dr Howard Ulfelder, a leading DES authority, continues to believe that hysterectomy is the most successful and therefore preferable method for treating clear cell adenocarcinoma. See Ulfelder, *supra* note 2, at 427-428.

19. See, e.g., J. BICHLER, *supra* note 3, at 128-29, 152-53 (1981).

20. A number of studies posit the expectation that DES-related cancer will occur with increasing frequency as women who were exposed *in utero* grow older, since vaginal cancer is so rare among young women. See, e.g., Herbst, Poskanzer, Robboy, Friedlander & Scully, *Prenatal Exposure to Stilbestrol*, 292 N. ENG. J. MED. 334, 339 (1975); Stafil & Mattingly, *Vaginal Adenosis: A Precancerous Lesion?*, 120 AM. J. OBST. & GYN. 666, 672 (1974). While participating in several DES cases, Ms. Musgrave noted that some physicians spoke informally of menopause as the focal point of their concern, based on the

For those who do reach the damages issue, we offer an alternative to traditional measures.²¹ We propose restitution—the disgorgement of profits unjustly enriching the drug industry—as the proper remedy for those plaintiffs who successfully traverse the DES labyrinth.

II. A ROADMAP OF OBSTACLES

A. Prenatal Exposure and Adult Damages

Upon entering the maze, the DES plaintiff immediately confronts two impediments, both of which focus on the timing of her injuries. Resolutions of the issues concerning both the duty to a fetus and the running of the statute of limitation require examination of the progressive effects of exposure to DES *in utero*. Those effects begin with adenosis, which has been called a “precancerous” condition.²² Adenosis is “tissue placed abnormally on the cervix or vagina,”²³ and it reveals itself as fibrous ridges in those organs, cervical erosion, and failure of part of the vagina or cervix to stain with iodine.²⁴ This cellular alteration may occur *in utero*: “It is . . . possible that stilbestrol alters fetal vaginal cells in utero, with changes that do not become manifest in a malignant form until years later.”²⁵ Another possibility is that “an increase in adenosis occurs at menarche . . . and results in greater quantities of benign tissue at risk for malignant change.”²⁶

Either way, “adenosis has been reported in 30% to 90% of postpubertal girls . . . whose mothers received diethylstilbestrol

fact that vaginal cancer began occurring after puberty among DES daughters, and the fact that menopause is the time during women's lives, in addition to puberty and pregnancy, when hormonal changes are at their maximum. See also Herbst, Kurman, Scully & Poskanzer, *Clear-Cell Adenocarcinoma of the Genital Tract in Young Females: Registry Report*, 287 N. ENG. J. MED. 1259, 1263 (1972); Whitehead, Townsend, Pryse-Davies, Path, Ryder & King, *Effects of Estrogens and Progestins on the Biochemistry and Morphology of the Postmenopausal Endometrium*, 305 N. ENG. J. MED. 1599 (1981).

21. See Part II.E. *infra*.

22. See FORDHAM Comment, *supra* note 2, at 965; Herbst, Ulfelder & Poskanzer, *supra* note 6, at 880 (“predisposing condition”); Staff & Mattingly, *supra* note 20 (“precancerous lesion”).

23. FORDHAM Comment, *supra* note 2, at 965 n.10.

24. Poskanzer & Herbst, *supra* note 6, at 1893-94.

25. Herbst, Ulfelder & Poskanzer, *supra* note 6, at 880.

26. *Id.*

or a closely related congener during pregnancy.”²⁷ At the same time, benign adenositis is found “in over 97% of vaginal clear cell adenocarcinomas, whether a history of DES exposure is confirmed or not, even though primary vaginal adenositis is almost unknown in the normal population in this age group.”²⁸ These statistics prompted one leading authority to conclude that the “high concurrence of benign vaginal adenositis with these adenocarcinomas suggests that an anomaly of vaginal epithelial development may be a predisposing condition.”²⁹

Thus, “[w]hen carcinoma is found, coexistent benign adenositis is the rule.”³⁰ The transition from the benign condition to the malignant “is assumed to be the probable sequence of events.”³¹ Detection of the cancer then becomes crucial. Most cases are diagnosed by examination and biopsy in young girls who complain of “abnormal bleeding or bloody intermenstrual discharge. A few are detected in the presymptomatic stage of disease during examination carried out because of known prenatal exposure to DES.”³² Once the cancer is detected, treatment by radical surgery³³ or radiation³⁴ follows; in a significant percentage of cases treated by these methods, recurrence and death may nevertheless result.³⁵

Two legal issues arise from this sequence of events that begins with fetal exposure to DES *in utero* and ends with detection and treatment of cancer during postpubertal adolescence. Both center on the fact that DES affects the plaintiff when she is exposed to it *in utero*; in essence, the injury occurs at that time, although the damages do not become manifest until years later. Accordingly, the DES plaintiff must demonstrate, first, that the drug companies that marketed DES to her mother had a duty to her as an unborn fetus and, second, that her action has not been barred by the applicable statute of limitation.

27. 40 Fed. Reg. 32,773 (1975).

28. Ulfelder, *supra* note 6, at 428.

29. Herbst, Ulfelder & Poskanzer, *supra* note 6, at 880.

30. Ulfelder, *supra* note 6, at 430.

31. *Id.*

32. *Id.* at 427.

33. See note 18 and accompanying text *supra*; FORDHAM Comment, *supra* note 2, at 965 n.9.

34. FORDHAM Comment, *supra* note 2, at 965 n.9.

35. One group of women who received such treatments experienced a 24% recurrence rate and a 16% fatality rate. *Id.*

1. *Duty to a Fetus*.—The first American case to consider whether a person could recover for a prenatal common-law tort was *Dietrich v. Inhabitants of Northampton*,³⁶ in which Justice Holmes, writing for the Massachusetts Supreme Court, held that recovery for injuries to a fetus would not lie. This rule remained virtually uncontroverted until *Bonbrest v. Kotz* in 1946.³⁷ Dean Prosser cites two reasons for the original holding:

First, that the defendant could owe no duty of conduct to a person who was not in existence at the time of his action; and second, that the difficulty of proving any causal connection between negligence and damage was too great, and there was too much danger of fictitious claims.³⁸

Nearly sixty years after *Dietrich*, Chief Justice Brogan's dissent in *Stemmer v. Kline*³⁹ attacked the Holmes opinion, asking "why the court should feel restrained from breaking with the doctrine that a child *en ventre sa mere* has no separate being in the field of torts when in every other field of law a child has a separate being, is a person, if being in that category is for its benefit."⁴⁰ Four years later, based on increasing acceptance of such criticism,⁴¹ *Bonbrest* decided that a child, if born alive, could recover for the consequences of prenatal injuries.⁴² This decision triggered a trend that Prosser calls "the most spectacular abrupt reversal of a well settled rule in the whole history of the law of torts."⁴³ Today, all jurisdictions allow a cause of action for prenatal injuries if the child is born alive.⁴⁴

Nevertheless, the DES plaintiff may have difficulty with her first obstacle in those few jurisdictions that require the injury to occur after viability,⁴⁵ because DES was usually administered

36. 138 Mass. 14 (1884).

37. 65 F. Supp. 138 (D.D.C. 1946).

38. W. PROSSER, HANDBOOK OF THE LAW OF TORTS 335 (4th ed. 1971) [hereinafter cited as W. PROSSER].

39. 128 N.J.L. 445, 465-66, 26 A.2d 684, 686-87 (1942).

40. Gordon, *The Unborn Plaintiff*, 63 MICH. L. REV. 579, 583 (1965).

41. W. PROSSER, *supra* note 38, at 336.

42. *Bonbrest v. Kotz*, 65 F. Supp. 138 (D.D.C. 1946).

43. W. PROSSER, *supra* note 38, at 336.

44. *Id.* at 337; FORDHAM Comment, *supra* note 2, at 971 n.24.

45. W. PROSSER, *supra* note 38, at 337; FORDHAM Comment, *supra* note 2, at 971 n.24.

early in pregnancy⁴⁶ and because "substantial medical authority . . . indicates that congenital structural defects occasioned by environmental factors can be sustained only within the earliest stages of the *previable* period."⁴⁷ In the context of DES litigation, the reasons for rejecting the minority position that requires viability become even stronger when it is recalled that a duty should extend to all *foreseeable* plaintiffs. Because "DES was specifically aimed at the placenta and fetus"⁴⁸ and because "[i]t was well known, before FDA approval was sought, that substances given a pregnant woman would pass through the placenta into the fetus,"⁴⁹ the DES daughter should have no difficulty in showing that the drug industry owed her a duty while she was a fetus. She was a *quite* foreseeable plaintiff.

2. *Statutes of Limitation*.—Furthermore, the DES daughter should have no difficulty satisfying the statute of limitation in the many jurisdictions where the "discovery rule" prevents the statute from running until she becomes or should become aware of her injuries.⁵⁰ But an alarming trend may deprive her of her cause of action even before she is aware of her injury if she is unfortunate enough to live in a state that has adopted a "date-of-sale" statute of limitation.⁵¹ Responding to questionable⁵² assertions of a crisis in products liability litigation and in the resulting increase in insurance premiums, sixteen states since 1977⁵³ have enacted date-of-sale statutes of limitation.

46. FORDHAM Comment, *supra* note 2, at 971 n.24.

47. Note, *The Impact of Medical Knowledge in the Law Relating to Prenatal Injuries*, 110 U. PA. L. REV. 554, 563 (1962) (emphasis in original).

48. Bichler v. Eli Lilly & Co., 79 A.D.2d 317, —, 436 N.Y.S.2d 625, 630 (1981).

49. *Id.* at —, 436 N.Y.S.2d at 629.

50. See generally W. PROSSER, *supra* note 38, at 144; Burch, *A Practitioner's Guide to the Statutes of Limitations in Product Liability Suits*, 5 BALT. L. REV. 23, 36-40 (1975); Massery, *Date of Sale Statutes of Limitation—A New Immunity for Product Suppliers*, 1977 INS. L.J. 535, 538; FORDHAM Comment, *supra* note 2, at 970-71 n.23.

51. See, e.g., Burch, *supra* note 50, at 23; Massery, *supra* note 50, at 535; Phillips, *An Analysis of Proposed Reform of Products Liability Statutes of Limitations*, 56 N.C.L. REV. 663 (1978); Note, *The Statute of Limitations in Strict Products Liability Actions*, 24 BUFFALO L. REV. 477 (1974-75); Note, *Date-of-Sale Statutes of Limitation: An Effective Means of Implementing Change in Products Liability Law*, 30 CASE W. RES. L. REV. 123 (1979); Comment, *State Legislative Restrictions on Product Liability Actions*, 29 MERCER L. REV. 619 (1978).

52. Note, *Date-of-Sale Statutes of Limitation*, *supra* note 51, at 124 n.6. See generally Nader, *The Corporate Assault on Products Liability*, 1977 TRIAL 38.

53. The first state was Utah. UTAH CODE ANN. § 78-15-3 (1977). The other jurisdictions include Alabama, ALA. CODE tit. 6, § 5-502 (1979); Arizona, ARIZ. REV. STAT. ANN. §

The feeling of the respective legislatures was perhaps best stated by the sponsor of the Utah act who explained the statute of limitations provision as a way "to prevent lawsuits where products manufactured 15 to 30 years ago have come back to haunt manufacturers when, at the time of manufacture, technology and safety practices were either nonexistent or not applicable to the industry."⁵⁴

However relevant this reasoning may be to strict liability cases, it is totally inapplicable to the DES case in which the plaintiff seeks to prove negligent failure to test, since the plaintiff in such a case must show that the drug manufacturer did know or should have known of the cancer-causing risks of its drug at the time of the sale.⁵⁵

The distinction between the two types of limitation is "essential . . . for DES plaintiffs because it may be twenty years or more before the carcinogenic effects of the drug become manifest."⁵⁶ On one hand, the discovery rule perfectly suits the con-

12-551 (1978); Colorado, COLO. REV. STAT. § 13-21-403(3) (1977); Connecticut, CONN. GEN. STAT. ANN. § 52-577a (1978); Florida, FLA. STAT. ANN. § 95.031(2) (1978); Georgia, GA. CODE ANN. § 105-106(b)(2) (1978); Indiana, IND. CODE ANN. § 33-1-1.5-5 (Burns 1978); Kentucky, KY. REV. STAT. ANN. § 411.310 (Baldwin 1978); Nebraska, NEB. REV. STAT. § 25-224(1), (2) (1978); New Hampshire, N.H. REV. STAT. ANN. § 507-D:2 (1978); North Dakota, N.D. CENT. CODE § 28-01.1-02 (1979); Oregon, OR. REV. STAT. § 30.905(1) (1977); Rhode Island, R.I. GEN. LAWS § 9-1-13 (1978); South Dakota, S.D. CODIFIED LAWS ANN. § 15-2-12.1 (1978); Tennessee, TENN. CODE ANN. § 29-28-103 (1978).

Among these statutes are several notable differences. The time period during which an action may be commenced ranges from five years after sale of the product in Kentucky to twelve years in Arizona, Florida, and New Hampshire. In addition, several statutes are structured differently. Some limitation periods are measured from the date of manufacture, as in North Dakota and Utah, while other limits reflect the anticipated life of the product, as in Tennessee. A number of date-of-sale limitations supplement the date-of-injury limitation, which further restricts the ability to bring a products liability action. *E.g.*, Alabama, ALA. CODE tit. 6, § 5-502 (1979); Colorado, COLO. REV. STAT. § 13-21-403(3) (1977); Connecticut, CONN. GEN. STAT. ANN. § 52-577a (1978); Florida, FLA. STAT. ANN. § 95-031(2) (1978); Indiana, IND. CODE ANN. § 33-1-1.5-5 (Burns 1978); Nebraska, NEB. REV. STAT. § 25-224(1), (2) (1978); New Hampshire, N.H. REV. STAT. ANN. § 507-D:2 (1978). One state has made an exception to the statute of limitation for negligence or breach of warranty on the part of the manufacturer or seller. ARIZ. REV. STAT. § 12-551 (1978). Still other states formulated a rebuttable presumption within their statutes. Under these statutes, the product is presumed to be nondefective upon expiration of the date-of-sale limitation. *E.g.*, Colorado, COLO. REV. STAT. § 13-21-403(3) (1977); Kentucky, KY. REV. STAT. ANN. § 411.310 (Baldwin 1978); North Dakota, N.D. CENT. CODE § 28-01.1-05 (1979).

54. Comment, *State Legislative Restrictions*, *supra* note 51, at 627.

55. See Part II.C. *infra*.

56. FORDHAM Comment, *supra* note 2, at 970 n.23.

text from which it arose: medical malpractice cases and products liability cases involving drugs⁵⁷ in which the plaintiff, however diligent, may not become aware of her injuries until long after the tortious conduct. On the other hand, "it would seem that rather than protecting innocent manufacturers from unwarranted claims, the adoption of the Model [date-of-sale] Bill may result in shielding clearly culpable defendants from the valid claims of severely injured plaintiffs."⁵⁸ Specifically citing as one of his examples the problems that DES daughters would face under date-of-sale statutes of limitation, Ralph Nader generalized the basic policy argument against this "corporate assault on products liability"⁵⁹ law:

There is now a tendency in corporate circles . . . to create a scare based upon wholly-insupportable allegations. [This] is the case in the products liability struggle.

For instance, until a year ago I used to hear from insurance circles that there were one million products liability cases filed in the courts. Everytime I wrote the insurance companies to challenge that statement, they could not support it. This confirms the belief of many lawyers that only a fraction of the injuries due to dangerously designed or constructed products, less than one percent, are brought to justice.

This illustrates an interesting point about the rights that we have in this country. As long as they are merely rights on paper they are generally publicized by the established interests, particularly those who want to compare our system favorably with others. But the moment some of these rights begin to have an effect, the moment they are used, like products liability rights, the moment a few people start getting compensation for grievous injuries, then the clarion call is, "The system is being abused," and it is time to curtail these rights—not time, please note—to curtail the hazards.⁶⁰

Mr. Nader's remarks seem particularly pertinent to the battles over DES; until late 1980 *only one case* had gone to judgment in favor of a plaintiff.⁶¹

Even more disconcerting than the policy arguments are the

57. Burch, *supra* note 50, at 36-40.

58. Massery, *supra* note 50, at 544.

59. Nader, *supra* note 52, at 40.

60. *Id.* at 38-39.

61. J. BICHLER, *supra* note 3, at 188.

constitutional objections to date-of-sale statutes of limitation. Although the courts are split over the constitutionality of such statutes,⁶² the Florida Supreme Court in *Diamond v. E.R. Squibb & Sons* recently expressed the better view.⁶³ Responding to a motion to dismiss based on the state's twelve-year date-of-sale statute, the DES plaintiffs in *Diamond* argued that application of the statute to them would altogether abolish their right of action in violation of due process principles and article I, section 21 of the Florida Constitution.⁶⁴ That section ensures that the "courts shall be open to every person for redress of any injury, and justice shall be administered without sale, denial, or delay."⁶⁵ The court agreed:

The operation of [the date-of-sale statute] in this case has the same effect as it had in *Overland Construction Co. v. Sirmons* The statute of limitations operated there to bar the cause of action before it ever accrued, so that no judicial forum was available to the aggrieved plaintiff. A majority of the members of this Court declared the limitations period unconstitutional as applied on the ground that it violated article I, section 21, Florida Constitution.

We find that binding precedent exists because petitioners' right of action was barred before it ever existed, as in *Overland*. We therefore hold that as applied in this case, [the statute] violates the Florida Constitution's guaranty of access to courts.⁶⁶

The same result seems compelled by analysis of date-of-sale limitations under federal standards governing due process and equal protection.⁶⁷ Accordingly, neither date-of-sale statutes of limitation nor allegations that drug manufacturers owed her no duty should prevent the DES plaintiff from plunging deeper into the labyrinth.

62. Compare *Tyson v. Johns-Manville Sales Corp.*, 399 So. 2d 263 (Ala. 1981); *Dague v. Piper Aircraft Corp.*, 418 N.E.2d 207 (Ind. 1981); and *Purk v. Federal Press Co.*, 387 So. 2d 354 (Fla. 1980) with *Overland Constr. Co. v. Sirmons*, 369 So. 2d 572 (Fla. 1979) and *Diamond v. E.R. Squibb & Sons*, 397 So. 2d 671 (Fla. 1981).

63. 397 So. 2d 671 (Fla. 1981).

64. *Id.* at 672.

65. FLA. CONST. art. I, § 21.

66. 397 So. 2d at 672 (emphasis omitted).

67. See Massery, *supra* note 50, at 545-48; Note, *Date-of-Sale Statutes of Limitation*, *supra* note 51, at 145-52.

B. Cause-In-Fact and Manufacturer Identity

Having demonstrated a duty to her while she was a fetus, as well as the impropriety of barring her action under the applicable statute of limitation, the DES plaintiff next encounters the issue that has proved fatal to numerous DES claims: the identification of the proper defendants, a necessary component of the cause-in-fact requirement.⁶⁸ Given the lapse of time between her mother's pregnancy and her present lawsuit, it is very difficult for the DES plaintiff to trace her mother's prescription to specific pharmacies and then to specific manufacturers. Inability to identify the particular producers of the pills her mother took requires the DES daughter to rely on substitute methods for satisfying the cause-in-fact element. If she fails, her suit is over even before she can argue that she is the victim of negligence.

Four substitutes for precise defendant identification have been accepted by a growing minority of courts.⁶⁹ The bulk of legal literature concerning DES litigation focuses on these substitutes,⁷⁰ because few cases ever move beyond the cause-in-fact inquiry. Although comparisons of the four theories abound, too little attention is paid to their practical similarities. To understand these similarities, a description of the drug industry's conduct in producing and marketing DES is necessary.

"The drug industry is one of both high profits and high returns,"⁷¹ in which parallel practices abound.⁷² Nowhere have such patterns been more evident than in the development of DES: common chemical standards, uniform labelling and product literature, and generic marketing techniques all combine to hinder the DES plaintiff's ability to specify the proper defendants.⁷³ A group of twelve manufacturers guided the industry through Federal Drug Administration (FDA) approval proceedings that eventually led to the marketing of DES. After initial

68. See FORDHAM Comment, *supra* note 2, at 972.

69. See notes 82-120 and accompanying text *infra*.

70. FORDHAM Comment, *supra* note 2, at 978-1007; Recent Developments, 4 AM. J. TRIAL ADVOC. 492, 492-98 (1980); Case Note, 16 TULSA L.J. 286, 298-316 (1980); Recent Cases, 49 U. CIN. L. REV. 926 (1980); Comment, 49 UMKC L. REV. 245, 250-56 (1981); Note, 42 U. PA. L. REV. 669 (1981); Note, 59 WASH. U.L.Q. 571 (1981).

71. FORDHAM Comment, *supra* note 2, at 975.

72. *Id.* at 976-78; Bichler, 79 A.D.2d at ___, 436 N.Y.S.2d at 633.

73. FORDHAM Comment, *supra* note 2, at 975. See also notes 102 & 114 and accompanying text *infra*.

applications to market the drug were rejected,

twelve manufacturers, including Lilly, were convened at the behest of the FDA and agreed to cooperate with each other in the approval process. Thereafter, these twelve worked through a voluntarily formed committee known as the "Small Committee," which consisted of representatives of four of these companies and which was chaired by Lilly. . . . The Small Committee pooled all clinical data pertaining to DES for submission. Lilly's literature became the model for the literature used as the package insert. . . . Although the subsequent FDA approval was limited to use for several conditions, none of which related to pregnancy, there was evidence . . . that Lilly was even then contemplating use of DES for toxemia in pregnancy.

In 1947, Lilly and other drug companies filed supplemental applications with the FDA for permission to market DES for treatment of certain complications of pregnancy involving early termination of the pregnancy or death of the fetus. The dosage contemplated for this use was several times stronger than the maximum permitted in 1941.⁷⁴

Approval of the supplemental applications triggered manufacturing of DES by hundreds of drug companies⁷⁵ and prescription of the drug for millions of pregnant women.⁷⁶ Despite the number of DES manufacturers, the original applicants continued to dominate the market: "it has been estimated that Eli Lilly & Co. and five or six other manufacturers accounted for 90% of the market for this drug."⁷⁷ Expert evidence indicates that Lilly was the largest producer of DES⁷⁸ with a 45% share of the market.⁷⁹

In 1971 the FDA responded to studies linking DES use with later development of vaginal cancer in the users' daughters by contraindicating DES for use by pregnant women.⁸⁰ Thus the drug was "effectively banned . . . for this purpose both because of its danger and ineffectiveness."⁸¹

74. *Bichler*, 79 A.D.2d at ___, 436 N.Y.S.2d at 628.

75. FORDHAM Comment, *supra* note 2, at 964.

76. *Id.*

77. *Id.* at 977.

78. *Bichler*, 79 A.D.2d at ___, 436 N.Y.S.2d at 627, 633.

79. *Id.* at ___, 436 N.Y.S.2d at 627, 634.

80. FORDHAM Comment, *supra* note 2, at 966.

81. *Id.*

Armed with such evidence, DES plaintiffs today assert four distinct but related theories to overcome the traditional requirement of identifying the proper defendants with precision. "Concert of action" and "alternative liability" both represent novel applications of established theories; "enterprise liability" represents a novel synthesis of concerted action and alternative liability; and "modified alternate liability," often called "market share" liability, represents an innovative extension of an established theory. Each theory satisfies the cause-in-fact requirement by identifying a group of joint tortfeasors rather than specifying the precise manufacturer of the pills taken by the plaintiff's mother. The judiciary's reception of these theories has been mixed; the cause-in-fact issue accordingly remains one of the most difficult impediments encountered by DES daughters.

1. *Concerted Action*.—Prosser explains that "[t]he original meaning of a 'joint tort' was that of vicarious liability for concerted action."⁸² The principle holds that

[a]ll those who, in pursuance of a common plan or design to commit a tortious act, actively take part in it, or further it by cooperation or request, or who lend aid or encouragement to the wrongdoer, or ratify and adopt his acts done for their benefit, are equally liable with him.⁸³

Under concerted action each defendant becomes a "substantial factor" in causing the plaintiff's injury because all of the joined defendants have combined to generate the harm.⁸⁴ Evidence of a tacit agreement suffices to establish the theory,⁸⁵ and inference of such a tacit understanding may be based on consciously parallel or imitative conduct.⁸⁶ The leading products liability case is *Hall v. E.I. DuPont De Nemours & Co.*,⁸⁷ which applied the concerted action theory to the dynamite blasting cap industry.

Only a few courts, however, have accepted the concerted action theory in the context of DES litigation. In *Abel v. Eli Lilly*

82. W. PROSSER, *supra* note 38, at 291.

83. *Id.* at 292.

84. *Id.* at 240; FORDHAM Comment, *supra* note 2, at 980.

85. W. PROSSER, *supra* note 38, at 292.

86. See FORDHAM Comment, *supra* note 2, at 980, 983, 984. Useful analogies are found in antitrust conspiracy cases. See *id.* at 983.

87. 345 F. Supp. 353 (E.D.N.Y. 1972). See also FORDHAM Comment, *supra* note 2, at 981-82.

& Co.,⁸⁸ the Michigan Court of Appeals reversed a summary judgment for defendants, holding that allegations of concerted action do state a proper cause of action, but the court failed to specify what evidence would suffice to establish the joint tort.⁸⁹ More recently the New York Supreme Court in *Bichler v. Eli Lilly & Co.*,⁹⁰ affirmed the first⁹¹ final judgment in favor of a DES daughter based on the concerted action theory. The New York court held that the evidence of acting in concert was "overwhelming"⁹² after detailing the grounds for inferring both express agreement and tacit understanding rooted in conscious parallelism:

The original cooperation by the twelve manufacturers and pooling of information, the agreement on the same basic chemical formula, and the adoption of Lilly's literature as a model for package inserts for joint submission to the FDA in 1941, can rationally be construed as an express agreement for purposes of finding concerted action, even if such cooperation was first invited by the FDA. And Lilly, it will be remembered, was the leader of the voluntarily formed Small Committee, which organized and expedited the effort for the twelve. By this activity, these manufacturers were acting on behalf of all later manufacturers of DES inasmuch as they set the pattern for acceptance by the FDA. There was evidence in abundance of conscious parallel activity thereafter by the drug companies which later sought FDA approval of DES for use in treating risks of pregnancy, evidence from which may be inferred a tacit understanding. In fact, by terms of the FDA supplemental application form, applicants for this new usage of DES could, and did, rely on the data contained in the original application for DES usage concerning which no change was proposed. There was also some evidence that Lilly encouraged others to so rely. And, again, it is to be remembered that the data of the original application for DES approval used by each drug company was that which was commonly agreed upon and submitted by the original twelve manufacturers, in accordance with the work of the Small Committee chaired by Lilly. It follows that all such reliance and cooperation was beneficial to each producer of

88. 94 Mich. App. 59, 289 N.W.2d 20 (1980).

89. *Bichler*, 79 A.D.2d at —, 436 N.Y.S.2d at 632.

90. 79 A.D.2d 317, 436 N.Y.S.2d 625 (1981).

91. J. BICHLER, *supra* note 3, at 188.

92. *Bichler*, 79 A.D.2d at —, 436 N.Y.S.2d at 633.

DES. It is obvious that to hold up a product's distribution for further testing would not be economically feasible in the race to win a market share. Although Lilly was the second manufacturer to make the supplemental application, it was also the leading manufacturer, and subsequent applications by others requested the same standard new dosage and relied on the same set of research studies as Lilly.⁹³

Other courts, however, have rejected the concerted action theory, holding that its application "to this situation would expand the doctrine far beyond its intended scope and would render virtually any manufacturer liable for the defective products of an entire industry."⁹⁴

2. *Alternative Liability*.—Rather than relying on concerted action, the DES litigant might persuade the court to apply the theory of alternative liability:

When all defendants have acted tortiously, but not in concert, and not all have caused the plaintiff's injury, liability has been imposed on all defendants under the theory of alternative liability. Under this theory the burden of proof shifts to each defendant, who must prove that he did not cause the injury. In *Summers v. Tice* the plaintiff could not determine which of two negligent hunters fired the shot that injured him. Rather than exonerate both tortfeasors because plaintiff could not prove by a preponderance of the evidence which defendant was responsible, the court held both defendants jointly and severally liable.⁹⁵

This theory was also accepted by the Michigan Court of Appeals in *Abel*⁹⁶ and by the Superior Court of New Jersey in *Ferrigno v. Eli Lilly & Co.*⁹⁷ The court in *Ferrigno* specified five reasons for its acceptance. First, the defendants were members of a group in which every member was potentially blameworthy;⁹⁸ second, the defendants owed a special duty to the plaintiffs;⁹⁹ third, the

93. *Id.*

94. *Sindell v. Abbott Laboratories*, 26 Cal. 3d 588, 605, 607 P.2d 924, 933, 163 Cal. Rptr. 132, 141 (1980), *cert. denied*, 449 U.S. 912 (1981).

95. Note, 49 U. CIN. L. REV. 926, 930 (1980).

96. *Abel*, 94 Mich. App. at 73-77, 289 N.W.2d at 25-27.

97. 175 N.J. Super. 551, 420 A.2d 1305 (1980).

98. *Id.* at 567, 420 A.2d at 1313.

99. *Id.* at 568, 420 A.2d at 1313.

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plaintiffs were totally innocent;¹⁰⁰ fourth, the plaintiffs' injuries, unrelated to the purpose for ingesting DES, were not foreseeable by them;¹⁰¹ and

[f]ifth, while defendants in the DES cases may not have knowledge superior to that of plaintiffs as to identification, the frustration which plaintiffs have continuously experienced has been caused to some degree by defendants themselves, albeit inadvertently. Defendants marketed the drug generically, making it a fungible item without a name tag. In addition, the drug by its very nature did not give any clues of its ill effects until a generation after its use, long after any records that any consumer might keep were reasonably discarded.¹⁰²

The court's ultimate focus on the reasons why a DES plaintiff has difficulty identifying the manufacturer is especially appropriate in light of the marketing practices of the drug industry.¹⁰³ Nevertheless, most courts reject alternative liability's shift of the burden because of the plaintiff's typical inability to join "all the parties who were or could have been responsible for the harm caused."¹⁰⁴

3. *Enterprise Liability*.—To avoid the difficulties of applying concerted action and alternative liability to DES litigation, a novel synthesis of the two has been proposed. Enterprise liability focuses on industrywide conduct, as does concerted action, but does not require a tacit agreement.¹⁰⁵ Enterprise liability also allows the defendant to exculpate itself after the burden has been shifted to it, as does alternative liability, but, unlike alternative liability, does not require that *all* potential wrongdoers be joined.¹⁰⁶ In essence, enterprise liability borrows from both of the traditional theories by requiring the plaintiff to satisfy the following elements:

- 1) Plaintiff is not at fault for his inability to identify the causative agent, and such inability is due to the nature of the defendants' conduct.

100. *Id.* at 568, 420 A.2d at 1313.

101. *Id.* at 568, 420 A.2d at 1313-14.

102. *Id.* at 568, 420 A.2d at 1314.

103. See notes 72 & 73 and accompanying text *supra*.

104. *Sindell*, 26 Cal. 3d at 602, 607 P.2d at 931, 163 Cal. Rptr. at 139.

105. FORDHAM Comment, *supra* note 2, at 996-97.

106. *Id.*

- 2) A generically similar defective product was manufactured by all the defendants.
- 3) Plaintiff's injury was caused by this product defect.
- 4) The defendants owed a duty to the class of which plaintiff was a member.
- 5) There is clear and convincing evidence that plaintiff's injury was caused by the product of some one of the defendants. For example, the joined defendants accounted for a high percentage of such defective products on the market at the time of plaintiff's injury.
- 6) There existed an insufficient, industrywide standard of safety as to the manufacture of this product.
- 7) All defendants were tortfeasors satisfying the requirements of whichever cause of action is proposed: negligence, warranty, or strict liability.

Once plaintiff proves these elements, the burden of proof as to causation shifts to defendants, each of which can exonerate itself only by showing, according to the standards of proof already proposed, that its product could not have been the one which injured this particular plaintiff. Defendants, of course, may also attempt to disprove any and all elements of plaintiff's case. Damages will be apportioned among those defendants found liable in proportion to their market share.¹⁰⁷

Although this novel theory has received much attention in both commentary and case law, it has yet to be accepted by any court. Recently, a federal district court labeled it "repugnant to the most basic tenets of tort law,"¹⁰⁸ because it would "render every manufacturer an insurer not only of the safety of its own products, but of all generically similar products made by others. . . ."¹⁰⁹

4. *Modified Alternate Liability*.—Rejection of concerted action, alternative liability, and enterprise liability did not, however, prevent the ever-innovative California Supreme Court from creating a modified form of alternative liability to obviate the harshness of leaving DES daughters wholly without remedy.¹¹⁰ Recognizing the complexity of modern industrial society, in which "advances in science and technology create fungible

107. *Id.* at 995.

108. *Ryan v. Eli Lilly & Co.*, 514 F. Supp. 1004, 1017 (D.S.C. 1981).

109. *Id.*

110. *Sindell*, 26 Cal. 3d at 598, 610, 607 P.2d at 928, 936, 163 Cal. Rptr. at 136, 144.

goods which may harm consumers and which cannot be traced to any specific producer,"¹¹¹ the court in *Sindell v. Abbott Laboratories*¹¹² identified "[t]he most persuasive reason for finding plaintiff states a cause of action [as] that advanced by *Summers*: as between an innocent plaintiff and negligent defendants, the latter should bear the cost of the injury."¹¹³ Like the court in *Ferrigno*, the majority in *Sindell* focused on the industry's conduct as playing a significant role in making unavailable proof of which specific producers marketed drugs used in filling particular prescriptions.¹¹⁴ Moreover, the industry was deemed better able to bear the cost of consumer injuries, better able to discover and prevent defects, and better able to warn of harmful effects—considerations that are particularly important when drugs are involved, "for the consumer is virtually helpless to protect himself from serious, sometimes permanent, sometimes fatal, injuries caused by deleterious drugs."¹¹⁵ Thus, when "all defendants produced a drug from an identical formula and the manufacturer of the DES which caused plaintiff's injuries cannot be identified through no fault of plaintiff, a modification of *Summers* is warranted."¹¹⁶

The substance of the *Sindell* modification measures the likelihood that any of the defendants supplied the drugs that allegedly injured the 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."¹¹⁷ Using this measure, the injustice of shifting the burden of proof to the defendants to demonstrate they could not have manufactured the drug that injured the plaintiff "is significantly diminished" so long as the plaintiff "joins in the action the manufacturers of a substantial share of the DES" market.¹¹⁸ The court in *Sindell* further held that damages would be apportioned among those defendants who did not meet this burden of proof according to the same market shares that measured the

111. *Sindell*, 26 Cal. 3d at 610, 607 P.2d at 936, 163 Cal. Rptr. at 144.

112. 26 Cal.3d 588, 607 P.2d 924, 163 Cal. Rptr. 132 (1980).

113. *Id.* at 610-11, 607 P.2d at 936, 163 Cal. Rptr. at 144.

114. *Id.* at 601, 610-11, 607 P.2d at 930, 936, 163 Cal. Rptr. at 144.

115. *Id.* at 611, 607 P.2d at 936, 163 Cal. Rptr. at 144.

116. *Id.* at 611, 607 P.2d at 936, 163 Cal. Rptr. at 144.

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

118. *Id.* at 612, 607 P.2d at 937, 163 Cal. Rptr. at 145.

likelihood of their being the precise causal agent.¹¹⁹ Admitting that market share and apportionment of damages might be difficult to calculate, the California Supreme Court observed that under its approach "each manufacturer's liability would approximate its responsibility for the injuries caused by its own product."¹²⁰ That result is preferable to refusing to adjudicate the DES plaintiff's claim.

The *Sindell* modification prompted a flurry of casenotes and comments,¹²¹ some laudatory and some critical,¹²² but most agreeing that "market share liability" represented a unique approach to the DES problem.¹²³ Upon analysis, however, the *Sindell* approach proves to be innovative but not unique. The innovation simply extends the theory of alternative liability to a complex problem increasingly characteristic of modern industrial society. The court itself viewed its holding as simply a "modification" of *Summers*.

5. *Market Share Liability as a Unifying Concept.*—Indeed, "modified alternate liability" more accurately describes the *Sindell* holding than does "market share liability"¹²⁴—and the difference is more than semantic. Properly understood, "market share liability" could be used to describe three of the four methods that DES plaintiffs invoke to satisfy the cause-in-fact requirement. Although the court in *Sindell* tied market share liability to its modification of alternative liability, the seminal article on DES litigation, while proposing the enterprise liability synthesis, also stated that under *its* approach "[d]amages will be apportioned among those defendants found liable in proportion to their market shares."¹²⁵ Explaining this aspect of her proposal, the author placed market share liability in its proper context

119. *Id.* at 612, 607 P.2d at 937, 163 Cal. Rptr. at 145.

120. *Id.* at 612, 607 P.2d at 937, 163 Cal. Rptr. at 145.

121. Recent Developments, 4 AM. J. TRIAL ADVOC. 492 (1980); Case Note, 16 TULSA L.J. 286 (1980); Recent Cases, 49 U. CIN. L. REV. 926 (1980); Comment, 49 UMKC L. REV. 245 (1981); Note, 42 U. PA. L. REV. 669 (1981); Note, 59 WASH. U. L.Q. 571 (1981).

122. Compare Recent Cases, 49 U. CIN. L. REV. 926 (1980) and Note, 42 U. PA. L. REV. 669 (1981) with Recent Developments, 4 AM. J. TRIAL ADVOC. 492 (1980); Case Note, 16 TULSA L.J. 286 (1980); Comment, 49 UMKC L. REV. 245 (1981) and Note, 59 WASH. U. L.Q. 571 (1981).

123. See, e.g., Recent Developments, 4 AM. J. TRIAL ADVOC. 492 (1980); Case Note, 16 TULSA L.J. 286 (1980); Comment, 49 UMKC L. REV. 245 (1981).

124. See *Bichler*, 79 A.D.2d at —, 436 N.Y.S.2d at 631.

125. FORDHAM Comment, *supra* note 2, at 995.

by identifying it as a form of comparative contribution:

Much of the strength and justice of enterprise liability rests in the suggestion that damages be apportioned among defendants in proportion to their market shares. Since enterprise liability results in joint and several liability, each defendant is liable for the whole amount of the damages. Because contribution exists in the majority of jurisdictions, damages in fact will generally be divided among the defendants. Unfortunately, only a minority of jurisdictions recognizes a comparative form of contribution where the amount of damages each defendant pays is based on the degree to which each defendant caused plaintiff's injury, although such contribution is more equitable where the degree of responsibility among defendants is ascertainably unequal. It is suggested that comparative contribution should exist in enterprise liability. . . .¹²⁶

Interestingly, the only DES case that has gone to judgment in favor of the plaintiff based on a concerted action theory hails from New York,¹²⁷ a jurisdiction that recognizes comparative contribution by statute.¹²⁸ That statute apportions comparative contribution according to "equitable shares" and "relative culpability."¹²⁹ Application of these standards to a DES judgment based on concerted action, which itself focuses on the industry's conduct in the marketplace,¹³⁰ results in yet a third way of arriving at "market share liability." Since DES was produced and marketed as a fungible substance, relative fault correlates poorly with any attributes of the drug specific to any manufacturer; for the same reasons, equity and relative fault correlate well with market shares, especially when the gravamen of the legal claim implicates the conduct of all participants in the market as a whole.¹³¹ In short, *Sindell* is not unique in proposing that damages be apportioned among jointly liable defendants according to their relative market shares. Enterprise liability does the same thing, and concerted action arrives at the same result in those jurisdictions that recognize comparative contribution.

Thus, "market share liability" should be viewed as a *unify-*

126. *Id.* at 999-1000.

127. *Bichler*, 79 A.D.2d 317, 436 N.Y.S.2d 625 (1981).

128. N.Y. CIV. PRAC. LAW § 1400 (McKinney 1976).

129. *Id.* § 1402.

130. See notes 82-93 and accompanying text *supra*.

131. *Id.* See also FORDHAM Comment, *supra* note 2, at 978-85, 996-97.

ing concept rather than as a distinguishing feature of *Sindell*. As a unifying concept, market share liability provides the thread that thematically binds the theories invoked by DES plaintiffs to avoid dismissal on cause-in-fact grounds. Each of the theories has merit in light of the facts surrounding the production and marketing of DES; each can lead to apportionment of damages based on market shares; each accordingly reflects the sentiments of Learned Hand, uttered four decades ago: "the single tortfeasor cannot be allowed to escape through the meshes of a logical net. He is a wrongdoer; let him unravel the casuistries resulting from his wrong."¹³² DES plaintiffs should successfully hurdle the cause-in-fact obstacle in any jurisdiction enlightened enough to adapt its tort law to "contemporary complex industrialized society."¹³³ But even if she successfully negotiates the cause-in-fact requirement, the DES plaintiff still must confront the remaining impediments awaiting her in the labyrinth.

C. *Standard of Care and Collateral Estoppel*

To establish negligent failure to test, the DES daughter must prove that the drug manufacturers breached their standard of care.¹³⁴ The standard applicable to manufacturers of prescription drugs is a standard of expertise, as stated in *Krug v. Sterling Drug Co.*¹³⁵

[T]he manufacturer and distributor of a prescription drug to be administered to human beings, as with the manufacturer of a weed killer or a hair dye, should be "held to the skill of an expert in that particular business" and "to an expert's knowledge of the arts, materials and processes," and is bound to keep reasonably abreast of scientific knowledge and discoveries concerning his field and, of course, is deemed to possess whatever knowledge is thereby imparted." And it follows as a matter of course that there was no error in the court's . . . [i]nstruction . . . defining "negligence" as "failure to use the skill of an expert in the defendant's business."¹³⁶

132. *Navigazione Libera Triestina Societa Anonima v. Newtown Creek Towing Co.*, 98 F.2d 694, 697 (2d Cir. 1938), cited in Note, 49 U. CIN. L. REV. 926, 935 (1980).

133. *Sindell*, 26 Cal.3d at 610, 607 P.2d at 936, 163 Cal. Rptr. at 144.

134. See generally W. PROSSER, *supra* note 38, at 143-80.

135. 416 S.W.2d 143 (Mo. 1967).

136. *Id.* at 152 (citations omitted).

To fulfill this standard, the drug manufacturer must do more than comply with Federal Drug Administration requirements.¹³⁷ It is bound to have knowledge of medical journals warning of hazardous side effects of drugs it markets.¹³⁸

Reading all available data, however, is not sufficient. "The manufacturer has an obligation to test and inquire to determine the adverse effects of the drug A manufacturer can be liable for the failure to test and secure the information *The duty to test is commensurate with the potential for harm that a drug may have.*"¹³⁹ This additional obligation to test was characterized by Judge Wisdom as "even more important"¹⁴⁰ than the duty to be familiar with available knowledge: "A product must not be made available to the public without disclosure of those dangers that the application of reasonable foresight would reveal."¹⁴¹ In essence, existing knowledge triggers a duty to generate additional information.

1. *Evidence of Negligent Failure to Test.*—These duties arising from the drug industry's standard of expertise guide the jury when it balances "the risk, in light of the social value of the interest threatened, and the probability and extent of the harm, against the value of the interest which the actor is seeking to protect, and the expedience of the course pursued."¹⁴² Application of this formula to the DES context demonstrates the woeful inadequacy of drug industry precautions. As discussed below, evidence available before the withdrawal of DES from the market establishes that the drug was not effective in preventing miscarriages. The benefits of the drug were minor at best. Evidence available before DES was sold to pregnant women establishes that synthetic estrogens like DES were known to be carcinogenic and that the risks were high. Evidence that tests on mice were

137. See, e.g., *Stromstadt v. Parke-Davis & Co.*, 257 F. Supp. 991, 997 (D.N.D. 1966), *aff'd*, 411 F.2d 1390 (8th Cir. 1969).

138. See *Krug*, 416 S.W.2d at 143. As articulated by Judge Wisdom in the context of asbestosis litigation: "status as expert means that at a minimum he must keep abreast of scientific knowledge, discoveries, and advances, and is presumed to know what is imparted thereby." *Borel v. Fibreboard Paper Prods. Corp.*, 493 F.2d 1076, 1089 (5th Cir. 1973), *cert. denied*, 419 U.S. 869 (1974).

139. Dixon, *Drug Product Liability: Information for Safety*, 16 TRIAL 62-63 (Nov. 1980) (emphasis added).

140. *Borel*, 493 F.2d at 1089-90.

141. *Id.* at 1090.

142. W. PROSSER, *supra* note 38, at 149.

common even four decades ago and that such tests when performed confirmed the carcinogenic effects of DES demonstrates that "the burden of adequate precautions"¹⁴³ was low. Yet "none of the companies producing or marketing DES had performed any tests on the drug's effect on the fetus itself, either in humans or in animals."¹⁴⁴

In connection with efficacy, "[t]wo medical sources in the 1940's were primarily responsible for the belief that DES would significantly reduce the incidence of threatened abortions."¹⁴⁵ Both of these studies were, however, "historical" rather than "controlled studies,"¹⁴⁶ and both "were soon criticized for their lack of adequate controls."¹⁴⁷ Later controlled studies did not substantiate the earlier claims of efficacy.¹⁴⁸

Stilbestrol was synthesized in 1938 and was widely used from the mid-1940s to 1970 in the United States to prevent threatened miscarriage, though doubt was cast upon its value as a therapeutic agent in that situation as early as 1953. A statistical analysis of available studies in 1958 concluded that *there was no statistical evidence for the value of stilbestrol therapy in pregnancy*, but it continued to be regarded as appropriate treatment in many centers. . . .¹⁴⁹

In fact, in 1938 Dr. Charles Dodd, who originally synthesized the drug, published findings indicating DES actually caused rather than prevented miscarriages.¹⁵⁰

Not until 1962, however, did the FDA require proof of efficacy.¹⁵¹ In the late 1960s the FDA reviewed the effectiveness of drugs it had approved before 1962 and rated them as "effective,"

143. *United States v. Carroll Towing Co.*, 159 F.2d 169 (2d Cir. 1947) (Learned Hand, C.J.), cited in W. PROSSER, *supra* note 38, at 149.

144. *Bichler*, 79 A.D.2d at ___, 436 N.Y.S.2d at 630.

145. FORDHAM Comment, *supra* note 2, at 963 n.2.

146. J. BICHLER, *supra* note 3, at 134.

147. FORDHAM Comment, *supra* note 2, at 963 n.2; See also *Bichler*, 79 A.D.2d at ___, 436 N.Y.S.2d at 630.

148. See, e.g., Davis & Fugo, *Steroids in the Treatment of Early Pregnancy Complications*, 142 J.A.M.A. 778 (1950); Dieckmann, Davis, Pynkiewicz & Pottinger, *Does the Administration of Diethylstilbestrol During Pregnancy Have Therapeutic Value?*, 66 AM. J. OBST. & GYN. 1062 (1953); Robinson & Shettles, *The Use of Diethylstilbestrol in Threatened Abortion*, 63 AM. J. OBST. & GYN. 1330 (1952).

149. Poskanzer & Herbst, *supra* note 6, at 1892-93 (emphasis added).

150. *Bichler*, 79 A.D.2d at ___, 436 N.Y.S.2d at 630.

151. FORDHAM Comment, *supra* note 2, at 966 n.12.

"probably effective," "possibly effective," or "ineffective."¹⁵² DES was rated as "possibly effective," which meant "there is little evidence of effectiveness under any of the criteria stated."¹⁵³ Since 1973 drugs rated "possibly effective" have not been allowed FDA approval.¹⁵⁴ In short, before withdrawing DES from the market in 1971, the drug industry knew or should have known that the drug was not efficacious in preventing accidents of pregnancy.

The industry before 1971 also knew or should have known of the carcinogenic effects of DES. "As early as 1959 the FDA withdrew approval of the use of DES in chicken feed [as a growth stimulant] on the ground that it was a known carcinogen."¹⁵⁵ Indeed, knowledge that synthetic estrogens are carcinogenic was widespread in the 1940s,¹⁵⁶ and several studies during that time specifically questioned whether DES was carcinogenic and whether it would adversely affect the fetus *in utero*.¹⁵⁷ Those fears were not unfounded. In 1939 three physiologists administered DES to rats and mice and concluded that the drug crossed the placenta and had malforming action on the fetus.¹⁵⁸

The tests done on mice in 1939 demonstrate that such tests were available before FDA approval of DES was sought. Today, of course, animal testing is merely the first of several phases of testing required for FDA approval.¹⁵⁹ Testing on mice is especially useful in the DES context because of certain crucial similarities between the reproductive physiology of mice and that of humans.¹⁶⁰ When controlled testing of mice finally occurred, the "results . . . clearly demonstrate[d] the association between prenatal exposure to DES in mice and subsequent female genital tract abnormalities, including neoplasia [tumors]."¹⁶¹ In light of the high risks and questionable benefits associated with DES, one cannot help wondering why the drug industry failed to carry

152. *Id.*

153. *Id.* See also Poskanzer & Herbst, *supra* note 6, at 1893.

154. FORDHAM Comment, *supra* note 2, at 966 n.12.

155. *Id.* at 963 n.2.

156. Staff & Mattingly, *supra* note 20, at 676.

157. Bichler, 79 A.D.2d at ___, 436 N.Y.S.2d at 629.

158. *Id.* at ___, 436 N.Y.S.2d at 629.

159. See Dixon, *supra* note 139, at 64-65.

160. McLachlin, Newbold & Bullock, *supra* note 6, at 3994.

161. *Id.* at 3992.

its "burden of adequate precaution" before marketing DES to pregnant women between 1947 and 1971.

2. *The Collateral Estoppel Strategy*.—After hearing evidence of negligent failure to test adequately, the jury in *Bichler v. Eli Lilly & Co.*¹⁶² returned a general verdict in favor of Joyce Bichler and answered the following written interrogatories in support of that verdict:

(1) Was DES reasonably safe in the treatment of accidents of pregnancy when it was ingested by plaintiff's mother in 1953?
No.

(2) Was DES a proximate cause of plaintiff's cancer?
Yes.

(3) In 1953 when plaintiff's mother ingested DES, should the defendant, as a reasonably prudent drug manufacturer, have foreseen that DES might cause cancer in the offspring of pregnant women who took it?
Yes.

(4) Foreseeing that DES might cause cancer in the offspring of pregnant women who took it, would a reasonably prudent drug manufacturer test it on pregnant mice before marketing it?
Yes.

(5) If DES had been tested on pregnant mice, would the tests have shown that DES causes cancer in their offspring?
Yes.

(6) Would a reasonably prudent drug manufacturer have marketed DES for use in treating accidents of pregnancy at the time it was ingested by plaintiff's mother, if it had known that DES causes cancer in the offspring of pregnant mice?
No.

(7) Did defendant and other drug manufacturers act in concert with each other in testing and marketing of DES for use in treating accidents of pregnancy?
Yes.¹⁶³

Because the chemical structure of DES did not change during the time it was marketed to pregnant women,¹⁶⁴ questions (1), (3), (4), (5), (6) and (7) are identical to inquiries that would arise in any action based on negligent failure to test. A DES

162. No. 65534 (N.Y. Sup. Ct. Apr. 24, 1980).

163. *Id.*, judgment at 2-6.

164. Plaintiff's Third Set of Interrogatories to Defendant Eli Lilly & Co., question one, *Blanford v. Abbott Laboratories*, No. c 80-6445 (W.D. Wash. 1981).

daughter alleging such negligence may choose to avoid litigating the standard of care issue by offensively invoking collateral estoppel to preclude Eli Lilly from relitigating the six questions decided against it in *Bichler*. By seeking a partial summary judgment¹⁶⁵ on these questions, the DES plaintiff strengthens her litigation posture, shortens her trial, and seeks consistency in results—while still leaving the issues of proximate cause and ultimate liability for the jury.

The decision to invoke offensive collateral estoppel is not, however, as easy as it seems. If Eli Lilly is precluded from relitigating the six questions, then the plaintiff is likewise precluded from presenting some of her most potent evidence¹⁶⁶ to the jury, unless, of course, some of that evidence might creep in elsewhere in the trial. Allowing it to creep in, however, severely compromises the efficiency that is touted as one of collateral estoppel's advantages.¹⁶⁷ Moreover, recent commentators have criticized the use of collateral estoppel in products liability cases concerning mass produced products and nonsimultaneous injuries.¹⁶⁸ Courts sympathizing with this criticism may react with hostility to the plaintiff's use of the doctrine; the result might be that as much time would be spent debating its application as would otherwise have been spent in trying the six issues themselves. Nevertheless, the United States Supreme Court has upheld a plaintiff's offensive use of collateral estoppel,¹⁶⁹ and the trend supports its expansive application in the DES context.

165. See Fed. R. Civ. P. 56.

166. See notes 145-61 and accompanying text *supra*.

167. *Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 328 (1979); *Blonder-Tongue Laboratories, Inc. v. University of Ill. Found.*, 402 U.S. 313, 329 (1971).

168. See, e.g., Weinberger, *Collateral Estoppel and the Man Produced Product: A Proposal*, 15 N. ENG. L. REV. 1 (1979). Although Mr. Weinberger's critique repeatedly suggests its applicability to DES litigation, see *id.* at 1 n.2, 22 n.112, 46 n.192, not one of his examples nor the reasoning accompanying them confronts a DES claim based on negligent failure to test. Indeed, none of his specific examples of his distinction between "intrinsic" and "extrinsic" design defects, see *id.* at 39-41, 52-54, and none of his reasoning in connection with his analysis of the quadrigen cases, see *id.* at 42-52, even contemplates the existence of failure to test as a distinguishable theory of recovery.

Compare Wilner, *Can An Industry Be Collaterally Estopped From Litigating Product Liability Issues?*, 4 J. PROD. LIAB. 189 (1981) (opposes use of offensive collateral estoppel in products liability cases) with Kroll, *Principles of Collateral Estoppel in Products Liability*, 677 INS. L.J. 313, 327 (June 1979) (approves of use of offensive collateral estoppel: "for once it appears that the tail is not wagging the tiger").

169. *Parklane*, 439 U.S. at 332-33.

Four threshold requirements determine the applicability of collateral estoppel. First, the issue to be concluded must be identical to that involved in the prior action; second, the issue must have been actually litigated in the prior action; third, the issue must have been litigated against the party or one in privity with the party against whom the doctrine is invoked; and finally, the determination of the issue in the prior action must have been necessary to the resulting judgment.¹⁷⁰ All requirements are met when a DES plaintiff seeks to invoke *Bichler* against Eli Lilly: the six issues, as we have seen, are identical in both cases, Eli Lilly fully litigated them during the thirty-five days of trial and subsequent appeal in *Bichler*;¹⁷¹ and each was necessary to the jury's general verdict against the drug company in that case. The plaintiff need show nothing else to invoke the doctrine of collateral estoppel.

The former rule of mutuality, which required both parties in a present action to have been parties to or in privity with a party to the prior judgment before estoppel could be used to foreclose subsequent litigation on an issue, has been discarded by the Supreme Court.¹⁷² The Court first abandoned the mutuality requirement in *Blonder-Tongue Laboratories v. University of Illinois Foundation*,¹⁷³ when it asked "whether it is any longer tenable to afford a litigant more than one full and fair opportunity for judicial resolution of the same issue"¹⁷⁴ and answered negatively in the context of defensive collateral estoppel.¹⁷⁵ Eight years later the Court relied heavily on its reasoning in *Blonder-Tongue* when it upheld offensive collateral estoppel.

In *Parklane Hosiery v. Shore*,¹⁷⁶ the district court had refused to apply collateral estoppel offensively because it would deny the defendants their seventh amendment right to a jury trial.¹⁷⁷ The Second Circuit reversed, holding that a party who

170. *Lucas v. Velikanje*, 2 Wash. App. 888, 894, 471 P.2d 103, 107 (1970).

171. *Bichler*, No. 65534, judgment at 2 (N.Y. Sup. Ct. Apr. 24, 1980).

172. *Parklane*, 439 U.S. at 327; *Blonder-Tongue Laboratories*, 402 U.S. at 327-29.

173. 402 U.S. 313 (1971).

174. *Id.* at 328.

175. *Id.* at 329 (citations omitted). The Court emphasized that "the requirement of determining whether the party against whom an estoppel is asserted had a full and fair opportunity to litigate is a most significant safeguard" to assure that the issue was actually litigated in the prior suit. *Id.*

176. 439 U.S. 322 (1979).

177. *SEC v. Parklane Hosiery Co.*, 422 F. Supp. 477 (S.D.N.Y. 1976).

has had issues of fact determined against it after a full and fair opportunity to litigate in a bench trial is collaterally estopped from obtaining a subsequent jury trial of these same issues of fact.¹⁷⁸ The Supreme Court affirmed the Second Circuit's decision and concluded that the preferable approach is not to preclude the use of offensive collateral estoppel but to grant trial courts discretion to determine its applicability.¹⁷⁹

The Supreme Court's more recent treatments of collateral estoppel support the expanded use of the doctrine. In late 1980 the Court summarized the trend and added the following:

Indeed, though the federal courts may look to the common law or to the policies supporting *res judicata* and collateral estoppel in assessing the preclusive effect of decisions of other federal courts, Congress has specifically required all federal courts to give preclusive effect to state-court judgments whenever the courts of the State from which the judgments emerged would do so:

"The . . . judicial proceedings of any court of any State . . . shall have the same full faith and credit in every court within the United States and its Territories and Possessions as they have by law or usage in the courts of such State. . . ."¹⁸⁰

The Court's reference to full faith and credit concepts, twice in the same passage,¹⁸¹ may in fact reveal a constitutional basis for the expanding use of collateral estoppel: rather than being precluded from utilizing the doctrine, trial courts may find their discretion shrinking as they are compelled to use it in satisfaction of the requirements of full faith and credit.¹⁸²

This trend toward expanded use of collateral estoppel has been followed in products liability cases involving mass-produced products and nonsimultaneous injuries—cases exemplified by DES and asbestosis litigation. In *Flatt v. Johns-Manville Sales Corp.*,¹⁸³ the plaintiff sought to preclude relitigation of the issue of whether products containing asbestos are unreasonably

178. *Shore v. Parklane Hosiery*, 565 F.2d 815, 819 (2d Cir. 1977).

179. 439 U.S. at 331.

180. *Allen v. McCurry*, 449 U.S. 90, 95-96 (1980) (citations omitted).

181. *Id.*

182. U.S. CONST. art. IV, § 1.

183. 488 F. Supp. 836 (E.D. Tex. 1980).

dangerous and defective. The plaintiff moved for partial summary judgment against not only Johns-Manville, who had lost on that issue in *Borel v. Fibreboard Paper Products Corp.*,¹⁸⁴ but also against defendant Certain-Teed, who had never been a party to an adverse judgment in an asbestosis case. The court in *Flatt* granted the motion against both:

Defendants Johns-Manville and Certain-Teed are precluded from relitigating the issue of whether their asbestos products which were manufactured by each of said defendants were defective and unreasonably dangerous, under the provisions of the Restatement (Second) of Torts (1965). The Court directs that each defendant be collaterally estopped from raising said issue in the course of this trial.

The Court finds as a matter of law that products placed in the stream of commerce containing asbestos are defective for the reason that the same are unreasonably dangerous to the users of such products. *Borel, supra*. The Court holds as a matter of law that asbestos dust is a competent producing cause of certain lung diseases, including asbestosis and mesothelioma.¹⁸⁵

Even stronger are the reasons for collaterally estopping Eli Lilly, the drug industry's leader in DES development and sales,

184. 493 F.2d 1076 (5th Cir. 1974), *cert. denied*, 419 U.S. 869 (1974).

185. 488 F. Supp. at 841. Whether Certain-Teed was precluded from relitigation of the issue by operation of collateral estoppel or stare decisis or both is unclear from this quote. The court expressly included "each defendant" in its collateral estoppel holding, even though that inclusion with respect to Certain-Teed patently violates the requirement that the party being estopped had to be a party to the prior suit. Recently the Fifth Circuit in an astonishingly analogous case, *Migues v. Fibreboard Corp.*, 662 F.2d 1182 (5th Cir. 1981), interpreted *Flatt* to preclude Johns-Manville from relitigation on the basis of collateral estoppel, while correctly observing that Certain-Teed could only be precluded on the basis of stare decisis. *See id.* at 1186-87. The appellate panel in *Migues* then expressly declined to review the collateral estoppel issue because it was not squarely "presented in the case before us," *id.* at 1185, but proceeded to hold that *Borel* did not establish that asbestos products are unreasonably dangerous as a matter of law. *Id.* at 1187-89. Instead, *Borel* merely held that the jury possessed sufficient evidence to find for the plaintiff. *Id.* at 1189. Thus *Migues* effectively overturns *Flatt's* reasoning with respect to Certain-Teed while leaving its collateral estoppel holding against Johns-Manville intact. The Fifth Circuit's analysis correctly distinguishes between the issues, reaches an appropriate result, and is thoroughly consistent with the approach of this article—even to the point of subtly recognizing the possible propriety for greatly expanding collateral estoppel in other cases: "we do note that the juggernaut of modern technology has repeatedly given rise to new concepts in our torts jurisprudence and procedure." *Id.* at 1189. *See also* *Hardy v. Johns-Manville Sales Corp.*, 509 F. Supp. 1353 (E.D. Tex. 1981).

from relitigating the issues decided against it in *Bichler*. Eli Lilly has been named as a defendant in virtually every lawsuit involving DES, so the difficulties addressed by *Flatt*'s holding with respect to Certain-Teed do not arise. Moreover, because the composition of DES did not vary during the time it was sold to pregnant women,¹⁸⁶ all DES cases involve identical products and therefore identical issues. Most importantly, the specificity of the written interrogatories in *Bichler* leaves no question about whether the identical issues were actually litigated and resulted in the verdict in that case.¹⁸⁷

Yet in the first reported decision in which a DES plaintiff sought to rely on *Bichler* while invoking collateral estoppel, a new twist was added to the serpentine path. *Katz v. Eli Lilly & Co.*¹⁸⁸ held that Eli Lilly could depose two of the *Bichler* jurors in order to demonstrate that *Bichler* was based on a compromise verdict that should not be given collateral estoppel effect.¹⁸⁹ Although one commentator has extolled the virtues of the *Katz* holding,¹⁹⁰ three criticisms may be leveled against it. First, as another commentator has noted, *Katz* violates "the long-established Mansfield rule which prohibits a juror from impeaching his verdict."¹⁹¹

Second, as the same critic observed,¹⁹² *Katz* inadequately distinguished¹⁹³ Professor Moore's assertion:

A judgment on a compromise verdict, like any other erroneous

186. Plaintiff's Third Set of Interrogatories to Defendant Eli Lilly & Co., question one, *Blanford v. Abbott Laboratories*, No. c 80-6445 (W.D. Wash. 1981).

187. See generally *Bichler*, 79 A.D.2d at ___, 436 N.Y.S.2d at 634-36. The affirmance of *Bichler* on appeal against a panoply of asserted errors, see *id.* at ___, 436 N.Y.S.2d at 634-36, greatly enhanced one DES user's ability to negotiate the legal labyrinth successfully. See J. BICHLER, *supra* note 3, at 188. She does, however, face her decisive test in the New York Court of Appeals. See *DES Users*, Nat'l L.J., Mar. 15, 1982, at 19, col. 4.

188. 84 F.R.D. 378 (E.D.N.Y. 1979).

189. *Id.* at 381-82. The court in *Katz*, relying on the requirement that a party must have a full and fair opportunity to litigate an issue before it can be collaterally estopped, reasoned that "fundamental notions of fairness require that Lilly be afforded every reasonable opportunity to explore the factual basis for" its claim that *Bichler* was based on a compromise verdict, especially since the person invoking collateral estoppel was a stranger to the first suit and the depositions could not affect the finality of that first suit. *Id.*

190. See Weinberger, *supra* note 168, at 22 n.112, 46 n.192.

191. Note, 12 J. MAR. L. REV. 201, 207 (1980).

192. *Id.* at 217-18.

193. *Katz*, 84 F.R.D. at 382.

judgment, can be corrected in the trial court, or upon appeal. Collateral estoppel is by judgment, not by verdict; and a final judgment, though erroneous, is an adjudication entitled to collateral estoppel effect.¹⁹⁴

Indeed, on appeal of the *Bichler* verdict, the New York Supreme Court considered and rejected Eli Lilly's claim that the verdict was compromised. It explained that the trial court did not err in refusing the defendant's motion for a noncompromise verdict charge because the general verdict proved to be unanimous, the defendant failed to poll the jury to clarify its answers to the special interrogatories, and New York's civil practice rules authorize less than unanimous action by a jury with respect to such interrogatories.¹⁹⁵ Eli Lilly should no more be able to relitigate its claim that the verdict in *Bichler* was compromised than it should be able to relitigate the answers to the special interrogatories.

Finally, competent evidence of a genuine compromise verdict is tenuous. Eli Lilly was forced to seek depositions of members of the *Bichler* jury because of their apparent unwillingness to sign affidavits indicating that one juror conditioned her vote for liability on the understanding that the award of damages would be reduced by averaging the amounts thought proper by each juror.¹⁹⁶ Accordingly, Eli Lilly's effort to depose the jurors should be evaluated for exactly what it is: a defendant's attempt to use a hearsay account of conversations with the jurors to soften the impact of a dangerous precedent against it.¹⁹⁷ Furthermore, the averaging of individual jurors' awards to arrive at a final figure does not necessarily establish that the verdict was compromised in the legal sense.¹⁹⁸

194. 1B MOORE'S FEDERAL PRACTICE ¶ 0.443[4], at 3917 (2d ed. 1980).

195. *Bichler*, 79 A.D.2d at —, 436 N.Y.S.2d at 636 (citations omitted).

196. *Katz*, 84 F.R.D. at 380.

197. *Compare id. with Note*, 12 J. MAR. L. REV. 201, 206 n.25 (1980).

198. "A compromise verdict is one reached only by surrender of conscientious convictions on one material issue by some jurors in return for a similar relinquishment of matters in their opinion on another issue. The result is a verdict which does not have the full support of the entire jury." Note, 12 J. MAR. L. REV. 201, 206 n.24 (1980) (quoting BLACK'S LAW DICTIONARY 260 (5th ed. 1979)). "Quotient verdicts" indeed represent one type of compromise verdict, see 6A MOORE'S FEDERAL PRACTICE, *supra* note 194, ¶ 59.08[4], at 59-128, but the line between inappropriate averagings that constitute such verdicts and acceptable jury conduct is often a fine line:

While it may be accepted as settled that a verdict rendered in pursuance of an

Ironically, the ultimate test of *Katz* on appeal will never occur because, after securing the ability to depose *Bichler's* jurors, Eli Lilly settled the *Katz* case for \$235,000.¹⁹⁹ Given the three criticisms of *Katz*, DES daughters should be able to use the jury's answers to the special interrogatories from *Bichler* for collateral estoppel purposes.

The specificity of these interrogatories makes their availability for collateral estoppel use especially alluring. The DES plaintiff accordingly must choose between two strategies that will enable her to show a breach of the standard of care. She may present and rely on the evidence of the industry's negligent failure to test DES,²⁰⁰ or she may offensively invoke collateral estoppel. Both strategies should prove successful and enable her to proceed through the labyrinth to the next issue—legal cause.

D. Legal Cause and Statistical Association

Vaginal cancer is rare in women over the age of fifty years and was practically unknown in young women until the late 1960s.²⁰¹ Only three cases of clear cell adenocarcinoma of the vagina in young women were reported before 1966.²⁰² Between 1966 and 1969, however, eight girls between the ages of fifteen and twenty-two were treated for the disease in Boston.²⁰³

Given the rarity of this disease and the unusual number of young women with similar symptoms, an epidemiological case

agreement by the jurors to accept one-twelfth of the aggregate amount of their several estimates, without the assent of their judgment to such a sum as their verdict, is invalid, yet it is equally well settled that, although jurors divide the aggregate of their several estimates by 12, and return the quotient as their verdict, it will not be held to be legally objectionable if, after the amount has been ascertained, the respective jurors deliberately assent to and accept the amount so obtained as, in their opinion, a just verdict, and so return it. The essential ingredient of a 'quotient' verdict which renders it objectionable in the eye of the law is that there should be an antecedent agreement between the jurors to accept the result of the division without hesitation as the proper and true verdict to be rendered.

Consolidated Ice-Mach. Co. v. Trenton Hygeian Ice Co., 57 F. 898, 899 (C.C.D.N.J. 1893), quoted in 6A MOORE'S FEDERAL PRACTICE, *supra* note 194, ¶ 59.08[4], at 59-128 n.16.

199. Note, 12 J. MAR. L. REV. 201, 224 n.120 (1980).

200. See notes 144-161 and accompanying text *supra*.

201. Herbst, Ulfelder & Poskanzer, *supra* note 6, at 878.

202. Ulfelder, *supra* note 6, at 428.

203. Herbst, Ulfelder, & Poskanzer, *supra* note 6, at 878.

study was conducted to uncover facts that might be associated with the sudden appearance of these tumors.²⁰⁴ The result of the study demonstrated a "highly significant association between the treatment of mothers with estrogen diethylstilbestrol during pregnancy and the subsequent development of adenocarcinoma of the vagina in their daughters (p less than 0.00001)."²⁰⁵ This association has been confirmed in subsequent studies.²⁰⁶

The number of women who took DES will never be known, but estimates indicate that up to three million took it during pregnancies.²⁰⁷ Fortunately, the risk of clear cell adenocarcinoma developing in their exposed offspring appears to be small.²⁰⁸ Estimates range from a high of one in 250 to a low of one in 10,000.²⁰⁹ Before the DES-cancer connection is dismissed as extremely rare, however, it must be compared with the occurrence of clear cell adenocarcinoma among young women not exposed to DES *in utero*:

Among girls whose mothers were given stilbestrol during pregnancy, the cumulative incidence of vaginal adenocarcinoma to age 25 is somewhere between 1/1000 and 1/10,000. Let's assume the minimum incidence of 1/10,000. In non-exposed girls, the *maximum* incidence is 1/1,000,000. The difference in the rates (1/10,000-1/1,000,000) is .99/10,000, or 99% of the incidence in the exposed group. This figure, called the attributable risk percent in epidemiologic parlance, can be interpreted as the likelihood that the vaginal adenocarcinoma involved stilbestrol as a cause in this instance. Clearly, it is very likely (99%) that stilbestrol was involved.²¹⁰

In other words, the risk of vaginal adenocarcinoma is one hundred times greater among women exposed to DES *in utero*. In addition, the vast majority of these women suffer other abnor-

204. Poskanzer & Herbst, *supra* note 6, at 1892. The study referred to is reported in Herbst, Ulfelder & Poskanzer, *supra* note 6.

205. Herbst, Ulfelder, & Poskanzer, *supra* note 6, at 879.

206. See, e.g., Greenwald, Barlow, Nasca & Burnett, *supra* note 6; Nordquist, Fidler, Woodruff & Lewis, *Clear Cell Adenocarcinoma of the Cervix and Vagina*, 37 *CANCER* 858 (1976).

207. *FORDHAM Comment*, *supra* note 2, at 965 n.6.

208. See Herbst, Ulfelder & Poskanzer, *supra* note 6, at 880.

209. *FORDHAM Comment*, *supra* note 2, at 965 n.7.

210. Letter from Dr. Noel S. Weiss, Fred Hutchinson Cancer Research Center, Seattle, Wash., to James P. Moceris (Mar. 31, 1981) (on file with authors).

malities, the most common of which is the possibly precancerous condition called adenosis.²¹¹

Statistics cannot demonstrate a cause and effect relationship, but they demonstrate the close association between the exposure *in utero* to DES and the subsequent development of clear cell adenocarcinoma.

In an absolute sense, the causation of cancer could only be established through an understanding of the scientific mechanism whereby the introduction of a substance into the body creates a tumor. This is not understood in the case of DES. Neither is it understood in any instance of environmentally caused cancer.²¹²

Doctors are, however, able to observe the effects of DES on a woman's body. DES is a synthetic estrogen.²¹³ Its effects on the body are caused only if the hormone is capable of binding to a specific protein macromolecule within the cell called a receptor.²¹⁴ The only chemicals that will mimic the action of a particular hormone are those that will bind to a receptor. Conversely, the only tissues that respond to hormonal stimulation are those that contain the receptor. These tissues are called target tissues.²¹⁵ Estrogens have many target tissues. These include structures in the genital tract, the mammary gland, liver, kidney, pituitary gland, brain, and others.²¹⁶

The biochemical effects of DES on human fetal genital tissues are not fully understood because of the obvious restrictions placed upon scientific research on humans.²¹⁷ Scientists know, however, that estrogens stimulate the mullerian duct tissue, which is the embryonic origin of the vagina:

211. See FORDHAM Comment, *supra* note 2, at 968; Herbst, Ulfelder & Poskanzer, *supra* note 6, at 880.

212. See FORDHAM Comment, *supra* note 2, at 965 n.5.

213. Greenwald, Barlow, Nasca & Burnett, *supra* note 6, at 391.

214. See Munck, *General Aspects of Steroid Hormone-Receptor Interactions*, in RECEPTORS AND MECHANISMS OF ACTION OF STEROID HORMONES 2-3 (J.R. Pasqualini, ed. 1976). The principles governing such biochemical binding apply to both steroid and non-steroid hormones. Stump & Sar, *Autoradiographic Localization of Estrogen, Androgen, Progesterone and Glucocorticoid-steroid in "Target Tissues" and "Nontarget Tissues,"* in RECEPTORS AND MECHANISMS OF ACTION OF STEROID HORMONES 42 (J.R. Pasqualini, ed. 1976).

215. See generally Munck, *supra* note 214, at 2-5.

216. Stump & Sar, *supra* note 214, at 43-44.

217. See generally P. RAMSEY, *ETHICS OF FETAL RESEARCH* chs. 6-7 (1975).

Although it is also agreed that the vagina has an ancestry in both mullerian duct and urogenital sinus tissues, the exact contribution of each is not clear nor is the mechanism by which prenatal exposure to DES distorts the developing vagina and the embryonic mullerian epithelium develops into tumor

. . . After the mullerian ducts extend caudally during early fetal life to the level of the future hymen, they fuse and form a muscular scaffold on which the squamous cells, which derive from the urogenital sinus, invade from below, replacing completely the mullerian mucosa up to the level of the external os of the cervical canal. Since this entire process begins sometime after the fourth or fifth week of intrauterine life and it is not complete until sometime after the 20th week of pregnancy, it is possible that DES may act to inhibit the replacement of the mullerian epithelium by squamous epithelium or, possibly, to stimulate the persistence of the mullerian epithelium in the vagina. The residual mullerian epithelium results in adenosis and may give rise to clear-cell adenocarcinoma. If the surrounding mesodermal stroma from which the muscular walls of the vagina, cervix, and uterus derive is affected, one might also expect to see the ridges, partial strictures, obliterations, fish-mouth deformities of the cervix, and uterine abnormalities that have been described in the DES-exposed female.²¹⁸

Such abnormalities of the vagina and cervix are present and observable in 75% to 97% of all women exposed to DES *in utero* during the first four months of gestation.²¹⁹ These are the facts that bear on the question of legal cause.

Legal cause involves "a question of whether the policy of the law will extend the responsibility for the conduct to the consequences which have in fact occurred."²²⁰ The basic limitation on liability for creation of risk arises in connection with this policy question; this limitation "is to foreseeable consequences."²²¹ Because the gist of the plaintiff's action is negligent failure to test, the question becomes whether drug manufacturers should foresee unintended consequences from their drugs and respond by testing to confirm or deny those consequences. "[W]ith every

218. Robboy, Prat & Welch, *Vaginal and Cervical Pathology Associated with Prenatal Exposure to Diethylstilbestrol*, in *ESTROGENS AND CANCERS* 171-72 (Silverberg & Majors, eds. 1978).

219. Poskanzer & Herbst, *supra* note 6, at 1894.

220. W. PROSSER, *supra* note 38, at 244.

221. *Id.* at 251.

drug there is some good news and some bad news. The good news is that the drug can cure you; the bad news is that the drug is a poison."²²² In other words, because drugs are "foreign substances,"²²³ the manufacturer has a duty, as we have seen,²²⁴ "to test and inquire to determine the adverse effects of the drug."²²⁵ Thus unintended consequences *are* foreseeable in the absence of tests; if even the most rudimentary tests on mice had been performed, the unintended, adverse consequences of using DES in pregnancy would have been confirmed.²²⁶ For the DES plaintiff, foreseeability should not be a significant difficulty.

Instead, her problem involves demonstrating causation by expert testimony and statistical associations rather than by the observable cause-and-effect that "causation" connotes. Upon recognition that "proximate cause" itself is an "unfortunate"²²⁷ misnomer, that demonstration becomes easier:

The plaintiff is not, however, required to prove his case beyond a reasonable doubt. He need not negative entirely the possibility that the defendant's conduct was not a cause, and it is enough that he introduces evidence from which reasonable men may conclude that it is more probable that the event was caused by the defendant than that it was not. The fact of causation is incapable of mathematical proof, since no man can say with absolute certainty what would have occurred if the defendant had acted otherwise. Proof of what we call the relation of cause and effect, that of necessary antecedent and inevitable consequence, can be nothing more than "the projection of our habit of expecting certain consequents to follow certain antecedents merely because we had observed these sequences on previous occasions." If as a matter of ordinary experience a particular act or omission might be expected, under the circumstances, to produce a particular result, and that result in fact has followed, the conclusion may be permissible that the causal relation exists.²²⁸

222. Dixon, *supra* note 139, at 62.

223. *Id.* at 63.

224. See Part II.C. *supra*.

225. Dixon, *supra* note 139, at 62.

226. See text accompanying note 158 *supra*. See also Dunn & Green, *supra* note 6; McLachlan, Newbold & Bullock, *supra* note 6.

227. W. PROSSER, *supra* note 38, at 244.

228. *Id.* at 242.

Thus, a DES plaintiff must convince a jury that the drug her mother ingested nearly twenty years ago more probably than not caused her cancer. Evidence of ordinary experience or common knowledge is not available, because the basis for finding the causal sequence lies deep within circumstantial evidence and expert testimony.²²⁹ Such evidence and testimony are, however, perfectly appropriate,²³⁰ and they explain the biochemical reactions her body experienced because of the drug. The evidence also demonstrates the alarmingly high statistical correlation between maternal ingestion of DES and the subsequent development of cancer in female offspring. From this evidence, together with the DES studies done on mice and the extreme rarity of the disease before the marketing of DES, "reasonable men may conclude that it is more probable that the event was caused by the defendant than that it was not."²³¹

E. Remedies and Restitution

If the DES plaintiff successfully establishes the liability of drug companies for negligent failure to test as the cause of her injuries, then she should be entitled to damages calculated in a manner consistent with those generally awarded in other products liability cases. At least one court, however, has characterized the damages calculation differently:

In contrast to other pharmaceutical product liability cases involving prenatal injuries, such as the thalidomide cases, the damages comparison is rather elusive. With thalidomide, the damages attributable to the drug would be measured by comparing the condition of the plaintiff with the drug-induced defects to his condition had his mother not been prescribed the drug—which, presumably, would be normality. But, with DES, the damages attributable to the drug would be measured by comparing the condition of the plaintiff with the drug-induced carcinoma to her presumed condition had her mother not been prescribed the drug—which, ironically, could be nonexistence, since the drug was prescribed to decrease the incidence of spontaneous abortions in high-risk mothers. Nonetheless, the conceptual difficulties suggested by what is, admittedly, a

229. *Id.*

230. *Id.*

231. *Id.*

somewhat artificial and speculative analysis have forestalled neither the measurement nor cognition of damages in these cases.²³²

Application of this reasoning in a negligent failure to test context would, however, inappropriately distort the damages calculation by ignoring the very basis for liability in such a case.

As *Bichler* demonstrates, liability for negligent failure to test is premised on unsubstantiated claims of efficacy being outweighed by evidence of known risks.²³³ Because lack of effectiveness is crucial to a finding of liability under this theory, any damages calculation that presumes the plaintiff's condition had her mother not taken DES would "ironically . . . be nonexistence" inconsistently shields the defendants with a presumption of efficacy that already has been rejected by the jury's finding of liability. Accordingly, the damages calculation should disregard the argument that the DES daughter might not even be alive were it not for the drug.

Having removed this specious argument from the calculus, the jury should be instructed to find damages as in other routine products liability cases. The number of women who may be entitled to such damages,²³⁴ however, multiplied by either the amount awarded to Joyce Bichler by her jury²³⁵ or even by the amount of a typical settlement offer²³⁶ equals an astounding total amount of potential liability for the drug industry.²³⁷ This

232. *Phillips v. United States*, 508 F. Supp. 537, 544 n.12 (D.S.C. 1980).

233. See Part II.C. *supra*.

234. Estimates of the number of DES daughters range from one-half to three million. See FORDHAM Comment, *supra* note 2, at 965 n.6 and accompanying text. Because so little was known about the incidence of clear cell adenocarcinoma of the vagina and cervix among such young women, a registry was established in 1971 to study the DES phenomena. See Poskanzer & Herbst, *supra* note 6, at 1893. By January 1980 approximately 400 cases had been recorded. See *The State* (Columbia, S.C.), Dec. 6, 1981, at 4E, col. 1. See also Herbst, Robboy, Scully & Poskanzer, *Clear-Cell Adenocarcinoma of the Vagina and Cervix in Girls: Analysis of 170 Registry Cases*, 119 AM. J. OBST. & GYN. 713 (1974); Herbst, Kurman, Scully & Poskanzer, *supra* note 20.

235. Joyce Bichler was awarded \$500,000. See *Bichler*, 79 A.D.2d at ___, 436 N.Y.S.2d at 628; J. BICHLER, *supra* note 3, at 181.

236. Katz was settled for approximately \$235,000. See Note, 12 J. MAR. L. REV. 201, 224 n.120 (1980). Offers of settlement for \$100,000 were made to Joyce Bichler twice during her trial. See J. BICHLER, *supra* note 3, at 160-61, 177-78.

237. "It has been estimated that Lilly is a defendant in about three-quarters of the more than 500 DES actions filed nationwide." Note, 12 J. MAR. L. REV. 201, 206 n.26 (1980) (quoting NAT'L L.J., Dec. 17, 1979, at 5, col. 1). If each of these actions is settled

exposure has alarmed some commentators who advocate a legislatively established trust fund as a substitute for traditional tort damages:

One alternative proposed would be a system for "latent technological injury compensation." This system would be a governmental branch which would get the necessary operational funds through a tax on manufacturers' gross sales. The fund would be available to both plaintiffs who could identify the manufacturer and those who could not. Under this system, the statute of limitations would start to run from the date of purchase. Once the statute has run, tort litigation would no longer be an option. The plaintiff would have to apply to an administrative agency to get relief. Recovery would be based on the plaintiff's ability to show that he was injured, that the injury could be traced to a type of product, and that the injury could not have been discovered prior to the running of the statute. The plaintiff could recover damages for bodily injury and lost earnings according to a fixed scale. Pain and suffering would not be compensable. The government agency though would be allowed to seek indemnity from the manufacturer on the basis of fault.

This alternative would more readily satisfy the current societal concern for compensating victims without doing violence to traditional tort law. It also provides a solution to a problem which will occur with increasing frequency as increased technology leads to injuries which require, and, deserve compensation. In addition, the goal of loss spreading is served, especially since the loss is spread among those whose activity generated the harm.²³⁸

Even proponents of such a system, however, recognize its shortcomings: prevailing public opinion opposes the creation of new administrative agencies; manufacturers would resist the imposition of a new tax; and plaintiffs would resent the limitations placed on their ability to recover traditional damages.²³⁹ Additional persuasive reasons counseling against the legislative trust fund solution include the questionable constitutionality of the

for merely \$100,000, see note 236 *supra*, then a conservative estimate of total liability could easily exceed fifty million dollars.

238. Comment, *Manufacturer's Liability Based on a Market Share Theory*, *supra* note 6, at 303-04.

239. *Id.* at 304-05.

date-of-sale statute of limitation embodied in the scheme²⁴⁰ and the failure to demonstrate why DES daughters should be singled out for deprivation of damages for pain and suffering as well as punitive damages. While Dean Prosser questions the propriety of imposing punitive damages in "mass disaster" cases,²⁴¹ no such question exists with respect to pain and suffering. The intensely personal nature of the injuries and the consequences of corrective surgery combine to make pain and suffering a significant component of the damages calculation.²⁴² The cost of medical attention and loss of earnings pale in comparison with the loss of one's ability to procreate—an ability deemed to be a fundamental substantive right by the United States Supreme Court.²⁴³

The DES plaintiff's ability to recover traditional damages may be hampered, as we have seen, by the court's misapprehension of the basis of her theory of recovery. Her reliance on the legislative process to formulate a tax-funded mechanism for compensating "latent technological injuries" would be even more misplaced, once we recall the legislature's treatment of products liability plaintiffs generally in connection with the trend toward date-of-sale statutes of limitation.²⁴⁴ A different solution is needed.

The proper solution to the problem of remedying the harms caused by DES may lie in the application of principles governing restitution. "Restitution based on unjust enrichment cuts across many branches of the law, including contract, tort and fiduciary relationship, but it also occupies much territory that is its sole preserve."²⁴⁵ Restitution in the tort realm has been applied to remedy wrongs involving property, such as conversion, infringement on intellectual property, and misappropriation of trade secrets,²⁴⁶ as well as wrongs involving personal harms, such as

240. See Part II.A. *supra*. The resolution of the constitutional questions associated with date-of-sale statutes of limitation admittedly may differ, however, in the trust fund context because the proposal contemplates a substitution of means of recovery rather than a total extinguishment of one's ability to recover.

241. W. PROSSER, *supra* note 38, at 13.

242. See J. BICHLER, *supra* note 3, at 70, 128-29, 152-53.

243. See, e.g., *Skinner v. Oklahoma*, 316 U.S. 535 (1942).

244. See Part II.A. *supra*.

245. 1 G. PALMER, *THE LAW OF RESTITUTION* § 1.1, at 2 (1978).

246. See Douthwaite, *The Tortfeasor's Profits—A Brief Survey*, 19 HASTINGS L.J. 1071, 1077-84 (1968).

homicide, libel, and invasion of privacy.²⁴⁷ Although application of restitution to personal injuries in the products liability area might seem a novel expansion of the concept, the law governing restitution is a law of innovation:

Unjust enrichment is an indefinable idea in the same way that justice is indefinable. But many of the meanings of justice are derived from a sense of injustice, and this is true of restitution since attention is centered on the prevention of injustice. Not all injustice but rather one special variety: the unjust enrichment of one person at the expense of another. This wide and imprecise idea has played a creative role in the development of an important branch of modern law.²⁴⁸

So desirable is the inculcation of restitution's creativity that the leading treatise declares: "It would be a major advance if courts, having identified an enrichment felt to be unjust, were free to choose the form of relief that seems fairest and most appropriate to the circumstances. This is the largely hidden tendency of modern decisions. . . ."²⁴⁹ Echoing these sentiments, one survey of restitution's ability to disgorge the tortfeasor's profits has concluded:

Enough has been said to indicate that a court, once it has the equitable powers formerly exercisable by the ancient courts of chancery can, if it so chooses, decree that *any* tortfeasor, fiduciary or not, disgorge his profits. Objection has sometimes been made that there can be no constructive trust without a trust res, an identifiable subject matter to which the defendant has legal title. . . . But the courts have long overlooked this academic difficulty. The "trust" is nothing more than an analogy, a device employed by equity to compel restitution.²⁵⁰

Indeed, the invocation of a "constructive trust is accepted as a technique to be used in working out solutions to problems of unjust enrichment; a technique, as one court said, that 'is limited only by the inventiveness of men who find new ways to enrich themselves unjustly by grasping that which does not belong to them.'"²⁵¹

247. See *id.* at 1084-86.

248. G. PALMER, *supra* note 245, § 1.1, at 5.

249. *Id.* § 1.1, at 4 (emphasis in original).

250. Douthwaite, *supra* note 246, at 1074.

251. G. PALMER, *supra* note 245, § 1.4, at 17.

In short, restitution could respond to both the problems of assessing individual damages and the unresponsiveness of the legislative process. By focusing on profits unjustly enriching the drug industry from the sale of an unsafe, nonefficacious, untested drug, the focus shifts from discrete individual harms to mechanisms already within the courts' competence for remedying mass injuries. A number of specific benefits flow from this method of remedying the harms caused by DES. From the plaintiffs' standpoint, "[t]he availability of restitution is not dependent upon inadequacy of the alternative remedy."²⁵² From the defendants' standpoint, restitution represents, as Lord Mansfield observed, "the most favourable way in which he can be sued: he can be liable no further than the money he has received. . . ."²⁵³ And from the courts' standpoint, the search for a "figure" representing compensation leads not to speculation concerning the worth of the plaintiff's various injuries but instead to the world of facts and figures: the financial records of an oligopolistic industry²⁵⁴ whose profits were inflated by the sale of DES to pregnant women between 1947 and 1971. The market share figures that the court may have already used in connection with the cause-in-fact hurdle²⁵⁵ accordingly take on additional significance in the remedial context, for they may provide the basis for constructing a fund against which DES plaintiffs may claim.

The success of such an approach depends, of course, on a number of variables, including the availability of class action mechanisms²⁵⁶ and multidistrict litigation techniques. But DES cases represent precisely the sort of circumstances susceptible to such techniques. Owen Fiss, the respected Yale law professor, has argued that courts should not shy away from the task of "structural reform" in the context of constitutional cases involv-

252. *Id.* § 1.6, at 33.

253. *Moses v. Macferlan*, 2 Burr. 1005, 97 Eng. Rep. 676 (K. B. 1760), quoted in R. LEAVELL, J. LOVE & G. NELSON, *EQUITABLE REMEDIES & RESTITUTION* 498 (3d ed. 1980).

254. Recall that Eli Lilly and five or six other manufacturers accounted for an estimated 90% of the DES market. FORDHAM Comment, *supra* note 2, at 977. See generally *id.* at 975-78 (discussion of industry's high profits, high returns, and monopoly pricing patterns).

255. See Part II.B. *supra*.

256. See generally FED. R. CIV. P. 23; Note, *Diethylstilbestrol: Extension of Federal Class Action Procedures to Generic Drug Litigation*, *supra* note 6; FORDHAM Comment, *supra* note 2, at 968-70 n.22.

ing complex public institutions.²⁵⁷ His argument is premised on the assertion that courts do *more* than merely resolve disputes: "Adjudication is the social process by which judges give meaning to our public values."²⁵⁸ Professor Fiss' arguments apply with equal force in the DES context. The DES daughter who successfully reaches the exit from the maze should not be forced to speculate on the worth of her body. Restitution in the hands of a creative judiciary may respond to some of the problems of constructing a proper remedy in the DES context. In that regard, the words of Lord Mansfield in the seminal case of *Moses v. Macferlan*²⁵⁹ bear repeating: "In one word, the gist of this kind of action is, that the defendant, upon the circumstances of the case, is obliged by the ties of natural justice and equity to refund the money."²⁶⁰

III. CONCLUSION

The DES plaintiff, victorious or not, must pause to contemplate her experience. She has invoked the processes of litigation for the resolution of an intensely personal, individual dispute. Isn't that what she is supposed to do? Aren't courts the proper forums for individualized dispute-resolution, while legislatures are the places to go for broader changes?²⁶¹

Yet, rather than facilitating the telling of her personal story, the process of litigation *distanced* her from it.²⁶² Questions of fairness to individuals became questions involving "a utilitarian calculation of the public good."²⁶³ When she sought to invoke collateral estoppel, she was answered with arguments that its

257. See generally Fiss, *The Supreme Court, 1978 Term—Forward: The Forms of Justice*, 93 HARV. L. REV. 1 (1979).

258. *Id.* at 2. See also *id.* at 29-44.

259. 2 Burr. 1005, 97 Eng. Rep. 676 (K.B. 1760).

260. *Id.*, quoted in R. LEAVELL, J. LOVE, & G. NELSON, *supra* note 253, at 499.

261. See generally H. HART & A. SACKS, *THE LEGAL PROCESS: BASIC PROBLEMS IN THE MAKING AND APPLICATION OF LAW* chs. 3 (judicial process), 5 (legislative process) (tent. ed. 1958). Compare Fiss, *supra* note 269 (arguing that the essence of adjudication is the articulation of public values, or law declaration, rather than dispute resolution) with Lindgren, *supra* note 1, at 753-54 (arguing that courts are the best institutions for resolution of individualized disputes). As Hart and Sacks stress, however, courts obviously perform *both* functions, law declaration *and* dispute resolution. H. HART & A. SACKS, *supra* note 366-68.

262. See Lindgren, *supra* note 1, at 723-27.

263. *Id.* at 711.

use "could spawn a massive increase in the number of lawsuits initiated each year,"²⁶⁴ that "deleterious economic effects will result thereby,"²⁶⁵ and that "the interests affected adversely will include not only the commercial defendants' (including its stockholders), but also those of its employees."²⁶⁶ She never realized *she* could be the cause of increased unemployment.²⁶⁷ She was surprised to learn that the "primary argument against the application of collateral estoppel is that its application is manifestly unjust in light of the fact that the doctrine can only work in favor of plaintiffs."²⁶⁸ Why didn't anyone ask about fairness to *her*? Why didn't a converse critique accompany doctrines that could operate only in the defendant's favor?²⁶⁹ What had happened to her individualized story?

So perhaps she, too, could reason in terms of fairness and the public good. Yet when she framed her arguments in such terms, in connection with seeking "market share" liability for example, she was told that "since any solution to this problem will have effects not only on the substantive legal issues, but on industrial and . . . economic concerns, it is an appropriate question for legislation. . . . [T]he solution to the situation rests more appropriately with the legislature."²⁷⁰ The prospect of going to the same forum that enacted a date-of-sale statute of limitation was, however, hardly rosy. The reality that the odds were stacked against her on virtually every issue became clear soon after she entered the DES labyrinth.

Unfortunately, the DES daughter's experience is not unique.

From being acknowledged to be "public law in disguise," tort law seems increasingly to be emerging simply as "public law." That has occurred despite efforts such as Robert Keeton's to explain the imposition of liability for non-negligent, risky con-

264. Weinberger, *supra* note 168, at 22.

265. *Id.* at 23.

266. *Id.* at 52.

267. *Id.* at 53.

268. *Id.* at 21.

269. For example, the general requirement that causal agents be identified with precision can only operate to the benefit of defendants who are members of an industry that markets its goods without identifying characteristics. See Part II.B. *supra*.

270. Comment, *Manufacturer's Liability Based on A Market Share Theory*, *supra* note 6, at 303, 316.

duct as simply a variation in the meaning of fault and not "the substitution of social responsibility for individual responsibility." Increasingly, concern transcends the individuals involved. Individual interests are absorbed into a calculus which assumes that some individuals may be excluded from receiving certain benefits in order to achieve maximum social utility. That is built into the economic analysis being used to determine the cost of accidents, and is acknowledged by economists. Guido Calabresi suggests "that justice is a totally different order of goal from accident cost reduction," and Richard Posner describes the accident itself as a closed chapter in the enterprise of preventing future accidents, and thus reducing accident costs. "The issue becomes what is a just and fair result for a class of actions." Such analysis has been finding its way from the journals into court opinions.

George Fletcher, writing of fairness and utility in tort theory, summarizes the pervasiveness of current concern for the public that transcends concern for the individual in his "paradigm of reasonableness." That paradigm which he sees as currently dominant, "provides the medium for tying the determination of liability to maximization of social utility. . . ." As he puts it, "[t]he fashionable concerns of the time are instrumentalist."²⁷¹

The realities of DES litigation thus reflect the realities of tort law. Although the complexity and far-reaching ramifications of DES litigation suggest that it is unique, every element of such litigation can be treated according to accepted principles of tort law. The incongruity between the familiar nature of the DES action's components and the judiciary's uneasiness when faced with DES actions reflects judicial discomfort with the potentially large liabilities that accompany mass tort situations and a hesitance to afford compensation in this context.

These judicial qualms further compound handicaps the DES plaintiff shares with all tort plaintiffs. Significant among these is the atomized nature of the litigation, which results in a tort compensation system in which "[n]o social reform or scheme of compensation can be worked out. . . . The value is limited to those persons who accept the prospect of an expensive, unfriendly, impersonal experience in court."²⁷² As a "one-

271. Lindgren, *supra* note 1, at 746-47.

272. *Id.* at 762-63.

shotter,"²⁷³ the DES daughter sees her personal resources pitted against the institutional reserves of an industry of "repeat players."²⁷⁴ Even if she succeeds in obtaining a substantive change in the law, the "RP's" can often neutralize that change by redistributing their litigation resources.²⁷⁵ "The low potency of substantive rule-change is especially the case with rule-changes procured from courts."²⁷⁶ Describing these broader realities of "the basic architecture of the legal system,"²⁷⁷ Professor Marc Galanter has provided a more generalized treatment of the experiences of plaintiffs like the DES daughter; ironically it is entitled *Why the "Haves" Come Out Ahead*.²⁷⁸ His critique is profoundly disturbing, especially for the tort plaintiff seeking individualized treatment.

DES litigation may not be the proper context in which to raise such dilemmas of our society; nevertheless two inescapable inconsistencies flow from a critique of DES litigation on the macro level. First, there is inconsistency in the courts' methodologies. Viewed generally as forums for individualized dispute resolution²⁷⁹ and as limited in competency in ways a legislature is not,²⁸⁰ courts nevertheless are not expected to engage in "direct treatment"²⁸¹ of the parties. Instead, questions of fairness become questions of social or public utility. Second, there is an inconsistency in theory. On the one hand, individualized "direct treatment" by courts would seem to be consistent with the focus on individualism that pervades our classic liberal philosophy²⁸² and its capitalist economic system.²⁸³ Yet arguments in court

273. See Galanter, *Why the "Haves" Come Out Ahead: Speculations on the Limits of Legal Change*, 9 L. & Soc'y Rev. 95, 97-110 (1974).

274. *Id.*

275. Specific advantages of being a "repeat player" are listed in *id.* at 98-103. For a discussion of limits on the abilities of "have-not" "one-shotters" in securing substantive changes in the law, see *id.* at 135-149.

276. *Id.* at 149.

277. *Id.* at 95.

278. Galanter, *supra* note 273.

279. See note 261 and accompanying text *supra*.

280. *Id.* See also note 270 and accompanying text *supra*.

281. Compare Lindgren, *supra* note 1, at 749-58 with notes 262-263, 271 and accompanying text *supra*.

282. See generally R. UNGER, *LAW IN MODERN SOCIETY: TOWARDS A CRITICISM OF SOCIAL THEORY* 24-30 (1976). Cf. *University of Cal. Regents v. Bakke*, 438 U.S. 265 (1976) (Powell, J.).

283. See generally A. SMITH, *WEALTH OF NATIONS* (1776); Abrahams, *The Emer-*

tend to be based on the public suppression of individualism, rather than protection of it.

The DES labyrinth thus may be viewed as a structure built upon these inconsistencies and reinforced by a tradition of male dominance in both the medical and legal professions.²⁸⁴ "Women's problems" simply do not occupy a place of importance in the scheme of legal things.²⁸⁵ But young women afflicted with vaginal cancer are not mice who should be forced to wend their ways through a legal labyrinth. The time for testing mice was forty years ago.

gence of Critical Social Theory in American Jurisprudence: An Introduction of Professor Rosenberg's Perspective, 4 U. PUGET SOUND L. REV. 39 (1980).

284. Male dominance of the legal profession is demonstrated by the fact that only 2,183 of 54,265 law students in 1964 were women, compared with 38,627 of 122,801 law students in 1979. ASSOCIATION OF AMERICAN LAW SCHOOLS, 1980-82 PRE-LAW HANDBOOK 24.

285. For example, under present constitutional doctrine race discrimination is "strictly scrutinized" while gender-based discrimination is tested by the more lenient "middle-tier" analysis inaugurated by *Craig v. Boren*, 429 U.S. 190 (1976). Ironically, the United States Supreme Court has held that discrimination against pregnant women does not even constitute gender-based discrimination, although only women can become pregnant, and so discrimination against pregnant women is tested by the most lenient "rational basis" mode of equal protection analysis. *General Electric Co. v. Gilbert*, 429 U.S. 125 (1976); *Geduldig v. Aiello*, 417 U.S. 484 (1974).

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