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DPT VACCINE MANUFACTURER LIABILITY: CHIPPING AWAY AT STRICT LIABILITY TO SAVE THE PRODUCT

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I. INTRODUCTION

A vaccine liability crisis that threatened our supply of childhood vaccines may have been averted by Congressional passage and funding of the National Childhood Vaccine Injury Act (NCVI)¹ and recent court decisions removing unlimited strict products liability for vaccine manufacturers. The Supreme Court of New Jersey in *Shackil v. Lederle Laboratories*² recently rejected the risk-modified market-share liability theory for DPT vaccine manufacturers. The court rejected collective manufacturer liability theories by focusing on public policy and health considerations surrounding the DPT vaccine and recognizing the withdrawal phenomenon that has left only two commercial entities producing the DPT vaccine at the present time.³ While federal preemption of traditional state law tort claims was not recognized in *Shackil*,⁴ the court did acknowledge potential federal preemption of a products liability claim for defective design by inadequate warning.⁵ Whether the DPT vaccine has received the unavoidably, unsafe product classification under comment k of the Restatement (Second) of Torts § 402A⁶ is open to interpretation after *Shackil*⁷ and *White v. Wyeth Laboratories*⁸ and the NCVI. This article addresses the retreat from unlimited strict liability for DPT vaccine manufacturers, focusing on *Shackil* and its implications.

II. BACKGROUND

A. *Pertussis and the DPT Vaccine*

Children in the United States are required by law to have a series of immunizations before entering school. These immunizations include polio,

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1. 42 U.S.C.A. §§ 300aa-1 to -34 (West Supp. 1988).

2. 116 N.J. 155, 561 A.2d 511 (1989).

3. *Id.* at 167, 561 A.2d at 523.

4. *Id.* at 171, 561 A.2d at 527.

5. *Id.*

6. RESTATEMENT (SECOND) OF TORTS § 402A comment k (1979).

7. 116 N.J. at 171, 561 A.2d at 527.

8. 40 Ohio St. 3d 390, 533 N.E.2d 748 (1988).

measles-mumps-rubella (MMR), and diphtheria-pertussis-tetanus (DPT).⁹ While reactions to vaccination are not uncommon, the incidences and severity of these are a subject of much medical and legal debate. "DPT vaccine is a biological product made from three separate components: diphtheria toxoid, tetanus toxoid, and pertussis vaccine, each of which stimulates the production of antibodies that protect the body against those childhood diseases."¹⁰ Diphtheria and tetanus are adequately treated and controlled by the injections containing diphtheria and tetanus toxoids, but it is believed that the addition of the pertussis vaccine to the formula causes adverse side effects in a small number of treatments.¹¹

Pertussis, commonly known as whooping cough, is an acute, highly contagious infectious respiratory disease of children, of a relatively long duration.¹² Pertussis was once a major cause of childhood morbidity and mortality throughout the world—the incidence often reached 200,000 cases a year in the 1930's, and reached a maximum of 265,000 cases and 7,500 deaths in the United States in 1943.¹³

In 1906, French bacteriologists Jules Bordet and Octave Gengou first isolated the causative bacterium of pertussis.¹⁴ While there were early attempts to immunize against this disease, it was not until 1922 that a Danish physician, Thorvald Madsen, reported any success.¹⁵ In the late 1940's, the clinical use of pertussis vaccine became routine in this country. Since 1947, the medical community has recommended the administration of the pertussis vaccine through a composite absorbed triple vaccine, DPT.¹⁶

The American Academy of Pediatrics recommends that a child receive his first DPT shot at two months of age. "Additional doses of DPT are recommended at 4, 6 and 18 months and a final dose between 48 and 84 months of age."¹⁷ Recent data on the clinical efficacy of the pertussis vaccine indicate that seventy to ninety percent of those who have had at least three doses of vaccine are protected from the risk of pertussis.¹⁸

While minor reactions including moderate pain, swelling and fever occur on occasion, neurological damage attributed to pertussis vaccination

9. *Diphtheria, Tetanus, and Pertussis: Guidelines for Vaccine Prophylaxis and Other Preventative Measures*, 30:32 MORBIDITY AND MORTALITY WEEKLY REPORT 392.

10. *Shackil*, 116 N.J. at 165, 561 A.2d at 521.

11. R. FEIGIN & J. CHERRY, *TEXTBOOK OF PEDIATRIC INFECTIOUS DISEASES* 2268 (2d ed. 1987) ("Most common adverse reactions to DPT are more likely to be due to the pertussis component rather than to the toxoid components").

12. Cherry, *The Epidemiology of Pertussis and Pertussis Immunization in the United Kingdom and the United States: A Comparative Study*, 14 CURRENT PROBS. IN PEDIATRICS 7 (1984).

13. J. SMITH, *A TREATISE ON THE DISEASES OF CHILDREN* (7th ed. 1980).

14. H. COULTER & B. FISHER, *DPT: A SHOT IN THE DARK?* (1985).

15. T. Madsen, *Whooping Cough: Its Bacteriology, Diagnosis, Prevention and Treatment*, 192 B. MED. & SURGICAL J. 50 (1922).

16. Cherry, *supra* note 12, at 30.

17. *Pertussis Vaccine*, 74 PEDIATRICS 303, 304 (1984).

18. *Pertussis Surveillance, 1979-1981*, 31:25 MORBIDITY AND MORTALITY WEEKLY REPORT 333 (1982).

is the major risk considered today when the hazards and benefits of pertussis immunization are analyzed.¹⁹ Encephalopathy is the commonly used term to describe neurological events which may follow pertussis immunization. The most extensive case-controlled study to date on pertussis immunization and central nervous system damage is the British Childhood Encephalopathy Study (BCES).²⁰ This study evaluated all children from two to thirty-six months of age who were admitted to hospitals due to central nervous system disorders from 1976-1979. Hospital authorities concluded that there was an increased incidence of encephalopathy among children previously vaccinated with DPT. The frequency of serious acute disorders was estimated to be one in 110,000 doses of DPT, and the frequency of permanent damage was one in 310,000 doses. This study led to the estimation that encephalitis with residual effects will occur 3.2 times per million doses, an estimated 43.2 cases in the United States per year.²¹

Medical research estimates that the attack rate of pertussis would be 178-fold higher if DPT immunizations were not given. As part of this increase, severe neurological illness with permanent residual damage would occur four times more frequently if no DPT immunizations were performed.²² Analysis of the benefits, risks and costs of pertussis immunization demonstrate considerable economic and disease reduction benefit associated with pertussis vaccination. A recent study has shown the benefits of the nation's immunization program in reporting that cases of pertussis in 1934 numbered 265,269, with 7,518 deaths, to 2,276 cases and 12 deaths in 1984.²³ Notwithstanding the risk of occasional reaction and potential serious injury on rare occasion, the medical profession continues to recommend DPT vaccination because of its greater benefit than risk to the individual child and to society.²⁴

B. Vaccine Manufacturers

The manufacture of the DPT vaccine with the whole-cell organism of pertussis and inactivated toxins of diphtheria and tetanus began in 1940 with the product, Triojen, produced by Parke-Davis.²⁵ Thereafter, Wyeth,

19. Cherry, *supra* note 12, at 51.

20. ALDERSALE, BELLMAN & RAWSON, *THE NATIONAL CHILDHOOD ENCEPHALOPATHY STUDY IN WHOOPING COUGH: REPORTS FROM THE COMMITTEE ON SAFETY OF MEDICINES AND THE JOINT COMMITTEE ON VACCINATION AND IMMUNIZATION*, Department of Health and Social Security, Her Majesty's Stationery Office, London (1981).

21. *National Childhood Vaccine-Injury Compensation Act: Hearings Before the Senate Committee of Labor and Human Resources*, 98th Cong., 2d Sess. 183 (1984); see also Tower v. Lederle Laboratories, 779 F.2d 1429, 1430-31 (9th Cir. 1986), cert denied, 485 U.S. 442 (1988).

22. Hinman & Koplan, *Pertussis and Pertussis Vaccine: Reanalysis of Benefits, Risks and Costs*, 251 J. A.M.A. 3109 (1984).

23. STAFF OF HOUSE SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT OF THE HOUSE COMMITTEE ON ENERGY AND COMMERCE, 99TH CONG. 2D SESS., *CHILDHOOD IMMUNIZATIONS 9-10* (Comm. Print 1986) (hereinafter Comm. Print) (see other reductions in diseases in diphtheria, tetanus and polio).

24. "Continued use of our present vaccines, with careful attention to possible contraindications seems the only prudent course to follow." Hinman & Koplan, *supra* note 22, at 3113.

25. Ezagui v. Dow Chemical Corp., 598 F.2d 727, 731 (2d Cir. 1979).

Squibb/Connaught and Lederle Laboratories were the primary United States manufacturers of DPT vaccine until approximately 1983, when Wyeth stopped production, and Squibb/Connaught interrupted production because of product liability exposure and rising insurance costs.²⁶ A different type of DPT vaccine containing a split-cell pertussis component²⁷ was manufactured by Eli Lilly & Company from 1967 to 1975, when Eli Lilly left the vaccine business.²⁸ Wyeth had purchased the right to produce Eli Lilly's product Tri-Solgen but could not obtain licensing from the Food and Drug Administration (FDA) for its own split-cell product.²⁹

In Japan, an acellular pertussis vaccine has been used for mass immunization since the fall of 1981.³⁰ Although the Japanese use more than one acellular vaccine, field studies between 1978 and 1981 involving 5,000 children revealed that the Japanese acellular vaccine was as effective as the conventional whole-cell vaccine and also produced fewer side effects. However, Japan uses a different immunization schedule than the United States, beginning immunization with only one dose at less than two years of age.

To assess the effectiveness of the acellular vaccine, United States scientists collaborated with European researchers in a Swedish study involving a clinical trial of 2,000 to 3,000 children immunized with two acellular pertussis vaccines.³¹ The results are not conclusive of the benefits of the acellular pertussis vaccine over the whole-cell pertussis vaccine currently produced in the United States and discontinued in Sweden in 1979.³² It should be noted that whooping cough was considered to be endemic in Sweden in 1987 after the discontinuance of their general vaccination program in 1979 because of public concern about rare severe adverse events.³³

III. RELAXATION OF STRICT LIABILITY FOR DPT MANUFACTURERS

Vaccine manufacturers have been alarmed over the six-fold increase in lawsuits per year from approximately twenty-five in 1980 to approximately 150 in 1985.³⁴ While there are occasional actions in negligence³⁵ and

26. See Hinmann, *Immunizations: 1984-1985*, 20 IMMUNIZATIONS CONF. 7-9 (1985).

27. *Graham v. Wyeth Laboratories*, 666 F. Supp. 1483, 1486 (D. Kan. 1987).

28. *Id.*

29. See *Toner v. Lederle Laboratories*, 112 Idaho 328, 331, 732 P.2d 297, 300 (1987). See also Note, *DPT Vaccine-Related Injury Actions: Federal Preemptions Reconsidered*, 41 RUTGERS L. REV. 373, 378-79 (1988).

30. Bernier, *Current Status of New Pertussis Vaccine Studies*, 20TH IMMUNIZATION CONFERENCE PROCEEDINGS, ATLANTA, GEORGIA: CENTERS FOR DISEASE CONTROL 41-42 (1985).

31. *Placebo-Controlled Trial of Two Acellular Pertussis Vaccines in Sweden—Protective Efficacy and Adverse Events*, 1988 LANCET 955-60.

32. *Id.* at 955.

33. *Id.*

34. Comm. Print, *supra*, note 23, at 86.

35. *Toner v. Lederle Laboratories*, 779 F.2d 1429 (9th Cir. 1986), *cert denied*, 485 U.S. 942 (1988).

breach of express warranty,³⁶ the spectre of unlimited liability flows from the product liability actions. The seeds of the doctrine of strict liability in a defective product case grew from Justice Traynor's concurring opinion in *Escola v. Coca Cola Bottling Co.*³⁷ While concurring in 1944, Justice Traynor's position moved to the forefront in 1963, when the California Supreme Court held in *Greenman v. Yuba Power Products, Inc.*³⁸ that the cost of injuries from defective products should be borne by the manufacturer of such products without proof of negligence.³⁹ After *Greenman*, the law of strict liability governed rather than the law of contract warranties.⁴⁰ This began a national trend toward recognition of the strict liability theory. One year after *Greenman*, section 402A was added to the Restatement (Second) of Torts.⁴¹ Although this section embellished the strict liability principle, the standard remained the same. The Restatement provides that a seller or manufacturer who sells a product in an unreasonably dangerous defective condition is subject to liability for physical harm caused to the ultimate user or consumer even though the seller has exercised all possible care in the preparation and sale of the product. A product is not unreasonably dangerous if accompanied by appropriate directions or warnings, and the duty to warn is determined by the seller's knowledge.

The Restatement went a step further to ensure against the likelihood of liability for unavoidable injuries resulting from drugs beneficial to society as a whole. Comment k of section 402A concedes that there are some products which are incapable of being made safe, and that these are especially common in the pharmaceutical industry.⁴² Prescription drugs were thought to be and recently have been excepted from the imposition of strict liability when properly prepared and accompanied by adequate warnings.⁴³ Accordingly, vaccine manufacturers often defend against strict liability claims by arguing that (1) their vaccines are unavoidably unsafe products which are socially useful but associated with a small degree of risk, and (2) their vaccines were properly marketed for distribution with adequate warning. The defendant manufacturer must establish that the benefits of the product outweigh the inherent risks to obtain the unavoidably unsafe product classification and comment k protection from strict liability.

36. *Grinnel v. Charles Pfizer and Co.*, 274 Cal. App. 2d 424, 79 Cal. Rptr. 369 (1969).

37. 24 Cal. 2d 453, 150 P.2d 436 (1944)(carbonated beverage bottle exploded for undetermined reason).

38. 59 Cal. 2d 57, 377 P.2d 897, 27 Cal. Rptr. 697 (1963).

39. 59 Cal. 2d at 61, 377 P.2d at 901, 27 Cal. Rptr. at 701.

40. Greenman's injuries resulted from a piece of wood flying out of a power tool he had purchased. 59 Cal. 2d at 58, 377 P.2d at 898, 27 Cal. Rptr. at 698. Greenman brought suit in negligence and breach of warranty, but the court adopted a strict liability theory for public policy reasons. *Id.* at 61, 377 P.2d at 901, 27 Cal. Rptr. at 701.

41. RESTATEMENT (SECOND) OF TORTS § 402A (1964).

42. C. Newdick, *Strict Liability for Drugs in the Pharmaceutical Industry*, 101 L.Q. REV. 405-31 (1985).

43. *Brown v. Superior Court*, 44 Cal. 3d 1049, 245 Cal. Rptr. 412, 424 (1988).

Even if comment k protection is granted to a polio vaccine or a DPT vaccine, strict liability can still be imposed if the manufacturer did not supply an adequate warning with the product. Generally, with prescription drugs, the manufacturer's duty to warn goes to the prescribing physician, not the drug recipient, under the Learned Intermediary Doctrine.⁴⁴ The Learned Intermediary Doctrine applies when a patient receives a drug or vaccination through a physician who explains the risks and benefits and makes the decision to administer it.⁴⁵ Where the manufacturer has adequately warned the prescribing physician, the manufacturer will be protected from liability imposed for failure to warn the patient of the risks.⁴⁶ Vaccines, however, are often used in mass immunization programs which can remove the individualized medical judgment between the manufacturer and the ultimate consumer requiring adequate warning to the consumer by the manufacturer.⁴⁷

Recently, in *Hurley v. Lederle Laboratories*,⁴⁸ the Fifth Circuit did not recognize a mass immunization exception to the Learned Intermediary Doctrine. In *Hurley*, the patient-physician relationship existed before and at the time the immunization was given and the DPT vaccine was administered under the direction and control of the physician.⁴⁹ The question remained, however, of whether FDA approval of the warning of Lederle Labs implied federal preemption of a claim of defective warning when plaintiffs argued that Lederle withheld material information from the FDA.⁵⁰

Before it reached the Fifth Circuit Court of Appeals, *Hurley* had gained notoriety as one of the few district court cases holding that federal law impliedly preempted state law claims of inadequate warning and defective design.⁵¹ The lower court had found that the Food, Drug and Cosmetic Act, the Public Health Service Act, and the Regulations of the FDA were so comprehensive on DPT labeling to evidence a preemptive intent to occupy the field and preclude state regulation.⁵² The court, thereafter, considered federal preemption of design defects and similarly found "that the comprehensive and pervasive nature of the FDCA, the PHSA, and their respective regulations evidenced preemptive intent so strong that it precludes any state law determination that DPT is defectively designed."⁵³ In addition to rules and regulations governing licensing, testing, production, distribution, review and approval of all biologic DPT vaccines,

44. *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1276 (5th Cir.), *cert denied*, 419 U.S. 1096 (1974).

45. *Hurley v. Lederle Laboratories*, 863 F.2d 1173, 1178 (5th Cir. 1988).

46. *Id.*

47. *Id.*

48. *Id.*

49. *Id.*

50. *Id.* at 1179-80.

51. *Hurley v. Lederle Laboratories*, 651 F. Supp. 993 (E.D. Tex. 1986), *rev'd*, 863 F.2d 1173 (5th Cir. 1988).

52. *Id.* at 998-99.

53. *Id.* at 1003.

the court found dominant an overriding federal interest in promoting uniformity in the design and manufacture of DPT vaccines.⁵⁴ The concern of the lower court in *Hurley* was that a common law determination that DPT design and manufacture was defective would "seriously and irreconcilably conflict with the federal regulatory scheme and the national policies of immunization, adequate production, and supply of DPT."⁵⁵

The Fifth Circuit rejected the federal preemption arguments by recognizing that the great majority of United States District Courts addressing the issue have ruled against preemption.⁵⁶ The court reexamined earlier findings of federal preemption in light of the United States Supreme Court's analysis in *Hillsborough County v. Automated Medical Laboratories, Inc.*,⁵⁷ which examined federal preemption under FDA testing and approval of certain medical products.⁵⁸ The Supreme Court in *Hillsborough* was reluctant to find federal law implicitly preempting state law as a general rule,⁵⁹ and gave guidelines for implied preemption, either "where the scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that Congress 'left no room' for supplementary state regulation" or "where the field is one in which 'the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the subject.'"⁶⁰ If reexamination of FDA regulations after *Hillsborough* were not enough to reject theories of implied preemption, the Fifth Circuit in *Hurley* stated that any case for preemption "is doomed by the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-33," because of the express provision in the Act addressing the application of state law remedies to manufacturers in the sale of vaccines.⁶¹

With federal preemption arguments fading and the Court not interpreting the NCVI Act as Congressional occupation of the field of the nation's immunization program, DPT manufacturers were placed further at risk under a theory of collective responsibility borrowed from DES litigation and labelled "Risk-Modified Market Share Liability." This theory could be applied to all manufacturers of the DPT vaccine where the plaintiff is unable to prove the identity of the manufacturer whose vaccine injured the infant.⁶² After a comprehensive analysis of collective responsibility theories and the implications of a further expansion of strict liability for DPT vaccine manufacturers, the New Jersey Supreme Court rejected the risk-modified market-share liability theory in *Shackil*

54. *Id.* at 1003-04.

55. *Id.* at 1006.

56. *Hurley v. Lederle Laboratories*, 863 F.2d 1173, 1176 (5th Cir. 1988).

57. 471 U.S. 707 (1985).

58. *Hurley*, 863 F.2d at 1176-78.

59. 471 U.S. at 714.

60. *Id.* at 713.

61. 863 F.2d at 1178.

62. *Shackil v. Lederle Laboratories*, 219 N.J. Super. 601, 530 A.2d 1287 (App. Div. 1987), *rev'd*, 116 N.J. 155, 561 A.2d 511 (1989).

v. *Lederle Laboratories*.⁶³ The holding and implications of *Shackil* will be analyzed.

A. *Absence of Collective Liability*

The New Jersey Supreme Court in *Shackil* examined a theory of collective liability that would expand strict liability against DPT manufacturers in the absence of proof of which manufacturer produced the DPT vaccine administered to the infant plaintiff.⁶⁴ The supreme court explained the issue as whether New Jersey should substitute a theory of "market-share" liability for the element of causation-in-fact in a product liability case involving childhood vaccinations, thereby shifting the burden of proof on the issue of causation to defendant manufacturers.⁶⁵

The action in *Shackil* was brought by Deanna Marrero and her parents as a result of a seizure disorder that resulted in chronic encephalopathy suffered after Deanna's pediatrician, Dr. Feld, administered a final booster shot of DPT vaccine in 1972. Thirteen years after the inoculation, in 1985, Mrs. Shackil brought this action against Dr. Feld and Lederle after she became aware of a suspected linkage between Deanna's brain damage and the pertussis portion of the DPT vaccine.⁶⁶ Discovery revealed that Dr. Feld primarily used Lederle's vaccine but used DPT vaccines manufactured by Eli Lilly, Wyeth Laboratories, Parke-Davis and Pitman-Moore as well. National Drug Company had also manufactured DPT in 1972 but was not mentioned by Dr. Feld.⁶⁷ Plaintiffs added the additional manufacturers, except National Drug Company, but could not identify the manufacturer of the vaccine administered to Deanna. Plaintiffs suffered summary judgment to defendants when they failed to create a genuine issue of fact on a prima facie element of the case of the identity of the manufacturer of the DPT dosage.⁶⁸ The plaintiffs appealed and the appellate division reversed, finding a collective liability theory under what was called "risk-modified market-share," after examining collective liability theories of concert of action, alternative liability, enterprise liability, and market-share liability.⁶⁹ In rejecting all current theories, the appellate division selected the risk-modified market-share approach as most aptly suited to the circumstances of the case and explained its theory:

plaintiff should first demonstrate that the specific manufacturer of a defective product proven to have caused the injury can not be identified and join the manufacturers of a substantial share of the relevant market defined as all who could have distributed the product to the plaintiff. Once this has been accomplished, the burden is placed on

63. 116 N.J. 155, 561 A.2d 511 (1989).

64. *Id.* at 156, 561 A.2d at 512.

65. *Id.*

66. *Id.*

67. *Id.*

68. *Id.*

69. *Id.*

the defendants to exculpate themselves by proving either non-participation, possession of a reduced market share or that their product engendered a lower risk. Our aim should be to determine the percentage of the potential risk to the plaintiff caused by each manufacturer of the product, and in this respect our resolution of this issue departs somewhat from a pure market share analysis.⁷⁰

The lower court presumed to predict what the supreme court would do if faced with the problem before it. The court noted that rejection of collective liability theories in total would be an unwarranted deviation from existing New Jersey Supreme Court precedent which followed states with similar views of tort law.⁷¹

The supreme court took pains to highlight that causation-in-fact was a fundamental principle of products liability law. Causation-in-fact not only assigns blameworthiness to culpable parties, but it also limits the scope of potential liability to encourage useful activity that would not be pursued if there were excessive exposure to liability.⁷² Using traditional tort analysis from Prosser and Keaton on the Law of Torts, the court saw causation-in-fact as "that reasonable connection between the act or omission of the defendant and the damages which the plaintiff has suffered."⁷³ The court also extensively examined and then ultimately rejected the collective liability exceptions to proving causation-in-fact.

1. Concert of Action

The first theory rejected by both the appellate division and the supreme court was the concert of action theory that derived from the criminal concept of aiding and abetting. Both courts relied on Prosser & Keaton's discussion that permits the allocation of responsibility among several parties 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 . . . lend aid or encouragement to the wrongdoers, or ratify and adopt the wrongdoer's acts done for their benefit."⁷⁴ The supreme court examined the concerted action liability example from section 876 of the Restatement (Second) of Torts, involving a drag race where two drivers are racing and one collides with and injures a third party. Both drivers are jointly and severally liable for the injury to the third party even though only one driver caused the injuries.⁷⁵ Courts have applied this "concert of action" theory in selected DES cases. DES was a synthetic drug, later believed to be linked to cellular abnormalities, manufactured and prescribed for pregnant women to prevent miscarriages.⁷⁶

70. *Id.* at 157-58, 561 A.2d at 513-14.

71. *Id.* at 157, 561 A.2d at 513.

72. *Id.* at 158-59, 561 A.2d at 514-15.

73. *Id.* (citing W. KEATON, D. DOBBS, R. KEATON & D. OWEN, PROSSER & KEATON ON THE LAW OF TORTS § 323 (5th ed. 1984)).

74. W. KEATON, D. DOBBS, R. KEATON & D. OWEN, PROSSER & KEATON ON THE LAW OF TORTS § 323 (5th ed. 1984).

75. 116 N.J. at 159, 561 A.2d at 515; RESTATEMENT (SECOND) OF TORTS § 876 at 315-16 (1982).

76. 116 N.J. at 159, 561 A.2d at 515.

The supreme court rejected the concert of action theory because there were no allegations of conspiracy by DPT manufacturers nor were there allegations of any "tacit understanding or common plan" to produce a defective product or fail to adequately test the vaccine.⁷⁷ While DES manufacturers produced and marketed a generic product with over 200 drug companies using the same formula, DPT vaccine manufacturers involved in *Shackil* each used a different process that was separately licensed by the FDA and protected by patent or trade secret.⁷⁸ The court would not expand the doctrine of collective liability under a concert of action theory because of the potential for holding any manufacturer liable for the defective products of an entire industry without demonstration that the product causing the injury was made by that defendant manufacturer.⁷⁹

2. Alternative Liability

Courts have also fashioned collective liability in a product liability setting under an "alternative liability" theory developed from the negligence action in *Summers v. Tice*.⁸⁰ Section 433(B) of the Restatement (Second) of Torts codified this theory in 1965. The court in *Shackil* believed that *Summers* was the starting point for any analysis of market-share liability.⁸¹ In *Summers* two hunters fired their guns at quail, but in the direction of the plaintiff, and the plaintiff was struck in the eye as the result of only one gunshot. Plaintiff proved that both defendants were negligent at trial, but he couldn't identify which gunshot struck him in the eye. The Supreme Court of California, reviewing a verdict against both defendants, upheld the trial court's relaxation of the causation-in-fact requirement in negligence, holding that it would be unjust to require a victim to isolate a guilty defendant after proof that both defendants were negligent.⁸² As a consequence, the burden would be shifted to each defendant to prove the absence of negligence or suffer liability for the entire damages.⁸³

No court has applied the concept of alternative liability when all culpable defendants are not joined in the action.⁸⁴ The *Shackil* court noted that National Drug Company had also manufactured a DPT vaccine in 1972 but had not been joined as a party, defeating the alternative liability theory under these facts.⁸⁵ Further, comment g to section 433(B)(3) of

77. *Id.*

78. *Id.* at 159-60, 561 A.2d at 515-16. Each lot was separately tested by a division of the FDA. *Id.* at 160, 561 A.2d at 516; see 21 C.F.R. § 620.6 (1988).

79. 116 N.J. at 160, 561 A.2d at 516. The California Supreme Court, even in *Sindell v. Abbott Laboratories*, did not accept a concert of action theory in a DES case. 26 Cal. 3d 588, 605, 607 P.2d 924, 932, 163 Cal. Rptr. 132, 141, cert. denied, 449 U.S. 912 (1980).

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

81. 116 N.J. at 160, 561 A.2d at 516.

82. 33 Cal. 2d at 88, 199 P.2d at 3.

83. 116 N.J. at 160, 561 A.2d at 516.

84. *Id.*; see *Sindell v. Abbott Laboratories*, 26 Cal. 3d 588, 607 P.2d 924, 163 Cal. Rptr. 132, cert. denied, 449 U.S. 912 (1980).

85. 116 N.J. at 157, 561 A.2d at 513.

the Restatement states that alternative liability has no application where there is no proof that the conduct of more than one actor has been tortious, thus leaving the burden of proof of both tortious conduct and causal relationship to the plaintiff.⁸⁶

3. Enterprise Liability

The lower court in *Shackil* also addressed the enterprise or industry-wide liability theory that imposes liability on all members of an industry which have produced a product causing a particular harm.⁸⁷ Proof of a defective product shifts the burden to all defendants, who then have an opportunity to exculpate themselves. This collective liability theory has been described as a hybrid of the concert of action and alternative liability theories.⁸⁸

The enterprise liability theory was developed in the context of the blasting-cap industry when six blasting-cap manufacturers and their industry trade association chose not to place warnings directly on each blasting-cap, one of which injured the plaintiff.⁸⁹ The federal district court allowed a relaxation of the traditional burden of proving causation because the manufacturers and trade association "exercised actual collective control over a particular risk-creating product."⁹⁰ Neither the appellate division nor the supreme court discussed the enterprise or industry-wide liability theory except as it related to the market-share theory of liability recognized in *Sindell v. Abbott Laboratories*.⁹¹

4. Market-Share Liability

A general rule of products liability law is that a plaintiff must prove that the defendant manufacturer actually made the product that caused the injury.⁹² The appellate division, in an attempt to find a remedy for Deanna Marrero, described the last recognized collective liability theory as a "market-share" modification of the enterprise or alternative liability theory.⁹³ The supreme court discussed the "fashioning of a separate theory" from alternative liability, called "market-share liability," "which embodies the concept of 'alternative liability' while eliminating the ne-

86. RESTATEMENT (SECOND) OF TORTS § 433(B)(3) comment g at 446.

87. 219 N.J. Super. at 624, 530 A.2d at 1299.

88. *Id.*; see Comment, *DES and A Proposed Theory of Enterprise Liability*, 46 FORDHAM L. REV. 963, 974 (1978). The theory was described as one which imposes the industrywide standard . . . [as] the cause of the plaintiff's injury, just as defendants' joint plan is the cause of injury in the traditional concert of action plea. Each defendant's adherence perpetuates this standard, which results in the manufacture of the particular unidentifiable injury-producing product. Therefore, each industry member has contributed to plaintiff's injury.

Id. at 997.

89. *Hall v. E.I. DuPont De Nemours & Co.*, 345 F. Supp. 353 (E.D.N.Y. 1972).

90. *Id.* at 376.

91. 26 Cal. 3d 588, 607 P.2d 924, 163 Cal. Rptr. 132.

92. *Schmidt v. Archer Iron Works, Inc.*, 44 Ill.2d 401, 256 N.E.2d 6, *cert. denied*, 398 U.S. 959 (1970).

93. 219 N.J. Super. at 613, 530 A.2d at 1299.

cessity of joining all possible tortfeasors and the requirement of contemporaneous negligent acts."⁹⁴ The court found no New Jersey precedent for adoption of a market-share liability that would eliminate the requirement of proof of any connection between the defendant and the actual injury and found no trend in New Jersey toward wholesale adoption of market-share liability.⁹⁵

Turning to other jurisdictions for guidance, the supreme court first examined the seminal market-share case of *Sindell v. Abbott Laboratories*,⁹⁶ a class action suit alleging a design defect against manufacturers of the synthetic drug DES for injuries sustained in utero.⁹⁷ The plaintiffs in *Sindell* had difficulty identifying the manufacturer who actually produced the injury-causing product because over 200 manufacturers produced DES from a generic formula prescribed interchangeably. The California Supreme Court relaxed the traditional tort principle of causation-in-fact, rather than allow possibly negligent pharmaceutical manufacturers to escape liability. The court held that the inability to identify the single defendant was not fatal to plaintiff's case, provided that plaintiff joined a "substantial share" of manufacturers who produced or supplied "the DES which her mother might have taken."⁹⁸ Without proof of causation, the burden would shift to defendant manufacturers to prove that they could not have produced the DES ingested by plaintiff's mother, and if unable to do so, they would be held liable "for the proportion of the judgment represented by its share of the market."⁹⁹

The court in *Shackil* recognized that there were two important policy considerations supporting the *Sindell* court's decision to expand products liability theory by applying market-share liability in the absence of causation-in-fact evidence. The first "most persuasive" policy consideration was the one addressed in *Summers v. Tice*:

[a]s between an innocent plaintiff and negligent defendants, the latter should bear the cost of injury. Here, as in *Summers*, plaintiff is not at fault in failing to provide evidence of causation, and although the absence of such evidence is not attributable to the defendants either, their conduct in marketing a drug the effects of which are delayed for many years played a significant role in creating the unavailability of proof.¹⁰⁰

The second policy consideration from *Sindell* noted by the court in *Shackil* was that a DES manufacturer was in a better position to insure against the risk of injury so that liability for defects and failure to warn of harmful effects would provide an incentive for product safety.¹⁰¹

94. 116 N.J. at 160, 561 A.2d at 516.

95. 116 N.J. at 164-165, 561 A.2d at 520-521.

96. *Id.* at 160, 561 A.2d at 516.

97. *Id.*

98. 26 Cal. 3d at 612, 607 P.2d at 937, 163 Cal. Rptr. 145.

99. *Id.*

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

101. *Id.*

The court then reviewed cases which considered market-share theory, finding that two federal courts had adopted the theory,¹⁰² and the highest courts of three states had adopted it with modifications.¹⁰³ The Supreme Court of Iowa rejected the theory on grounds of public policy and legislative deferral,¹⁰⁴ and the Missouri Supreme Court rejected the theory on grounds that it would discourage desired pharmaceutical research and development and provide little incentive to provide safer products.¹⁰⁵ In addition, a federal court of appeals refused to apply market-share liability to DES manufacturers under Maryland and District of Columbia law because neither state recognized theories allowing the non-identification of specific defendants.¹⁰⁶

The court in *Shackil* noted that the *Sindell* decision had limited acceptance in DES cases and questioned whether the market-share liability theory was intended to apply beyond DES cases.¹⁰⁷ When it was raised in asbestos litigation, most courts held that the market-share liability theory was inapplicable for public policy reasons. For example, in *Thompson v. Johns-Mansville Corp.* the Fifth Circuit refused to apply the market-share theory because of its radical departure from traditional theories of tort liability.¹⁰⁸

Three reported decisions addressed market-share liability in vaccine cases. Only one of the three cases, *Senn v. Merrell-Dow Pharmaceuticals, Inc.*,¹⁰⁹ involved a claim of defective design, urged by the plaintiff in *Shackil*.¹¹⁰ In *Senn*, the Oregon Supreme Court rejected a market-share liability theory against two manufacturers on the grounds that "adoption of any theory of alternative liability requires a profound change in fundamental tort principles" which should be left to the legislature.¹¹¹ The two additional vaccine cases discussing market-share liability were *Sheffield v. Eli Lilly & Co.*¹¹² and *Morris v. Parke-Davis & Co.*,¹¹³ both distinguished from *Senn* because they involved manufacturing defects rather than defective designs. In *Sheffield*, the California Court of Appeals highlighted the different application of market-share liability when the alleged defect related to the method in which the vaccine was processed,

102. 116 N.J. at 161, 561 A.2d at 517 (citing *McCormick v. Abbott Laboratories*, 617 F. Supp. 1521 (D. Mass. 1985); *McElhaney v. Eli Lilly & Co.*, 564 F. Supp. 265 (D.S.D. 1983)).

103. *Id.* (citing *Hymowitz v. Eli Lilly & Co.*, 73 N.Y.2d 487, 541 N.Y.S.2d 941, 539 N.E.2d 1069, cert. denied, 110 S. Ct. 350 (1989); *Martin v. Abbott Laboratories*, 102 Wash. 2d 281, 689 P.2d 368 (1984); *Collins v. Eli Lilly & Co.*, 116 Wis. 2d 166, 342 N.W.2d 37, cert. denied, 469 U.S. 826 (1984)).

104. *Id.* (citing *Mulcahy v. Eli Lilly & Co.*, 386 N.W.2d 67 (Iowa 1986)).

105. *Id.* (citing *Zafft v. Eli Lilly & Co.*, 676 S.W.2d 241 (Mo. 1984)).

106. *Id.* (citing *Tidler v. Eli Lilly & Co.*, 851 F.2d 418 (D.C. Cir. 1988)).

107. 116 N.J. at 162, 561 A.2d at 517.

108. 714 F.2d 581, 583 (5th Cir. 1983), cert. denied, 465 U.S. 1102 (1984).

109. 305 Or. 256, 751 P.2d 215 (1988).

110. 116 N.J. at 163, 561 A.2d at 518.

111. 305 Or. at 271, 751 P.2d at 223.

112. 144 Cal. App. 3d 583, 192 Cal. Rptr. 870 (Ct. App. 1988).

113. 667 F. Supp. 1332 (C.D. Cal. 1987).

rather than the defective design of the product as in *Sindell*.¹¹⁴ The court in *Sheffield* stated it would be unfair to hold four innocent manufacturers responsible for an injury caused by one tortfeasor claimed to have manufactured the defective dosage.¹¹⁵ The court in *Shackil* also noted the recent California case of *Brown v. Superior Court of California*,¹¹⁶ where the court declined to apply a market-share theory of liability to fraud and breach of warranty claims.¹¹⁷

5. Rejection of Risk-Modified Market-Share Liability

After considering collective liability theories, the appellate division in *Shackil* adopted a risk-modified market-share theory which, in the context of collective liability theories without proof of causation, gave a defendant a fuller opportunity for exculpation.¹¹⁸ Once a plaintiff has demonstrated that the manufacturer of a defective product that caused injury cannot be identified, all manufacturers of a substantial share of the relevant market should be joined in the lawsuit, placing the burden upon defendants "to exculpate themselves by proving either non-participation, possession of reduced market share, or that their product engendered a lower risk".¹¹⁹ The appellate division predicted that the Supreme Court of New Jersey would adopt this collective liability theory, admonishing that "our Supreme Court has been in the forefront of jurisdictions to recognize and protect those injured by the wrongful acts of others."¹²⁰ The court's task was to employ a theory allowing collective responsibility without proof of causation while, at the same time, scrupulously protecting the rights of the defendant manufacturers to exculpate themselves.¹²¹

The supreme court rejected the invitation of the appellate division to place the DPT vaccine with DES risk-modified market-share liability. The court was unwilling to consider modifying and expanding traditional tort theory for these design defect claims except as a matter of sound public policy and only after examining "the general policies that formed the basis of the *Sindell* decision as well as the specific policy considerations that would accompany an expansion of tort law in the context of vaccines."¹²²

114. 144 Cal. App. 3d at 594, 192 Cal. Rptr. at 876. The reasoning of the court was: Here, unlike *Sindell*, the injuries did not result from the use of a drug generally defective when used for the purpose it was marketed, but because some manufacturer made or distributed a defective product. The product that allegedly injured plaintiffs was itself not a unit of a total generic pharmaceutical product, but a deviant defective vaccine.

Id.

115. *Id.* at 599, 192 Cal. Rptr. at 880.

116. 44 Cal. 3d 1049, 751 P.2d 470, 245 Cal. Rptr. 412 (1988).

117. 116 N.J. at 163, 561 A.2d at 518.

118. 219 N.J. Super. at 615, 530 A.2d at 1302.

119. *Id.*

120. *Id.* at 611, 530 A.2d at 1298.

121. *Id.*

122. *Id.*

Addressing the policy considerations underlying *Sindell*, the court noted that the negligent defendant should bear the cost of injury as between it and an innocent plaintiff and that a manufacturer was in a better position to insure against risk of injury than an innocent purchaser.¹²³ Strict liability thus provided an incentive to produce safer products. The court found these two policy decisions to be inapplicable to the risk-modified market-share theory involving DPT. Instead, the court looked to see whether DPT was a "generic" product that was uniformly harmful and, therefore, like DES, amenable to a market-share analysis.¹²⁴

Although raising this issue of whether DPT was a uniformly harmful product, the court did not make a finding in this regard and only quoted statistics that severe injury occurs once in every 110,000 doses of the vaccine. As between the five DPT manufacturers and the generic nature of the DPT products, the court recognized that five DPT manufacturers produced a whole-cell pertussis vaccine in 1972, and one, Eli Lilly, produced a split-cell vaccine from a chemical formula rather than producing it biologically.¹²⁵ The court therefore refused to sweep all producers into one market share because the product was not homogeneous, but left open the question of whether all whole-cell producers could be in one market share.¹²⁶ Technical distinctions between DES and DPT unresolved, the court finally addressed the "public-policy and public-health considerations that would accompany the imposition of market-share liability."¹²⁷

It has been argued that "the common law transformation of product liability law has not been preceded or accompanied by any detailed examination of either its distributive or allocative consequences."¹²⁸ Those major changes in the movement from contract to strict liability were introduced by common law decisions "without any empirical studies as to their consequences, and even without any armchair speculation as to their probable effects."¹²⁹ The supreme court in *Shackil*, however, did analyze the consequences of expanding liability concepts in the national market of vaccines. Before broadening liability to compensate innocent victims, the court needed to decide whether expanding liability would serve the goals of public policy and whether "innocent victims [would] have avenues of legal redress, absent a contrary, overriding public policy."¹³⁰ Arguably, to protect society's interests, the court should modify the

123. *Id.* at 160-61, 561 A.2d at 516-17.

124. *Id.* at 165, 561 A.2d at 521.

125. *Id.* at 165-66, 561 A.2d at 521-522.

126. *Id.* at 166, 561 A.2d at 522. Because whole-cell products were used interchangeably by pediatricians, even though they were separately patented or trade-named, the court stated they could be considered to have their own relevant market. *Id.*

127. *Id.*

128. Epstein, *The Unintended Revolution in Product Liability Law*, 10 CARDOZO L. REV. 2193, 2196 (1989).

129. *Id.*

130. 116 N.J. at 166, 561 A.2d at 522 (quoting *People Express Airlines, Inc. v. Consolidated Rail Corp.*, 100 N.J. 246, 254-55, 495 A.2d 107 (1985)).

common law and eliminate "the requirement of privity between the maker and his dealers and the reasonably expected ultimate consumer."¹³¹ The societal goals of encouraging the use and development of needed drugs, however, would be thwarted if the court placed unlimited liability on manufacturers in order to compensate those injured by their products.¹³²

The court viewed the DPT vaccine as a product essential to the public welfare. An earlier epidemic of pertussis afflicted 265,269 children and caused 7,518 deaths, whereas vaccine development and countrywide inoculation produced a 99% reduction in the number of reported cases per 100,000 population between 1943 and 1976.¹³³ The disease of pertussis, however, has not been stamped out and continues to pose a threat to the health of the country's children.

Of greater concern was the threatened supply of the DPT vaccine after Congressional hearings recognizing recent trends in the production and distribution of DPT.¹³⁴ The trends included (1) rapidly increasing prices for vaccines, (2) a decline in the number of companies and organizations producing and distributing the vaccine with the risk of future interruptions in supply, and (3) an increasing number of liability lawsuits against vaccine manufacturers.¹³⁵ Congressional hearings in 1986 demonstrated to the court that only two commercial entities producing the DPT vaccine were left, as compared with five in 1984.¹³⁶ Those withdrawing from the DPT market were frank in their reasons, citing "extreme liability exposure, cost of litigation and the difficulty of continuing to obtain adequate insurance."¹³⁷

Because the withdrawal phenomenon was a reality, the two remaining manufacturers were forced to concentrate on adequate production of vaccine supplies rather than develop a safer alternative vaccine.¹³⁸ The market reality for the product from the extreme liability exposure, increased product liability lawsuits, increased costs of insurance and litigation expenses forced the price of DPT from eleven cents a dose in 1984 to \$11.40 in 1986.¹³⁹ Expanded theories of liability, moreover, would further defer resources from developing a safer alternative vaccine whose cost is borne by the vaccine manufacturers.

Accepting the overriding public policy of encouraging the development of necessary drugs and examining the consequences of adding market-share liability to the field of DPT manufacturing, the court would not

131. *Henningsen v. Bloomfield Motors*, 32 N.J. 358, 370, 161 A.2d 69, 81 (1960).

132. 116 N.J. at 166, 561 A.2d at 522.

133. *Id.* See *Hinman & Koplan*, *supra* note 22, at 3109-13.

134. 116 N.J. at 167, 561 A.2d at 523.

135. *Id.* See *Comm. Print*, *supra* note 23, at 59.

136. *Comm. Print*, *supra* note 23, at 68.

137. *Vaccine Injury Compensation: Hearing Before Subcommittee on Health and the Environment of the House Committee on Energy and Commerce*, 98th Cong., 2d Sess. 295 (Sept. 10, 1984) (Statement of Daniel Shaw, Jr., Wyeth Laboratories).

138. *Comm. Print*, *supra* note 23, at 67-70.

139. *Shackil*, 116 N.J. at 167, 561 A.2d at 523; *Brown v. Superior Court*, 44 Cal. 3d 1049, 1064-65, 751 P.2d 470, 479, 245 Cal. Rptr. 412, 421 (1988) (eight dollars of the 1986 price went to insurance costs).

extend this new strict liability theory without proof of causation. The court looked through the invitation from the appellate division to accept this "trend" in modern tort law and examined the social policy underlying it to "guide the development of the common law."¹⁴⁰ The public policy that encouraged development of necessary drugs was already embodied in section 402A of the Restatement (Second) of Torts, giving producers of unavoidably unsafe products, including vaccines, relief from strict liability for the unfortunate consequences that might follow their use. The Restatement required, however, that the product must be properly prepared and accompanied by proper directions and warnings to receive the exemption from strict liability.¹⁴¹ The court recognized the Ohio Supreme Court decision in *White v. Wyeth Laboratories*,¹⁴² granting a DPT vaccine manufactured by Lederle Laboratories unavoidably unsafe product status because it was "against the public interest" to stifle medical research and testing by applying strict liability to these products. Without classifying the DPT vaccine product manufactured by the defendants in *Shackil* as an unavoidably unsafe product, the court relied on the policies underlying the exemption for unavoidably unsafe products in the Restatement as grounds for its decision.¹⁴³

B. *Alternative Remedy of the National Childhood Vaccine Injury Act*

The court in *Shackil* had the backdrop of the National Childhood Vaccine Injury Act of 1986¹⁴⁴ which provided a new system of vaccine-injury compensation to provide a remedy to those looking for expanded theories of strict liability. Because of the unique problems presented by childhood vaccine injuries, including state mandated inoculations before entry to school, dwindling supplies of the vaccine and the withdrawal phenomenon from extreme liability exposure, Congress devised a no-fault compensation scheme to handle vaccine-related injuries. Congress anticipated that the Act would create an environment "under which awards [could] be made to vaccine injured persons quickly, easily and with certainty and generosity."¹⁴⁵

Part One of the National Vaccine Program begins: "The Secretary shall establish in the Department of Health and Human Services a national vaccine program to achieve optimal prevention of human infectious dis-

140. *Frame v. Kothari*, 115 N.J. 638, 653, 560 A.2d 675, 683 (1989)(Wilentz, C.J., and Giribaldi, J., concurring).

141. RESTATEMENT (SECOND) OF TORTS § 402A comment k (1979).

142. 40 Ohio St. 3d 390, 533 N.E.2d 748 (1988).

143. 116 N.J. at 168, 561 A.2d at 524.

144. 42 U.S.C.A. §§ 300aa-1 to 34 (West Supp. 1988) (hereinafter the Act).

145. H. REP. NO. 908, 99th Cong., 2d Sess., at 3, reprinted in 1986 U.S. CODE CONG. & ADMIN. NEWS 6344 (hereinafter House Report). See generally 38 L. FRUMER & M. FREEDMAN, PRODUCTS LIABILITY § 51.02 (1988) (providing extensive analysis of the Act); Schwartz & Mahshagian, *National Childhood Vaccine Injury Act of 1986: An Ad Hoc Remedy or a Window for the Future?*, 48 OHIO ST. L.J. 367 (1987) (examining vaccine-liability crisis and the Act's remedies); Note, *The National Childhood Vaccine Injury Act of 1986: A Solution to the Vaccine Liability Crisis?*, 63 WASH. L. REV. 149 (1988) (addressing the "role of the tort system in the vaccine liability crisis" and the probable success of the Act in resolving that crisis).

eases through immunization and to achieve optimal prevention against adverse reactions to vaccines."¹⁴⁶ The court in *Shackil* reviewed features of the Act that discussed petitioning the claims court for a vaccine-related injury and the different manner of compensation for injuries from vaccines administered before October 1, 1988, including the ability of those presently in civil litigation to withdraw from their lawsuits to file a petition under the NCVI.¹⁴⁷ The court also examined the legislative history of the Act and found that the drafters envisioned an easy remedy "for plaintiffs who would otherwise engage in protracted litigation against a vaccine manufacturer with a consequent risk of being denied recovery because of failure to prove the prima facie elements of a tort law cause of action".¹⁴⁸ The court noted that, "The compensation scheme contained in the Act therefore does away with the traditional tort-law requirements of proof with respect to causation, injury, negligence and defect."¹⁴⁹ Congress, therefore, rather than the court, should recognize a theory of collective liability, because the NCVI would not require identification of the manufacturer.¹⁵⁰ The Act would be funded by an excise tax on the manufacturers of childhood vaccines, which tax would "generate sufficient annual income for the [National Vaccine Injury Compensation Trust] fund to cover all costs of compensation."¹⁵¹ At the time of the *Shackil* decision Congress had appropriated up to \$80 million for pre-Act vaccine injuries, permitting the court to find that the Act enjoyed sufficient funding which would be maintained by Congress in the future.¹⁵² This tax can be viewed as a safety tax added to the price of the vaccine, collected and paid by manufacturers to a compensation fund that would be used to pay out claims awarded under the NCVI to infants receiving vaccine-related injuries.¹⁵³ This excise tax or safety tax would increase the price of the DPT vaccine but ultimately would be collected and administered by a national program that would award those injured by rare reactions to the vaccine.

The court was convinced that the NCVI, in addition to serving the goal of compensation to injured vaccinees, was also passed to protect the unstable vaccine market by encouraging vaccine manufacturers to continue to produce supply. The court quoted from the legislative history of the Act:

[t]he loss of any of the existing manufacturers of childhood vaccines at this time could create a genuine public health hazard in this country.

146. 42 U.S.C.A. 300aa-1.

147. 116 N.J. at 169, 561 A.2d at 525.

148. *Id.*

149. *Id.*

150. *Id.* at 170, 561 A.2d at 526.

151. House Report, *supra* note 145, at 34.

152. 116 N.J. at 169, 561 A.2d at 525.

153. *Cf.* Huber, *Flypaper Contracts and the Genesis of Modern Tort*, 10 CARDOZO L. REV. 2263 (1989). The added cost of all goods because of liability exposure and tort liability was labeled a tax on goods collected and disbursed through litigation. *Id.* at 2264. Huber's safety tax accounts for over 95% of the price of childhood vaccines even before imposition of the excise tax under the NCVI. *Id.* at 2263.

Currently there [are] . . . two manufacturers of the DPT vaccine . . . [t]he withdrawal of even a single manufacturer would present the very real possibility of vaccine shortages, and in turn increasing numbers of unimmunized children, and perhaps, a resurgence of preventable diseases.¹⁵⁴

To further improve stability in the vaccine market and continue its supply, all victims injured after 1988 were required to initially prosecute their claim under the NCVI before pursuing a separate cause of action under tort law.¹⁵⁵ Those victims injured before 1988 had the option of filing a claim under the NCVI, but the Act did not allow double recovery if the victim agreed to accept the compensation award under the NCVI.¹⁵⁶ Therefore, the NCVI would lessen the number of lawsuits against manufacturers because of the expected acceptance of no fault compensation under the Act. Even in *Shackil*, the plaintiffs had the option of withdrawing their state tort claims without prejudice and filing a claim for compensation under the Act, but they did not choose that avenue.¹⁵⁷ The risk selected by the plaintiffs to pursue their tort claim under a collective liability theory which ultimately failed, thus leaving them remediless, was willingly assumed and was not a ground for allowing market-share liability or any modification of collective liability theories.

In the absence of the NCVI, a vaccine liability crisis would continue. The court in *Shackil* saw the Act's existence as critical to the accomplishment of the public policy goal of continued production of the DPT vaccine.¹⁵⁸ Although not a substitute for expanded tort law theory that would occur with risk-modified market-share liability, the Act made available compensatory relief that was certain, and satisfied the tort goal of encouraging safer products by establishing "a national program for the research and development of safer vaccines."¹⁵⁹ Because of the comprehensive nature of the NCVI, the issues of federal preemption were raised but unresolved by *Shackil*.

IV. FEDERAL PREEMPTION OF NCVI IN STATE TORT LAW CLAIMS

At the time the appellate division decided *Shackil* and recognized risk-modified market-share liability for DPT manufacturers, the courts were split on whether federal law would preempt state law tort claims involving injuries from DPT vaccines.¹⁶⁰ Federal preemption is premised on the supremacy clause of the United States Constitution, article VI, clause 2, which provides "[T]he Constitution and the laws of the United States,

154. House Report, *supra* note 145, at 7.

155. 42 U.S.C.A. § 300aa-11.

156. 116 N.J. at 170, 561 A.2d at 526.

157. *Id.*

158. *Id.* at 170-71, 561 A.2d at 526-527.

159. *Id.* at 171, 561 A.2d at 527.

160. See Note, *DPT Vaccine-Related Injury Actions: Federal Preemption Reconsidered*, 41 RUTGERS L. REV. 373, 384-93 (1988).

which shall be made in pursuance thereof . . . shall be the supreme law of the land; and the judges in every state shall be bound thereby, anything in the Constitution or laws of any state to the contrary, notwithstanding."¹⁶¹ The doctrine dates back to Justice Marshall's opinion in *Gibbons v. Ogden*¹⁶² where the Court struck down a state statute which was in opposition to a federal statute. Federal preemption can be either express or implied. Most federal statutes do not explicitly preempt state action and, therefore, federal preemption arguments focus on whether implied federal preemption exists.¹⁶³ Certain interests, which demand uniformity in our federalist society to achieve vital national interests, require the removal of conflicting state legislative enactments or state judicial remedies from inquiring juries.¹⁶⁴

The arguments for federal preemption were rejected in *MacGillivray v. Lederle Laboratories*,¹⁶⁵ which was typical of district court decisions at the time. In *MacGillivray*, the court held that comprehensive federal regulations for marketing and design of prescription drugs, including the pertussis vaccine, did not preempt the state's strict products liability law from applying to defective design of the vaccine.¹⁶⁶ The court suggested in *MacGillivray*, however, that the National Childhood Vaccine Injury Act "may indeed serve to prevent future injured parties from bringing state claims based on defective design."¹⁶⁷

The court in *Shackil* separately addressed the federal preemption issue of state tort law claims after reviewing the reversal of two court decisions finding federal preemption initially.¹⁶⁸ The court was satisfied that *Hurley v. Lederle Laboratories*¹⁶⁹ and *Abbot v. American Cyanamid*¹⁷⁰ thoroughly examined the issue of federal preemption by the NCVI and concurred that the Act "does not expressly or impliedly preempt traditional state tort law claims."¹⁷¹ The issue of blanket federal preemption by implication of this comprehensive Act, therefore, was well-settled.

It does appear, however, that selective federal preemption will be recognized in a claim of product liability for a defect in design by inadequate warning.¹⁷² The court in *Shackil* recognized in the provisions

161. U.S. CONST. art. VI, cl. 2.

162. 22 U.S. 1 (9 Wheat) (1824).

163. *Michigan Canners & Freezers Assoc. v. Agricultural Mktg. & Bargaining Bd.*, 467 U.S. 461, 469 (1984).

164. *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236 (1959). See also *Graves v. Walton County Bd. of Educ.*, 300 F. Supp. 188, 193 (M.D. Ga. 1968), *aff'd*, 410 F.2d 1153 (5th Cir. 1969) (preemption doctrine keystone in U.S. federalist system of government).

165. 667 F. Supp. 743 (D.N.M. 1987).

166. *Id.* at 746.

167. *Id.* at 746 ("Congress has quite recently chosen to address one important legal and public health issue raised by suits against vaccine manufacturers wherein certain aspects of state tort law are in fact preempted.")

168. 116 N.J. at 171, 561 A.2d at 527.

169. 851 F.2d 1536 (5th Cir. 1988).

170. 844 F.2d 844 F.2d 1108 (4th Cir.), *cert. denied*, 109 S. Ct. 260 (1988).

171. 116 N.J. at 171, 561 A.2d at 527.

172. 42 U.S.C.A. §§ 300aa-22(b)(1), (2).

of the NCVI and in the pronouncements in *MacGillivray* that certain aspects of state tort law are preempted:

The Act does, however, limit state tort claims based on an injury arising after the effective date of compensation program, to the extent that it codifies comment k of the Restatement (Second) of Torts, 42 U.S.C.A. § 300aa-22(b)(1), and creates a presumption that the vaccine's warning was valid if it complied with FDA requirements. 42 U.S.C.A. § 300aa-22(b)(2).¹⁷³

The general rule of no federal preemption is stated in the Act at 42 U.S.C.A. § 300aa-22(a): "[E]xcept as provided in subsections (b) (c) and (e) of this section, state law shall apply to a civil action brought for damages for a vaccine-related injury or death." The exceptions to application of state law are contained in subsection 300aa-22(b)(1):

(1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this subpart, if the injury or death resulted from side-effects that were unavoidable, even though the vaccine was properly prepared and was accompanied by proper directions and warnings, and

(2) for purposes of paragraph (1) a vaccine shall be presumed to be accompanied by proper directions and warnings, if the vaccine manufacturer shows that it complied in all material respects with the requirements under the Federal Food, Drug and Cosmetic Act, [21 U.S.C.A. § 301 *et seq.*] and Section 262 of this title

The presumption from the Act is that protection under section 402A of the Restatement (Second) of Torts would be given to a DPT vaccine that was not negligently produced or marketed without warnings. Further, the presumption is that FDA approval of the vaccine's warning exempts the manufacturer from a claim of defective design by inadequate warning. The exceptions to selected federal preemption under the Act were premised on activity supporting claims for punitive damages as included in section 300aa-23(d)(2), including fraud or intentional withholding of information under the approval process or relating to the vaccine's safety and effectiveness of the vaccines. A second exception permitted civil liability for damages if the plaintiff could prove by clear and convincing evidence that the manufacturer failed to exercise due care, even though it complied with the Act.¹⁷⁴ Therefore, the DPT vaccine is one of several under the NCVI that can qualify for unavoidably unsafe product status and have FDA approval of its warning as federal preemption of a state law tort claim for defective design.

V. CONCLUSION

Market-share liability theory is an expansion of strict liability theory because it removes the essential tort element of causation. Manufacturers

173. 116 N.J. at 171, 561 A.2d at 527.

174. 42 U.S.C.A. §§ 300aa-22(b)(2)(A), (B).

would be subject to greater potential liability under this theory, beyond traditional products liability because any injury to a person who consumed, used, or came into contact with a product alleged to be defective would subject those manufacturers producing that product to risk. The injured person could join all manufacturers of that product in the industry and allege their market-share liability, rather than alleging product liability from producing an allegedly defective product that caused injury.

The risk-modified market-share liability theory, proposed by the appellate division in *Shackil*, expands strict products liability, but gives manufacturers of a substantial market share a greater opportunity to defend themselves if they can prove nonparticipation, possession of a reduced market share, or lower risk of injury accompanying their products. The New Jersey Supreme Court in *Shackil*, however, refused to expand strict liability theory in the market of DPT vaccines. While *Sindell* expanded product liability theory by adopting the policy that a defendant manufacturer should bear the cost of injury as between it and an innocent plaintiff because a manufacturer could better insure against risk of injury than an innocent purchaser, the *Shackil* court did not view DPT vaccine as a uniformly harmful product that should be subject to market-share analysis. Since market-share liability had limited acceptance in the DES cases and little success outside of *Sindell*, the court in *Shackil* closely examined societal goals and public policy.

The New Jersey Supreme Court was more concerned with the consequences of expanding liability concepts for the national market of vaccines that included only two manufacturers of the DPT vaccine. Although the percentage of the market share of the two manufacturers, Lederle and Connaugh, is not known, there would be little incentive for continued production of the DPT vaccine if each could be held liable for their respective market share from an adverse reaction when their vaccine may not have caused injury. More difficult market-share arguments are raised where the respective manufacturer could have produced forty percent of the relevant market of DPT vaccine at the time of the inoculation, but because of the withdrawal phenomenon, be left with eighty percent of the national market at the time allegations are formulated by the injured vaccinee and representatives. Even though the risk-modified market-share theory permits the showing of a reduced market share, the manufacturer would be put to the burden of establishing its market share again in the absence of proof of causation in fact between its product and the adverse reaction to the vaccine.

Further expansion of the field of DPT vaccines or the return to the DPT vaccine market by withdrawing firms would be discouraged if those manufacturers could be exposed to market-share liability without proof of cause-in-fact. By maintaining the essential element of cause-in-fact for strict liability actions and not allowing unlimited liability for injury because one is in the business of manufacturing a DPT vaccine, the court gives Lederle and Connaugh some incentive to continue producing the DPT vaccine and other manufacturers can consider reentry into the DPT market.

Instead of further threatening the DPT vaccine supply, and cognizant of the crisis that shortages in supply would create, the court in *Shackil* on public policy grounds sought to encourage continued production of the DPT vaccine and re-entry to the market so that manufacturers could use funds otherwise diverted for unlimited liability exposure risks for research and development of safer drugs.

The National Childhood Vaccine Injury Act provides a new system of vaccine-injury compensation. The Act provides no-fault remedies to injured vaccinees, instead of expanding strict liability theory as fashioned in *Sindell*, "to further the risk spreading and deterrence goals of modern products liability law."¹⁷⁵ While "trends" could be recognized, the *Shackil* court gave thought and consideration to the social policy underlying the common law which, in this case, was the overriding public policy of encouraging and developing necessary drugs and preserving the supply of DPT vaccines to guard against a whooping cough epidemic. Rather than expand liability exposure for DPT manufacturers, the court recognized the NCVI as a program to compensate injured vaccinees, while still preserving traditional tort remedies in the state law context for a vaccinee dissatisfied with an NCVI award. Although courts have not recognized blanket federal preemption under the NCVI, selected federal preemption can be premised on proof of unavoidable, unsafe product status for a product prepared with due care and accompanied by a warning approved by the FDA. The combination of the refusal to expand strict liability theory in *Shackil* and the passage and funding of the NCVI can only create a more healthy environment for the DPT vaccine market and children exposed to the risk of the pertussis disease.

175. Fisher, *Products Liability—An Analysis of Market Share Liability*, 34 VAND. L. REV. 1623, 1658 (1981).