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INOCULATED AGAINST RECOVERY: A COMPARATIVE ANALYSIS OF VACCINE INJURY COMPENSATION IN THE UNITED STATES AND GREAT BRITAIN

*Rob Henson**

I. INTRODUCTION

Vaccination against infectious disease is hailed as one of the ten greatest public health achievements of the twentieth century.¹ When the twentieth century began, 160 of every 1000 children born in the United States died from an infectious disease before their fifth birthday.² At the dawn of the twenty-first century, many life-threatening infectious diseases have been nearly eradicated by childhood vaccination.³ Children in the United States are prohibited from attending school until they have received all of the required vaccinations.⁴ The typical diseases vaccinated against in the United States are polio, diphtheria, pertussis, tetanus, measles, mumps, rubella, congenital rubella syndrome, smallpox, influenza, hepatitis B, varicella (chicken pox), *Haemophilus influenzae* type b (hereinafter Hib), and pneumococcal disease.⁵ In Great Britain, vaccination is not mandatory; rather, it is officially recommended for the

* J.D. candidate, May 2008, University of Tulsa College of Law, Tulsa, Oklahoma. I want to thank my loving wife, Heather, and my wonderful children, Caroline, Grant, and Hayden for all of their love, support, and understanding. You all are the light of my life. I dedicate this paper to Eli Johnson, who paid the ultimate price for immunization.

1. CTRS. FOR DISEASE CONTROLS AND PREVENTION, *Ten Great Public Health Achievements-United States, 1900-1999*, 48 MORBIDITY & MORTALITY WKLY. REP. 241, 241 (1999), available at <http://www.cdc.gov/mmwr/PDF/wk/mm4812.pdf> [hereinafter HHS Report].

2. Susan S. Ellenberg & Robert T. Chen, *The Complicated Task of Monitoring Vaccine Safety*, 112 PUB. HEALTH REP. 10, 11 (1997).

3. See H.R. REP. NO. 106-977, at 2 (2000).

4. James G. Hodge, Jr. & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, 90 KY. L.J. 831, 868-69 (2002).

5. Walter A. Orenstein et al., *Immunizations in the United States: Success, Structure, and Stress*, 24 HEALTH AFF. 599, 600-01 (2005).

good of society.⁶ The British government recommends children be inoculated against polio, diphtheria, pertussis (whooping cough), tetanus, measles, mumps, rubella, meningitis C, Hib,⁷ tuberculosis,⁸ and smallpox.⁹ While the near eradication of vaccine-preventable diseases is cause for celebration, vaccines themselves are not perfectly safe¹⁰ and public reaction to vaccination has ranged from awe to outright hostility.¹¹ Properly manufactured and administered vaccines have resulted in injury and death.¹² In the United States, prior to 1987, vaccine injury victims had no choice but to take their chances in the court system and seek recovery for their injuries directly from vaccine manufacturers.¹³ Although vaccine injury victims sought devastating damage awards from pharmaceutical companies,¹⁴ many of these victims were unable to obtain recovery through the judicial system,¹⁵ but faced a lifetime of medical expenses.¹⁶ The potential for adverse verdicts against pharmaceutical companies in the United States increased the price of liability insurance and prompted pharmaceutical companies to raise vaccine prices or cease manufacturing them altogether.¹⁷ This led to a shortage of vaccines and a severe curtailment of vaccine research.¹⁸ Children injured by mandatory pediatric vaccination, who were unsuccessful in court or were unable to even be heard in court, had no means to recover.¹⁹ In the United States, Congress responded to the crisis by passing the National Childhood Vaccine Injury Act.²⁰

6. Stephanie Pywell, *A Critical Review of the Recent and Impending Changes to the Law of Statutory Compensation for Vaccine Damage*, 2000 J. PERS. INJ. L. 246, 246-47 (U.K.).

7. *Id.* at 247.

8. Vaccine Damage Payments Act, 1979, c. 17, § 1(2)(g) (U.K.).

9. § 1(2)(h).

10. Ellenberg & Chen, *supra* note 2, at 11.

11. Alexandra Minna Stern & Howard Markel, *The History of Vaccines and Immunization: Familiar Patterns, New Challenges*, 24 HEALTH AFF. 611, 613 (2005).

12. Lisa J. Steel, *National Childhood Vaccine Injury Compensation Program: Is This the Best We Can Do For Our Children?*, 63 GEO. WASH. L. REV. 144, 152 (1994).

13. H.R. REP. NO. 106-977, at 3 (2000).

14. *See* Steel, *supra* note 12, at 153 (“By 1985, plaintiffs bringing actions against vaccine manufacturers had requested damages in excess of \$3.5 billion.”).

15. *See* Percival v. Am. Cyanamid Co., 689 F. Supp. 1060, 1064 (W.D. Okla. 1987) (noting that the Court ruled against plaintiff who was injured by defendant’s vaccine).

16. *See* Caron v. United States, 410 F. Supp. 378, 392-93 (D. R.I. 1976) (combining plaintiff’s uncontested damage claims, exclusive of pain and suffering and loss of earnings, from birth to age 50 resulted in damages in excess of \$440,000 in 1975 dollars).

17. *See* Steel, *supra* note 12, at 153.

18. *See id.*

19. *See id.*

20. National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-2 to -33 (2000).

In Great Britain,²¹ prior to 1979, vaccine injury victims had no practical means of compensation or redress.²² Great Britain's common law tort system did not provide vaccine injury victims with relief because of the considerable difficulties plaintiffs faced in establishing causation in a vaccine injury lawsuit.²³ Further, a vaccine injury plaintiff had to try her case before a judge, not a jury.²⁴ There were no devastating damage awards against pharmaceutical companies or vaccine shortages in Great Britain, but several diverse factors converged to influence the passage of the Vaccine Damage Payments Act: the thalidomide tragedy,²⁵ the European Court of Human Rights' decision in the *Sunday Times v. United Kingdom*,²⁶ public pressure by parents of vaccine-injured children,²⁷ and the Royal Commission on Civil Liability and Compensation for Personal Injury Report.²⁸ Parliament responded to all of these events by enacting the Vaccine Damage Payments Act.²⁹

The National Childhood Vaccine Injury Act is a no-fault, non-tort compensation program that was intended to ensure adequate vaccine supplies and to fairly compensate³⁰ those injured by vaccines in the United States.³¹ However, the Vaccine Damage Payments Act in Great Britain is described as “[a]n Act to provide for payments to be made out of public funds in cases where severe disablement occurs as a result of vaccination against certain diseases or of contact with a person who has been vaccinated against any of those diseases”³² The Vaccine Damage Payments Act does not mention fairness, equity, or compensation.³³ In fact, members of Parliament and even the British Secretary of State (Health Services) have stated the Vaccine Damage Payments

21. Nicholas J. Wikeley, *Social Security Appeals in Great Britain*, 46 ADMIN. L. REV. 183, 211 n.4 (1994) (stating that “‘Great Britain’ . . . means England, Wales, and Scotland[,]” and that “[c]onstitutionally, Northern Ireland is part of the United Kingdom but not part of Great Britain . . .”).

22. See Pywell, *supra* note 6, at 246.

23. See RICHARD GOLDBERG, *Vaccine Damage and Causation: a Comparative Perspective*, in CAUSATION AND RISK IN THE LAW OF TORTS: SCIENTIFIC EVIDENCE AND MEDICINAL PRODUCT LIABILITY 132, 132 (Hart Publishing 1999).

24. See Bella Louise Morris, *Jury Trials in Personal Injury Claims – Is There a Place for Them?*, 2002 J. PERS. INJ. L. 310, 311 (U.K.).

25. See *infra* notes 186-279 and accompanying text.

26. See *Sunday Times v. United Kingdom*, 2 Eur. Ct. H.R. (ser. A) at 245 (1979).

27. See *infra* notes 320-332 and accompanying text.

28. See *infra* notes 333-339 and accompanying text.

29. Vaccine Damage Payments Act, 1979, c. 17 (U.K.).

30. H.R. REP. NO. 106-977, at 1 (2000) (stating that one of the goals of Congress was to “[p]rovide fair, expedited compensation to those who suffer vaccine injury . . .”).

31. H.R. REP. NO. 106-977, at 1.

32. Vaccine Damage Payments Act.

33. See Vaccine Damage Payments Act.

Act is neither a compensation scheme, nor a no-fault liability scheme.³⁴ A payment made under the Vaccine Damage Payments Act defies convenient classification,³⁵ but is the only viable form of remuneration available to vaccine injury victims in Great Britain.³⁶

While the Acts have arguably achieved some of the objectives of their respective countries—stable vaccine supplies and “fair” compensation in the United States,³⁷ and a one-time statutory payment to vaccine injury victims in Great Britain³⁸—many vaccine injury victims still go uncompensated.³⁹

This comment compares and analyzes the National Childhood Vaccine Injury Act and the Vaccine Damage Payments Act. Section II offers a brief overview of vaccination in the United States and Great Britain. Section III explores the traditional tort law remedies available to vaccine injury victims in the United States and Great Britain prior to Congress’ enactment of the National Childhood Vaccine Injury Act and Parliament’s enactment of the Vaccine Damage Payment Act. Section IV examines the events leading to the passage of the National Childhood Vaccine Injury Act in the United States and discusses the Act itself. Section V reviews the multiple events that led to the passage of the Vaccine Damage Payment Act in Great Britain and discusses the Act itself. Section VI argues that the respective Acts have achieved some of the intended objectives of their respective countries, but still leave many vaccine injury victims uncompensated. Section VII discusses possible future improvements to both Acts, and Section VIII concludes the comment.

II. VACCINATION: A BRIEF OVERVIEW

A. Vaccination in the United States

Vaccination programs are cornerstones of modern public health⁴⁰ and can be credited with the worldwide eradication of smallpox in 1980,⁴¹ the near worldwide eradication of polio,⁴² and significant decreases in the incidences of

34. Pywell, *supra* note 6, at 252.

35. *Id.*

36. *Id.*

37. H.R. REP. NO. 106-977, at 3.

38. Pywell, *supra* note 6, at 246.

39. *Id.*; *see also* H.R. REP. NO. 106-977, *supra* note 3, at 1.

40. H.R. REP. NO. 106-977, *supra* note 3, at 2.

41. *Small Pox, World Health Organization*, <http://www.who.int/mediacentre/factsheets/smallpox/en/> (last visited Oct. 29, 2007).

42. *Does Polio Still Exist? Is It Curable?*, World Health Organization, Jan. 23, 2007, <http://www.who.int/features/qa/07/en/index.html> (explaining that only India, Nigeria, Pakistan and Afghanistan remain polio-endemic and that there were only 1912 worldwide reported cases of polio in 2006).

diphtheria, pertussis (whooping cough), tetanus, measles, mumps, rubella, congenital rubella syndrome, smallpox, influenza, hepatitis B, varicella (chicken pox), and pneumococcal disease in the United States.⁴³ Vaccination is compulsory in the United States⁴⁴ and unless a verifiable medical,⁴⁵ religious,⁴⁶ or philosophical objection can be proven,⁴⁷ children are prohibited from attending school until they have received all of the required vaccinations.⁴⁸ State-mandated immunization has been held constitutional since 1905,⁴⁹ and all states now require proof of vaccination.⁵⁰ Modern school immunization laws were enacted in response to measles outbreaks during the 1960s and 1970s.⁵¹ Policy makers noted that school children in states with strictly enforced immunization laws suffered significantly lower incidence rates of measles than did children in states that did not strictly enforce immunization laws.⁵² Rather than immunizing strictly on an emergency basis in response to an outbreak, legislatures enacted positive laws mandating inoculation as a condition of school attendance.⁵³ The effectiveness of mandatory immunization programs in preventing disease outbreaks has resulted in the annual administration of twelve million vaccine doses to school age children every year.⁵⁴ Vaccination rates for children entering kindergarten in public schools for the 2005-2006 school year were above ninety-five percent for polio, DPT (diphtheria, pertussis, and tetanus), measles, mumps, rubella, and ninety-six percent for hepatitis B and varicella.⁵⁵ However, successful immunization comes at a price.⁵⁶ In rare

43. HHS Report, *supra* note 1, at 245.

44. Hodge & Gostin, *supra* note 4, at 833.

45. *Id.*

46. *Id.*; see *Berg v. Glen Cove City Sch. Dist.*, 853 F. Supp. 651, 655-56 (E.D.N.Y. 1994) (holding that Jewish parents' sincere religious beliefs prohibited school district from requiring their children to be immunized before attending school).

47. Hodge & Gostin, *supra* note 4, at 833; e.g., Okla. Stat. tit. 70 § 1210.192 (2007) (allowing "[a]ny minor child, through the parent, . . . may submit to the health authority . . . [a] written statement by the parent . . . objecting to the immunization of the child; . . . the child shall [then] be exempt from the immunization laws of this state.").

48. Hodge & Gostin, *supra* note 4, at 833.

49. *Jacobson v. Massachusetts*, 197 U.S. 11, 39 (1905) (holding that individuals may be required to be vaccinated provided that accommodations are provided consistent with the Due Process Clause).

50. Hodge & Gostin, *supra* note 4, at 868.

51. *Id.*

52. *Id.*

53. *Id.*

54. H.R. REP. NO. 106-977, at 2 (2000).

55. CTRS. FOR DISEASE CONTROL AND PREVENTION, *Vaccine Coverage Among Children Entering School—United States, 2005—06 School Year*, 55 MORBIDITY & MORTALITY WKLY.

cases, children have experienced vaccination side effects, including permanent disability, paralysis, and death.⁵⁷

B. Vaccination in Great Britain

Vaccination is not mandatory in Great Britain, but is officially recommended for the good of society.⁵⁸ The government recommends children be inoculated against polio, diphtheria, pertussis, tetanus, tuberculosis, smallpox, measles, rubella,⁵⁹ meningitis C, and Hib.⁶⁰ Great Britain relies on its citizens' sense of social responsibility to voluntarily undergo vaccination instead of relying on government-mandated vaccination, as does the United States.⁶¹ However, Great Britain's voluntary vaccination scheme has suffered national vaccine scares that the United States' mandatory vaccination scheme has avoided.⁶²

The first major vaccine scare in Great Britain began on October 26, 1973, when a pediatric neurologist, Dr. John Wilson, announced in his lecture at the Royal Society of Medicine (London) that he had discovered a link between the pertussis vaccine and brain damage.⁶³ The British Medical Association published Dr. Wilson's findings four months later in the *Archives of Disease in Childhood*.⁶⁴ After these findings were published, total pertussis vaccinations plummeted from nearly eighty percent in 1974,⁶⁵ to just thirty-three percent by

REP. 1124, 1124 (2006), available at <http://www.cdc.gov/mmwr/PDF/wk/mm5541.pdf>. According to the Centers for Disease Control:

For the 2005—06 school year, DC and all states except . . . (Illinois and Wyoming) submitted reports of vaccination coverage levels for children entering kindergarten. Of these, 49 reports included coverage for polio vaccine, DTP/DTaP/DT vaccine, measles-containing vaccine, and rubella-containing vaccine; 46 reports included coverage for mumps-containing vaccine; 43 reports included coverage for hepatitis B vaccine; and 41 reports included coverage for varicella vaccine.

Id.

56. See H.R. REP. NO. 106-977, at 2.

57. *Id.* at 2.

58. Pywell, *supra* note 6, at 246.

59. Vaccine Damage Payments Act, 1979, c. 17, § 1(2)(a)-(h) (U.K.).

60. Pywell, *supra* note 6, at 247.

61. Gary L. Freed, *Vaccine Policies Across the Pond: Looking at the U.K. and U.S. Systems*, 24 HEALTH AFF. 755, 755 (2005).

62. James Colgrove & Ronald Bayer, *Could It Happen Here? Vaccine Risk Controversies and the Specter of Derailment*, 24 HEALTH AFF. 729, 729-30 (2005).

63. Brian Deer, *The Vanishing Victims*, SUNDAY TIMES (London), Nov. 1, 1998, (Magazine), available at <http://briandeer.com/dtp-dpt-vaccine-1.htm>.

64. *Id.*

65. Colgrove & Bayer, *supra* note 62, at 729.

1977,⁶⁶ and as low as nine percent in some areas.⁶⁷ Four major pertussis outbreaks occurred during the decreased vaccination period.⁶⁸ In 1979, there were 102,500 pertussis cases reported in the United Kingdom and approximately thirty-six of those cases were fatal.⁶⁹

The second major vaccine scare in Great Britain began on February 28, 1998,⁷⁰ when a research team from London's Royal Free Hospital,⁷¹ led by gastroenterologist Dr. Andrew Wakefield,⁷² published the results of its investigation of the link between developmental regression and gastrointestinal problems in the British medical journal *Lancet*.⁷³ The research team's findings described a group of twelve children who had been referred to the hospital with gastrointestinal problems, which occurred concurrently with developmental regression.⁷⁴ Nine of the twelve children in the study developed autism spectral disorder.⁷⁵ The report suggested the combined measles, mumps, and rubella vaccination was the possible trigger.⁷⁶ While the group was careful to point out in the report that they had not proved a causal link,⁷⁷ Dr. Wakefield contradicted the report's careful wording at a press conference by encouraging parents to vaccinate their children with single doses of measles, mumps, and rubella instead of the combined dose currently in use.⁷⁸ An impassioned debate about the vaccine's safety followed,⁷⁹ and measles, mumps, and rubella immunization rates declined steadily in Great Britain for the next several years.⁸⁰ In 2003, measles, mumps, and rubella immunization rates had fallen to eighty percent across the United Kingdom, and to as low as sixty-two percent in some areas of London.⁸¹

66. Rachel Casiday, *Risk and Trust in Vaccine Decision Making*, 13 DURHAM ANTHROPOLOGY J. (SPECIAL ISSUE) 1, 4.5 (2005), <http://www.dur.ac.uk/anthropology.journal/vol13/iss1/casiday/casiday.pdf>.

67. *Id.*

68. *Id.*

69. *Id.*

70. Colgrove & Bayer, *supra* note 62, at 731-32.

71. *Id.*

72. Casiday, *supra* note 66, at 5.1.

73. Colgrove & Bayer, *supra* note 62, at 731.

74. Casiday, *supra* note 66, at 5.1.

75. *Id.*

76. *Id.*

77. Colgrove & Bayer, *supra* note 62, at 732.

78. *Id.*

79. Casiday, *supra* note 66, at 5.1.

80. Colgrove & Bayer, *supra* note 62, at 732.

81. *Id.* at 733.

The tide turned in November 2003 when one of Dr. Wakefield's collaborators, Simon Murch, asserted there was no link between measles, mumps, and rubella vaccinations and autism.⁸² In March 2004, ten of Dr. Wakefield's collaborators also rejected the autism hypothesis.⁸³ Dr. Wakefield also failed to disclose the fact that the research had been funded by lawyers representing parents who claimed their children had been injured by the measles, mumps, and rubella vaccine.⁸⁴ The focus shifted from Dr. Wakefield's debunked autism hypothesis to the sudden increase in measles cases across the United Kingdom.⁸⁵

In Ireland, a measles outbreak infected more than 1600 children because measles, mumps, and rubella vaccination rates fell drastically as a result of Dr. Wakefield's report.⁸⁶ Three hundred fifty of those infected had to be hospitalized and three children died.⁸⁷ In Great Britain, 442 cases of measles were confirmed in 2003,⁸⁸ approximately four times higher than the average before the publication of Dr. Wakefield's study.⁸⁹ In 2004, there were still several hundred measles cases reported in Great Britain.⁹⁰

The United States has experienced similar concerns and controversies about the safety of childhood vaccines.⁹¹ The link between autism spectral disorder and the measles, mumps, and rubella vaccine has been the subject of numerous media reports, investigations, and congressional hearings.⁹² The link between the vaccine preservative thimerosal⁹³ and autism has also been hotly debated in the United States.⁹⁴ Even as the controversies intensified, childhood immunization rates in the United States actually rose.⁹⁵ Between 1999 and 2003, the percentage of children receiving one or more doses of the measles,

82. *Id.*

83. *Id.*

84. *Id.*

85. *Id.*

86. Nina Goswami & Jon Ungoed-Thomas, *These Boys Were Disabled by Measles, a Disease They Never Should Have Had. They Are the Real Victims of Britain's MMR Scare*, SUNDAY TIMES (London), Apr. 4, 2004, at 21.

87. *Id.*

88. *Id.*

89. *Id.*

90. *Id.*

91. See Colgrove & Bayer, *supra* note 62, at 730.

92. *Id.*

93. Bartholomew C. Wacek, *Taking Sides in the Vaccine/Autism Legal Battle*, 8 DEPAUL J. HEALTH CARE L. 305, 305 (2004) (stating that thimerosal is a mercury-based preservative that inhibits fungal and bacterial growth in stored vaccines).

94. See *id.* at 306.

95. Colgrove & Bayer, *supra* note 62, at 730.

mumps, and rubella vaccine increased from ninety-one percent to ninety-three percent.⁹⁶ Overall, vaccine controversies have produced dramatic consequences on vaccination rates in Great Britain, but similar controversies have had no effect on vaccination rates in the United States.⁹⁷

III. TRADITIONAL TORT LAW REMEDIES BEFORE PASSAGE OF THE RESPECTIVE ACTS

A. Traditional Tort Law Remedies in the United States

Prior to the enactment of the National Childhood Vaccine Injury Act, vaccine injury victims and their families sought relief directly from vaccine manufacturers by filing traditional state law tort claims.⁹⁸ Plaintiffs typically filed suit under any or all of the following three theories of liability: negligence,⁹⁹ failure to warn,¹⁰⁰ and strict liability.¹⁰¹ Plaintiffs have had modest success with general negligence theories¹⁰² and failure to warn theories.¹⁰³ However, they have experienced the most difficulty prevailing under strict liability¹⁰⁴ because the Restatement (Second) of Torts, section 402A, comment k, specifically characterizes vaccines as unavoidably unsafe products.¹⁰⁵ Most jurisdictions that have considered vaccine injury litigation

96. *Id.*

97. *Id.*

98. H.R. REP. NO. 106-977, at 3 (2000).

99. *See, e.g., Toner v. Lederle Labs.*, 732 P.2d 297, 299 (Idaho 1987).

100. *See, e.g., Percival v. Am. Cyanamid Co.*, 689 F. Supp. 1060, 1061 (W.D. Okla. 1987).

101. *See, e.g., Grinnell v. Pfizer & Co.*, 79 Cal. Rptr. 2d 369, 373 (Ct. App. 1969).

102. *See, e.g., Toner*, 732 P.2d at 312.

103. Victoria Bennett, *Health Law—Vaccine Injuries—Federal Law Prescribes Procedures for Alternatives to Tort Actions for Vaccine-Related Injuries. The National Childhood Vaccine Injury Compensation Act of 1986*. 42 U.S.C. §§ 300aa-1 to -34 (Supp. IV 1986), 11 U. ARK. LITTLE ROCK L. REV. 749, 754 (1989).

104. *Id.* at 753-54.

105. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965) reads in part:

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like The seller of such products . . . with the qualification that they are properly prepared and marketed, and proper warning is given, . . . is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Id.

have adopted comment k,¹⁰⁶ but courts in different jurisdictions have issued opposing rulings on nearly identical sets of facts.¹⁰⁷ The following sections briefly examine plaintiffs' successes and failures with the tort law theories of negligence, failure to warn, and strict liability prior to 1987.

1. Negligence

In *Toner v. Lederle Laboratories*,¹⁰⁸ the three-month-old plaintiff became permanently paralyzed from the waist down shortly after he was injected with the defendant's DPT¹⁰⁹ vaccine, Tri-Immunol.¹¹⁰ The jury rejected the plaintiff's strict liability claims,¹¹¹ but found the manufacturer was negligent for failing to market a safer, alternative form of the vaccine.¹¹² The defendant appealed the decision to the Ninth Circuit Court of Appeals¹¹³ and, rather than rendering a decision, the Ninth Circuit sent two certified questions to the Idaho Supreme Court.¹¹⁴ The first question asked whether comment k applied to strict liability claims.¹¹⁵ The second question asked whether comment k applied to negligence claims.¹¹⁶ The Idaho Supreme Court stated that plaintiffs who are injured by an unavoidably unsafe product, such as a vaccine, may only proceed against the manufacturer on a negligence theory.¹¹⁷ The court went on to discuss comment k¹¹⁸ and upheld the jury's finding that the defendant was negligent for failing to market a safer, alternative form of the vaccine.¹¹⁹ Thus,

106. *Brown v. Superior Court*, 751 P.2d 470, 476 (Cal. 1988).

107. *Compare Percival v. Am. Cyanamid Co.*, 689 F. Supp. 1060, 1064 (W.D. Okla. 1987) (holding that the drug company only had a duty to warn the physician, but not the patient), with *Davis v. Wyeth Labs.*, 399 F.2d 121, 131 (9th Cir. 1968) (holding that the drug company did not meet its duty to warn the patient).

108. *Toner v. Lederle Labs.*, 732 P.2d 297 (Idaho 1987).

109. HARRIS L. COULTER & BARBARA LOE FISHER, *DPT: A SHOT IN THE DARK 1* (Harcourt Brace Jovanich 1985) (explaining that the DPT shot stands for diphtheria, pertussis and tetanus. "Today, nearly all our children get the DPT shot These three different vaccines are combined into one shot to combat three dreaded diseases that have, in past centuries, caused children to die or become permanently handicapped.").

110. *See Toner v. Lederle Labs.*, 732 P.2d 297, 299 (Idaho 1987) (noting that Tri-Immunol was manufactured by Lederle Laboratories, which is a division of American Cyanamid Company).

111. *Id.* at 299.

112. *Id.* at 301-02.

113. *Id.* at 299.

114. *Id.*

115. *Id.* at 303.

116. *Toner*, 732 P.2d at 303.

117. *Id.* at 309-10.

118. *Id.* at 311.

119. *Id.* at 312.

Toner allowed plaintiffs to file suit on a negligence theory centered on marketing an alternative, safer vaccine.¹²⁰

2. Failure to Warn

In *Percival v. American Cyanamid Co.*,¹²¹ the infant plaintiff, Charles Percival, suffered severe and permanent neurological damage after he was injected with the defendant's DPT vaccine, Tri-Immunol.¹²² Charles Percival's parents sued the vaccine manufacturer on the theory the manufacturer failed to directly warn them of any possible adverse side effects of the DTP vaccine.¹²³ The defendant countered that it only had a duty to warn the patient's physician.¹²⁴ The court noted that manufacturers generally have a duty to warn consumers of potential dangers arising from the use of its product,¹²⁵ but held that in cases where prescription drugs (vaccines) were involved, manufacturers only have a duty to warn the patient's physician.¹²⁶ The court stated the physician is best situated to evaluate the patient's needs and presumably, the patient relies upon the advice and judgment of the physician.¹²⁷ The result of this relationship is that the physician acts as a learned intermediary between the patient and the manufacturer.¹²⁸

Contrary to *Percival*, the plaintiff's failure to warn theory was upheld in *Davis v. Wyeth Laboratories*.¹²⁹ The thirty-nine year old plaintiff, Glynn Richard Davis, was diagnosed with polio after he was vaccinated at a mass immunization clinic.¹³⁰ The court found the defendant manufacturer had taken an active role in organizing, promoting, and administering the vaccination program,¹³¹ and the injections were administered without a physician's individual assessment of the risks involved.¹³² Since no physician was present to counsel and warn the vaccine recipients of the potential risks of the vaccine,¹³³ the court found it was the manufacturer's duty to warn the recipients

120. *See id.* at 301-02.

121. *Percival v. Am. Cyanamid Co.*, 689 F. Supp. 1060 (W.D. Okla. 1987).

122. *Id.* at 1061.

123. *Id.* at 1061-62.

124. *Id.* at 1062.

125. *Id.*

126. *Id.*

127. *Percival*, 689 F. Supp. at 1062.

128. *Id.*

129. *Davis v. Wyeth Labs.*, 399 F.2d 121, 131 (9th Cir. 1968).

130. *Id.* at 122.

131. *See id.* at 131.

132. *Id.*

133. *See id.*

directly.¹³⁴ The court concluded that the manufacturer's failure to warn the recipients rendered the injections unreasonably dangerous and strict liability, absent a warning to the recipient, attached to the vaccinations.¹³⁵

3. Strict Liability

Overall, the tort recovery system "has been called a 'forensic lottery' in which a small minority obtain a pot of gold but the majority go empty-handed or obtain only tokens of solace."¹³⁶ While the *Grinnell*¹³⁷ and *Davis*¹³⁸ courts allowed the plaintiffs to proceed, and ultimately prevail, under strict liability theories, their successes are not typical.¹³⁹ Although the *Toner* court found the defendant vaccine manufacturer was negligent and allowed the jury to consider comment k, the court rejected the plaintiff's promising strict liability theory.¹⁴⁰ Jurisdictions that adopted the Restatement (Second) of Torts, section 402A, comment k, essentially precluded most, if not all, strict liability claims since comment k characterizes vaccines as unavoidably unsafe products.¹⁴¹

B. Traditional Tort Law Remedies in Great Britain

The Vaccine Damage Payments Act does not bar a vaccine injury victim from bringing a negligence claim against a vaccine manufacturer.¹⁴² However, no common law tort claim for vaccine injuries has ever been successful in England or Wales.¹⁴³ The Vaccine Damage Payments Act is essentially the only means of compensation available to vaccine injury victims.¹⁴⁴ The leading vaccine injury case in Great Britain is *Loveday v. Renton*.¹⁴⁵ The plaintiff sought to prove that the pertussis vaccine caused brain damage in young children.¹⁴⁶ Justice Stuart-Smith issued a 139-page judgment holding the plaintiff failed to prove her case, but stating it was impossible to prove the pertussis vaccine did not cause her brain damage.¹⁴⁷ The first and only

134. *Id.*

135. *Davis*, 399 F.2d at 130.

136. John G. Fleming, *Drug Injury Compensation Plans*, 30 AM. J. COMP. L. 297, 317 (1982) (quoting the title of TERENCE G. ISON, *THE FORENSIC LOTTERY* (Staples Press 1967)).

137. *Grinnell v. Pfizer & Co.*, 79 Cal. Rptr. 2d 369 (Ct. App. 1969).

138. *Davis*, 399 F.2d at 121.

139. See Bennett, *supra* note 103, at 753-54.

140. See *Toner v. Lederle Labs.*, 732 P.2d 297 (Idaho 1987).

141. See RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

142. Vaccine Damage Payments Act, 1979, c. 17, § 6(4) (U.K.).

143. Pywell, *supra* note 6, at 246.

144. *Id.*

145. *Id.* at 248; *Loveday v. Renton* (1988) Q.B.D. (U.K.).

146. Pywell, *supra* note 6, at 248.

147. *Id.*

successful claim for vaccine injury in all of the United Kingdom and Europe was *Best v. Wellcome Found. Ltd.*¹⁴⁸ decided in Dublin, Ireland on May 11, 1993.¹⁴⁹ The Irish High Court approved a £2.75 million (\$5.4 million)¹⁵⁰ award to the mother of a child who had been severely injured by a pertussis vaccine that was administered in September 1969.¹⁵¹ The case was finally resolved more than twenty-three years after the vaccine had been administered to the child.¹⁵² However, other United Kingdom and European plaintiffs have not, and likely will not benefit from the *Best v. Wellcome Found. Ltd.*¹⁵³ decision.¹⁵⁴ The Irish High Court decision was based on the finding that the entire batch of the triple dose vaccine manufactured by the defendant, Wellcome, should have never entered the market.¹⁵⁵ The court noted the vaccine was substandard and it had failed several laboratory tests.¹⁵⁶ The Irish court's decision focused more on the fact that the particular batch of the pertussis vaccine was defective, rather than the general fact that pertussis vaccine recipients sometimes suffer irreversible brain damage after being inoculated.¹⁵⁷

IV. THE NATIONAL CHILDHOOD VACCINE INJURY ACT: RUNAWAY JURIES AND RUNNING AWAY FROM VACCINES

A. The Crisis: Runaway Juries and Running Away From Vaccines

The uncertain outcome of civil litigation and the risk of no remedy did not dissuade vaccine injury victims from filing suit against pharmaceutical companies.¹⁵⁸ Both vaccine manufacturers and vaccine injury victims found the traditional tort system inadequate for their needs.¹⁵⁹ The 1980s saw an explosion in vaccine litigation, and in 1985, vaccine injury lawsuits filed against manufacturers sought damages in excess of \$3.5 billion.¹⁶⁰ The increase in

148. *Id.*; *Best v. Wellcome Found. Ltd.* [1993] 3 I.R. 421 (Ir.).

149. Diana Brahams, *Court Award for Pertussis Vaccine Damage*, 341 LANCET (1993) (U.K.).

150. *Id.*; (noting that the conversion of the amount in U.S. Dollars is the 2007 Conversion from British Pounds Sterling to U.S. Dollars as of September 2007, http://coinmill.com/GBP_USD.html) (last visited Sept. 30, 2007) (A conversion to historical equivalents is not possible with this web site) [hereinafter Conversion].

151. See Brahams, *supra* note 149; see *Best*, 3 I.R. at 421.

152. See Brahams, *supra* note 149.

153. *Best*, 3 I.R. at 421.

154. See Brahams, *supra* note 149.

155. *Id.*

156. *Id.*

157. See generally *id.*

158. See Steel, *supra* note 12, at 153.

159. *Id.*

160. *Id.*

lawsuits caused the manufacturers' litigation costs to rise,¹⁶¹ and insurance premiums skyrocketed while coverage amounts plummeted.¹⁶² Some smaller manufacturers were unable to obtain liability insurance at all.¹⁶³ The result was an exodus of vaccine manufacturers from the market.¹⁶⁴ At the time of the passage of the National Childhood Vaccine Injury Act, there were only two companies manufacturing polio vaccines,¹⁶⁵ and two companies and two state health departments manufacturing DPT vaccines.¹⁶⁶ Vaccine stockpiles were at a critically low level and Congress found that the withdrawal of even one manufacturer from the market would likely cause nationwide vaccine shortages.¹⁶⁷ Thus, Congress recognized that the tragic injuries suffered by children, the extreme liability exposure facing vaccine manufacturers, and the danger facing society if any more manufacturers stopped producing vaccines all combined to create the perfect storm.¹⁶⁸

B. The Response: Everyone Stop Running

Congress enacted the National Childhood Vaccine Injury Act in order to respond to the crisis. The Act was passed to further three objectives: 1) fair and expeditious compensation for vaccine injury victims through a no-fault scheme; 2) enhancement of the childhood immunization system; and 3) preservation and the protection of the national vaccine supply by providing a liability shield to manufacturers.¹⁶⁹

The Act itself consists of two parts. The first part is the National Vaccine Program that focuses on enhancing national immunization programs, improving vaccines, and monitoring adverse vaccine reactions.¹⁷⁰ The second part is the Vaccine Injury Compensation Program that established the federal no-fault compensation program for vaccine injury victims.¹⁷¹

161. *See id.*

162. *See generally id.*; Philip H. Abelson, *Product Liability in a Litigious Society*, 240 SCI. MAG. 1589 (1988) http://www.sciencemag.org/cgi/issue_pdf/edboard_pdf/240/4859.pdf, (stating that “[i]n 1984, a pharmaceutical firm paid \$72,000 for \$100 million in liability coverage (after deductions)[,] and “[b]y 1986 insurers were asking \$1.8 million for \$15 million in coverage.”).

163. Steel, *supra* note 12, at 153.

164. *Id.*

165. *Id.*

166. *Id.*

167. *Id.* at 153-54.

168. *See generally id.* at 154.

169. H.R. REP. NO. 106-977, at 1 (2000).

170. *See generally* National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to-6 (2000).

171. *See generally* §§10-34.

Under the Vaccine Injury Compensation Program, any person who has suffered an injury or death as a result of polio, diphtheria, pertussis, tetanus, measles, mumps, or rubella vaccination is eligible for compensation.¹⁷² No showing of fault is required.¹⁷³ A vaccine injury victim is prohibited from filing suit against a vaccine manufacturer until he first files a claim and receives a judgment under the Act.¹⁷⁴

The first step for a vaccine injury victim seeking compensation is to file a petition with the United States Court of Federal Claims.¹⁷⁵ The Secretary of the Department of Health and Human Services is automatically appointed as respondent to the vaccine injury victim's petition.¹⁷⁶ A special master is then assigned¹⁷⁷ to determine if the petition shows, by a preponderance of the evidence, that the vaccine injury victim was actually injured, or died, as a result of vaccination.¹⁷⁸ The victim's medical records must also be included in the petition.¹⁷⁹ Records that must be compiled are prenatal and delivery records, vaccination records, pre-injury medical records, post-injury hospital records, and a death certificate and autopsy results, if applicable.¹⁸⁰

A vaccine injury victim may satisfy his burden of proof by showing his injury or injuries are listed on the Vaccine Injury Table.¹⁸¹ If the injuries listed on the Vaccine Injury Table occurred within the period of time specified by the Table, vaccination is presumed to have been the cause.¹⁸² If the vaccine injury victim shows his injuries satisfy the Vaccine Injury Table criteria, the burden of proof shifts to the Department of Health and Human Services to show that the injuries were caused by something other than vaccination.¹⁸³

If a vaccine injury victim's injuries are not listed in the Table,¹⁸⁴ he may still be awarded compensation if he demonstrates by a preponderance of the evidence that his injuries were caused by vaccination.¹⁸⁵ However, the district court will not simply accept the vaccine injury victim's petition as proof of

172. § 11(b)(1)(A); *see also* § 14(a).

173. *See* § 11(c).

174. *See* § 11(a)(2)(A) (noting that an exception is made for claimed damages less than \$1000).

175. § 11(a)(1) (service upon the Secretary of the Department of Health and Human Services is also required).

176. National Childhood Vaccine Injury Act, § 12(b)(1).

177. § 12(c)(1).

178. §§ 12(c), 13(a).

179. § 11(c)(2).

180. § 11(c)(2).

181. § 14(a).

182. *Dileo v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 796, 798 (Cl. Ct. 1991).

183. *See id.*

184. § 11(c)(1)(C)(ii)(I).

185. § 13(a)(1).

causation.¹⁸⁶ He must present additional evidence or expert medical testimony to satisfy the burden of proof.¹⁸⁷

V. THE VACCINE DAMAGE PAYMENT ACT: A DANGEROUS DRUG, CONTEMPTUOUS JOURNALISTS, VOCAL PARENTS, AND ONE ROYAL COMMISSION

A. *A Dangerous Drug: Thalidomide*

The path leading to the passage of the Vaccine Damage Payments Act in Great Britain was not a direct one, and actually began in Germany with a drug, not a vaccine, named thalidomide.¹⁸⁸ The thalidomide debacle provided the crucial momentum for products liability and personal injury compensation reform in Great Britain.¹⁸⁹ The Vaccine Damage Payment Act¹⁹⁰ was enacted by Parliament after the Royal Commission on Civil Liability and Compensation for Personal Injury¹⁹¹ published its findings.¹⁹² The Royal Commission on Civil Liability and Compensation for Personal Injury was the British government's 1972 response to the thalidomide tragedy.¹⁹³ The history of thalidomide in Great Britain dates back to April 14, 1958 when thalidomide began selling in England as Distaval, Asmaval, Tensival, Valgis, and Valgraine,¹⁹⁴ and continued more than twenty-one years into 1979 after the Vaccine Damage Payments Act received the Royal Assent on March 22, 1979,¹⁹⁵ and after the final ruling of the European Court of Human Rights was handed down in *Sunday Times v. United Kingdom*¹⁹⁶ on April 26, 1979.¹⁹⁷

186. § 13(a)(1)(B).

187. § 13 (a)(1)(B).

188. See Max Sherman & Steven Strauss, *Thalidomide: A Twenty-Five Year Perspective*, 41 FOOD DRUG COSM. L.J. 458-60 (1986).

189. See Jane Stapleton, *Products Liability Reform—Real or Illusory?*, 6 O.J.L.S. 392, 392-93 (1986), available at <http://www.jstor.org/view/01436503/ap030020/03a00050/0> (last visited Oct. 29, 2007).

190. Vaccine Damage Payments Act, 1979, c. 17 (U.K.).

191. ROYAL COMMISSION ON CIVIL LIABILITY AND COMPENSATION FOR PERSONAL INJURY, REPORT, 1977-8, Cmnd. 7054-I available at <http://www.bopcris.ac.uk/bopall/ref19170.html> (last visited Oct. 29, 2007).

192. Pywell, *supra* note 6, at 248.

193. *Id.*

194. Patricia Howlett, *Compensation for Drug Induced Fetal Deformities in Common and Civil Law Systems*, 2 TOURO J. TRANSNAT'L L. 243, 245 (1991).

195. Pywell, *supra* note 6, at 248.

196. *Sunday Times v. United Kingdom*, 2 Eur. Ct. H.R. (ser. A) at 245 (1979).

197. *Id.*

Thalidomide was synthesized in 1953, and later discarded, by a Swiss¹⁹⁸ company named Ciba.¹⁹⁹ A German company, Chemie Grünenthal, began testing thalidomide on laboratory animals.²⁰⁰ Chemie Grünenthal's laboratory tests showed it was not possible to administer lethal doses of thalidomide to laboratory rats or other laboratory test animals,²⁰¹ so the company declared that thalidomide was nontoxic.²⁰² The company initially experimented with the drug as an anticonvulsant,²⁰³ but discovered it worked well as a hangover-free sedative.²⁰⁴ Human clinical trials were never conducted,²⁰⁵ and as far as clinical testing and human pregnancy were concerned, there was a general belief²⁰⁶ that the placenta would filter most deleterious substances.²⁰⁷ However, even in 1959, twenty-five different compounds had been discovered that were known to kill or deform a human fetus.²⁰⁸

Chemie Grünenthal began selling thalidomide as a sedative on October 1, 1957.²⁰⁹ The company initially marketed the drug in pill form as a sleep aid²¹⁰ and later marketed the drug in liquid form, specifically for children.²¹¹ Thalidomide became West Germany's favorite babysitter.²¹² Thalidomide also became the drug of choice for pregnant women;²¹³ it was non habit-forming,²¹⁴ prevented the nausea associated with pregnancy,²¹⁵ and provided a good night's

198. TRENT STEPHENS & ROCK BRYNNER, DARK REMEDY: THE IMPACT OF THALIDOMIDE AND ITS REVIVAL AS A VITAL MEDICINE 8 (Perseus Publishing 2001).

199. Sherman & Strauss, *supra* note 188, at 459.

200. *Id.* at 459-60.

201. STEPHENS & BRYNNER, *supra* note 198, at 9; *see also* Sherman & Strauss, *supra* note 186, at 459. ("Despite the fact that the hypnotic potency of thalidomide is similar to barbiturates, its acute toxicity is so negligible that it would be almost impossible to commit suicide taking the drug.")

202. STEPHENS & BRYNNER, *supra* note 198, at 9.

203. Sherman & Strauss, *supra* note 188, at 460.

204. *Id.*

205. STEPHENS & BRYNNER, *supra* note 198, at 9-10 (explaining that the company distributed samples to doctors and company employees but never monitored or followed up to see if there had been any adverse reactions to the drug).

206. Sherman & Strauss, *supra* note 188, at 461 (emphasizing that the thalidomide tragedy would shatter that belief).

207. *Id.*

208. STEPHENS & BRYNNER, *supra* note 198, at 23.

209. *Id.* at 14.

210. Sherman & Strauss, *supra* note 188, at 460.

211. *Id.*

212. *See id.*

213. Howlett, *supra* note 194, at 245.

214. *Id.*

215. Sherman & Strauss, *supra* note 188, at 460.

sleep.²¹⁶ Chemie Grünenthal's 1958 advertising campaign was aimed directly at pregnant women:²¹⁷ "In pregnancy and during the lactation period, the female organism is under great strain. Sleeplessness, unrest and tension are constant complaints. The administration of a sedative and hypnotic that will hurt neither mother nor child is often necessary."²¹⁸ Demand²¹⁹ for thalidomide became overwhelming²²⁰ and pharmaceutical companies in several countries, including Australia, Canada, Great Britain, New Zealand, and Portugal began manufacturing or marketing it under various brand names.²²¹ At its peak, thalidomide was sold worldwide in forty-six countries under thirty-seven different brand names.²²²

The first child with birth defects²²³ caused by thalidomide was born on Christmas Day in 1956.²²⁴ She was the daughter of a Chemie Grünenthal employee who had given his wife sample thalidomide tablets during her pregnancy.²²⁵ Thalidomide caused extensive teratogenic²²⁶ injuries.²²⁷ Obstetricians all over Germany began noting the rare abnormality tetraphocomelia (literally, "four seal's limbs") in newborn infants.²²⁸ Tetraphocomelia is a condition in which the infant's limbs are so short that the hands and feet are often attached directly to the trunk.²²⁹ Tetraphocomelia was the most noted teratogenic effect of thalidomide.²³⁰ Doctors and neurologists also began reporting an increase in peripheral neuropathy²³¹ in adults taking thalidomide as a sedative.²³² However, Chemie Grünenthal suppressed all

216. *Id.*

217. Howlett, *supra* note 194, at 245.

218. *Id.*

219. *See generally* STEPHENS & BRYNNER, *supra* note 198, at 3-4 (suggesting a few reasons why British and German citizens may have been craving a sleep aid).

220. Sherman & Strauss, *supra* note 188, at 460.

221. *Id.*

222. STEPHENS & BRYNNER, *supra* note 198, at 16.

223. *Id.* at 19 (noting she was born without ears).

224. *Id.*

225. *Id.*

226. Teratogenic means: "Causing congenital anomalies or birth defects." STEADMAN'S MEDICAL DEFINITION 1947 (Julie K. Stegman et al eds., Lippincott Williams & Wilkins 2006) (1911).

227. Howlett, *supra* note 194, at 245.

228. STEPHENS & BRYNNER, *supra* note 198, at 21.

229. *Id.*

230. Howlett, *supra* note 194, at 245.

231. "Peripheral neuropathy is a problem with the nerves that carry information to and from the brain and spinal cord. This produces pain, loss of sensation, and inability to control muscles." MedlinePlus Medical Encyclopedia, Peripheral Neuropathy, <http://www.nlm.nih.gov/medlineplus/ency/article/000593.htm> (last visited Oct. 29, 2007).

232. STEPHENS & BRYNNER, *supra* note 198, at 20-21.

reports of injuries and side effects,²³³ and no connection was made between the peripheral neuropathy cases and thalidomide until December 1960 when a letter written by Dr. A. Leslie Florence titled "Is Thalidomide to Blame?" was published in the *British Medical Journal*.²³⁴ An Australian obstetrician named William McBride would eventually make the connection between birth defects and thalidomide in June 1961.²³⁵

Even though Chemie Grünenthal had received notices of dangerous side effects from thalidomide,²³⁶ the company was eager to sell the drug in the United States.²³⁷ In October 1958, the William S. Merrell Company of Cincinnati (later renamed Richardson-Merrell) signed a contract with Chemie Grünenthal to distribute thalidomide in the United States.²³⁸ The Richardson-Merrell Company sought approval from the Food and Drug Administration (FDA) to sell thalidomide as Kevadon.²³⁹ The company submitted its application to the FDA on September 12, 1960.²⁴⁰ The drug was to be labeled for use as a nausea combatant during pregnancy.²⁴¹ Richardson-Merrell had ten million tablets ready for U.S. distribution while awaiting FDA approval;²⁴² however, that approval never came.²⁴³ Frances Kelsey, a doctor and pharmacologist,²⁴⁴ was a newly appointed medical officer at the FDA²⁴⁵ and forced Richardson-Merrell to resubmit its application for approval six times.²⁴⁶ Doctor Kelsey felt the application was deficient and suspected the company was not being candid in its applications or with her.²⁴⁷ Dr. Kelsey's belief was supported by the FDA pharmacologist who "felt the chronic toxicity studies [of thalidomide] had not run for a sufficient length of time."²⁴⁸ Dr. Kelsey's suspicions were confirmed when she read "Is Thalidomide to Blame?" in the *British Medical Journal*.²⁴⁹ Dr. Kelsey subsequently demanded that

233. *Id.* at 29.

234. *Id.* at 23.

235. *Id.* at 29.

236. *Id.* at 20.

237. *Id.* at 17.

238. STEPHENS & BRYNNER, *supra* note 198, at 17.

239. *Id.*; see Sherman & Strauss, *supra* note 188, at 460.

240. S. REP. NO. 87-1744, at 52 (1962), as reprinted in 1962 U.S.C.C.A.N. 2884, 2905.

241. S. REP. NO. 87-1744, at 52.

242. STEPHENS & BRYNNER, *supra* note 198, at 39.

243. See *id.* at 54.

244. Sherman & Strauss, *supra* note 188, at 461.

245. STEPHENS & BRYNNER, *supra* note 198, at 44.

246. *Id.* at 53.

247. See *id.* at 52.

248. *Id.* at 48.

249. *Id.* at 23, 51.

Richardson-Merrell disprove the reports.²⁵⁰ In response, the company withdrew its application for approval of Kevadon on March 8, 1962.²⁵¹ John F. Kennedy awarded Dr. Kelsey with the President's Award for Distinguished Federal Civilian Service on August 8, 1962.²⁵²

Great Britain did not have a vigilant Dr. Kelsey to protect its children from thalidomide.²⁵³ Instead, it had a Liverpool based company named Distillers Company (Biochemicals) Limited (hereinafter Distillers), better known for its scotch and gin than pharmaceutical products,²⁵⁴ that was looking for "the ideal tranquilizing agent to replace alcohol among those people who would prefer to 'transform their minds' by . . . alternative means."²⁵⁵ Distillers would find that "ideal tranquilizing agent" in June 1956, when Chemie Grünenthal offered Distillers the opportunity to manufacture and distribute thalidomide in the United Kingdom.²⁵⁶ Distillers never bothered to hire a pharmacologist²⁵⁷ or perform any clinical trials before purchasing the rights to thalidomide.²⁵⁸ On April 14, 1958, Distillers started selling thalidomide in Great Britain.²⁵⁹ Distillers sent many British doctors notes stating, "[Thalidomide] can be given with complete safety to pregnant women, and nursing mothers, without adverse effect on mother or child."²⁶⁰ Other Distillers' advertisements proclaimed children who took the drug from the medicine cabinet could not accidentally ingest a lethal dose of thalidomide.²⁶¹ Dr. A. Leslie Florence²⁶² and Dr. William McBride²⁶³ would soon discover the horrible truth about thalidomide.²⁶⁴

On November 29, 1961, thalidomide was pulled from the German market.²⁶⁵ Thalidomide was pulled from the British market on November 27,

250. *Id.* at 51.

251. STEPHENS & BRYNNER, *supra* note 198, at 54.

252. *Id.* at 55.

253. *See id.*

254. *A Scandal Too Long Concealed*, TIME, May 7, 1979, <http://www.time.com/time/magazine/article/0,9171,920320,00.html>.

255. STEPHENS & BRYNNER, *supra* note 198, at 5.

256. *Id.*

257. *Id.* at 16.

258. *Id.*

259. Howlett, *supra* note 194, at 245.

260. *Id.*

261. STEPHENS & BRYNNER, *supra* note 198, at 17.

262. *See id.* at 23.

263. *See id.* at 29.

264. *Id.*

265. *Id.* at 53.

1961.²⁶⁶ In England alone, 456 children were ultimately identified as victims of thalidomide.²⁶⁷ Worldwide, it is estimated that 40,000 people suffered from peripheral neuropathy because of thalidomide,²⁶⁸ and between 8000 and 12,000 children were born with birth defects caused by thalidomide.²⁶⁹ Approximately 5000 of those survived past childhood.²⁷⁰

During the thalidomide crisis, Enoch Powell was England's Minister of Health.²⁷¹ A delegation of parents met with Powell to persuade him, as Minister of Health, to urge the public to throw out any thalidomide tablets that might still remain in their medicine cabinets.²⁷² Powell regarded the idea as "foolish."²⁷³ Further, Powell refused to meet any children who were thalidomide victims²⁷⁴ and refused to publicly acknowledge he had met with the delegation of parents.²⁷⁵ The message Powell gave the parents was, "I hope you're not going to sue the government[]"²⁷⁶ because "[n]o one can sue the government."²⁷⁷

One of the British government's greatest failures during the thalidomide crisis was its refusal to investigate the tragedy.²⁷⁸ Powell, as Minister of Health, refused to begin an inquiry.²⁷⁹ The House of Commons voted down a proposed thalidomide inquiry in July of 1962.²⁸⁰ Distillers exercised such overwhelming influence over the House of Lords that there was never even a proposed thalidomide inquiry to vote down.²⁸¹ Other than the victims and their barristers and solicitors, the only group of people who appeared interested in learning about the full scope of the tragedy was the *Sunday Times* Insight Team.²⁸²

266. MURRAY ROSEN, THE SUNDAY TIMES THALIDOMIDE CASE: CONTEMPT OF COURT AND THE FREEDOM OF THE PRESS 103 (1979) (U.K.).

267. STEPHENS & BRYNNER, *supra* note 198, at 83.

268. *Id.* at 37.

269. *Id.*

270. *Id.*

271. *Id.* at 80.

272. *See id.* at 80-81.

273. STEPHENS & BRYNNER, *supra* note 198, at 81.

274. *Id.*

275. *Id.*

276. *Id.*

277. *Id.*

278. *Id.*

279. STEPHENS & BRYNNER, *supra* note 198, at 81.

280. *Id.*

281. *See id.* at 82-83.

282. *See id.* at 82.

B. Contemptuous Journalists: The Sunday Times Insight Team²⁸³ and Their Refusal to "Go Gentle into That Good Night"²⁸⁴

The first thalidomide lawsuit²⁸⁵ was filed against Distillers on November 17, 1962.²⁸⁶ Once the case became *sub judice*,²⁸⁷ British contempt laws prohibited any mention of the case in the press.²⁸⁸ In fact, ten years would pass before the thalidomide cases were mentioned in the *Times* again,²⁸⁹ and fifteen years passed before any journalists, other than the *Sunday Times* Insight Team, published anything about the thalidomide children.²⁹⁰ The policy behind the contempt laws was to prevent potential jurors from being influenced by the press, rather than evidence presented at trial.²⁹¹ In reality, the gag order kept many victims from even knowing a lawsuit had been filed,²⁹² prevented Parliament and the public from knowing details about the case and the scope of the thalidomide epidemic,²⁹³ and ultimately prevented public criticism of Distillers.²⁹⁴

Many of the early plaintiffs who sued Distillers were forced to rely on public funds to pay their legal expenses.²⁹⁵ The Law Society controlled the funds and dictated which experts, barristers, and solicitors could be paid.²⁹⁶ The Law Society was not confident in the plaintiffs' cases: "We have known virtually from the beginning that there was no case."²⁹⁷ The plaintiffs' barristers were no more confident about the case than the Law Society.²⁹⁸ One barrister made it clear to plaintiffs in 1967²⁹⁹ that there was no way to win and they

283. See ROSEN, *supra* note 266.

284. DYLAN THOMAS, THE POEMS OF DYLAN THOMAS 239 (Daniel James ed., New Directions 2003) (citing title of poem).

285. See STEPHENS & BRYNNER, *supra* note 198, at 83 (noting that the suit was a class action involving sixty-two families).

286. *Id.* at 81.

287. Sub *judice* is defined as "[b]efore the court or judge for determination; at bar" BLACK'S LAW DICTIONARY 1466 (8th ed. 2004).

288. STEPHENS & BRYNNER, *supra* note 198, at 81.

289. *Id.* at 81-82.

290. *Id.* at 82.

291. *Id.*

292. *Id.*

293. See *id.* at 94.

294. See generally STEPHENS & BRYNNER, *supra* note 198, at 87-88 (demonstrating that the first article published about the case criticized the small settlements Distillers had offered the victims).

295. *Id.* at 83.

296. *Id.*

297. *Id.*

298. See *id.* at 84.

299. Virtually nothing happened in the case for five years. *Id.* at 83.

should settle for any amount Distillers offered.³⁰⁰ Distillers offered the families an all-or-nothing deal.³⁰¹ “[forty percent] of the maximum they might have received from a trial.”³⁰² Children with the worst injuries would receive a one-time payment of \$21,700,³⁰³ while children with lesser injuries would receive smaller sums.³⁰⁴ Six of the families refused to settle³⁰⁵ and the case ground to a halt.³⁰⁶

The *Sunday Times* Insight Team kept abreast of the case events by acquiring internal Distillers’ documents from various sources.³⁰⁷ On September 24, 1972, ten years after the initial lawsuit was filed, the *Sunday Times* could keep silent no more; it published a three page story titled “Our Thalidomide Children: a National Shame.”³⁰⁸ The story was accompanied by pictures of the thalidomide children and also provided the details of Distillers’ £3.25 million settlement offer, while noting the company’s pretax profits that year were £64 million.³⁰⁹ The *Sunday Times* published another article the following week that included letters from victims’ parents.³¹⁰ The *Sunday Times* planned a third and final article for the following week, but this time, the Attorney General obtained an injunction against the newspaper from the British High Court.³¹¹ The final article planned to disclose critical information culled from Distillers’ internal documents regarding animal testing and reports of injuries from thalidomide use.³¹² The Court of Appeal overturned the injunction on February 18, 1973,³¹³ but the House of Lords reinstated it on July 18, 1973.³¹⁴ The article would not be printed until June 27, 1976,³¹⁵ but the critical information the Insight Team wanted to publish was still bound by the injunction and the article did not appear in its original form.³¹⁶ In July 1975, the *Sunday Times* filed suit against the

300. STEPHENS & BRYNNER, *supra* note 198, at 84.

301. *Id.* (emphasizing that all of the families were required to accept the settlement or Distillers would withdraw the offer).

302. *Id.* at 85.

303. *Id.*

304. *Id.*

305. *Id.*

306. STEPHENS & BRYNNER, *supra* note 198, at 86.

307. *See id.*

308. *Id.* at 87.

309. *Id.*

310. *Id.* at 88.

311. *Sunday Times v. United Kingdom*, 2 Eur. Ct. H.R. (ser. A) at 245 (1979).

312. STEPHENS & BRYNNER, *supra* note 198, at 89.

313. ROSEN, *supra* note 266, at 10.

314. *Id.*

315. STEPHENS & BRYNNER, *supra* note 198, at 97.

316. *See id.*

British government in the European Commission of Human Rights,³¹⁷ alleging the government violated their right to freedom of expression guaranteed by Article Ten of the European Convention on Human Rights.³¹⁸ In July 1977, the European Court of Human Rights held in favor of the *Sunday Times*,³¹⁹ and stated the House of Lords had denied their right to free expression.³²⁰ The European Court of Human Rights gave the *Sunday Times* and the thalidomide victims an extraordinary gift that neither the House of Lords, nor the entire British government could suppress: it attached the entire forbidden *Sunday Times* article in the appendix to its decision making it a public record.³²¹ Fifteen years after the first thalidomide lawsuit was filed and nearly twenty years after thalidomide went on sale in Great Britain, the story of the victims (no longer children, but teenagers) and their families was finally told in its entirety.³²²

C. Vocal Parents: The Association of Parents of Vaccine Damaged Children

The Association of Parents of Vaccine Damaged Children was founded in 1973 by Rosemary Fox.³²³ Fox's eldest daughter, Helen, was vaccinated against polio in 1962.³²⁴ Two days after Helen was vaccinated, she became violently sick.³²⁵ Fox notified her family physician, but was told not to worry and to watch for any new developments in Helen.³²⁶ Five months later, Helen began having convulsions, which the doctors said were due to teething.³²⁷ When Helen was two years old, Helen's doctor told Fox that Helen's brain was damaged.³²⁸ Fox asked the doctor if the polio vaccine could be the cause of the brain damage, but was emphatically told no.³²⁹ Helen was taken to several different doctors and Fox asked if the polio vaccine could be the cause of the

317. *See id.* at 96.

318. *Id.*

319. *Id.* at 97.

320. *Id.* at 97-98.

321. STEPHENS & BRYNNER, *supra* note 198, at 97-98.

322. *See id.*

323. 614 PARL. DEB., H.L. (5th ser.) (2000) 975, available at <http://www.publications.parliament.uk/pa/ld199900/ldhansrd/vo000628/text/00628-21.htm> (as debated on June 28, 2000).

324. Emma Brady, *My Battle for Justice Over MMR; Controversy over the Safety of a Combined Measles, Mumps and Rubella Vaccination for Children Has Led to a Measles Epidemic in Britain as Parents Shun the Three-in-One Jab. Health Reporter Emma Brady Spoke to Rosemary Fox Who Knows All Too Well What Can Happen When Vaccines Do More Harm Than Good*, BIRMINGHAM POST (England), June 19, 2006, at 3.

325. *Id.*

326. *Id.*

327. *Id.*

328. *Id.*

329. *Id.*

brain damage, but again, was told it was not possible the polio vaccine was the cause of Helen's condition.³³⁰ Helen was seven years old before a doctor finally said the polio vaccine was the cause of her brain damage.³³¹ Through Helen's ordeal, it became clear to Mrs. Fox that there were hundreds of other children in Great Britain who also suffered from vaccine injuries and she decided to form the Association of Parents of Vaccine Damaged Children.³³² In 1974, Fox persuaded Jack Astley, a Member of Parliament, to take the cause of vaccine injury victims directly to Parliament.³³³ The debate over vaccine injury compensation raged in Parliament for the next three years until Parliament agreed to pay the vaccine-injured children £10,000.³³⁴ The following year, the Vaccine Damage Payments Act was passed to administer the payments and set out the eligibility criteria to determine who would actually be compensated.³³⁵

D. The Royal Commission on Civil Liability and Compensation for Personal Injury

The Royal Commission on Civil Liability and Compensation for Personal Injury (hereinafter, Royal Commission) was part of the British government's response to the thalidomide tragedy.³³⁶ The principal task of the Royal Commission was to redefine the relationship between social security and tort liability.³³⁷ The five-year study was undertaken to consider the feasibility and availability of government sponsored compensation for personal injury or death occurring in any of the following circumstances: (1) during the course of employment; (2) using a motor vehicle or other similar method of transportation; (3) using goods or services (including injury caused by vaccines); (4) on property owned or occupied by another; or (5) by an act or omission of another.³³⁸ The Royal Commission published its findings in March of 1978,³³⁹ and the Report recommended that the United Kingdom maintain a blended system of tort liability complemented by social security.³⁴⁰ The Royal

330. Brady, *supra* note 324, at 3.

331. Helen Carroll, *Victim of a Vaccine Heartbreak Over My Brain-Damaged Daughter*, MIRROR (U.K.), (Mar. 11, 2006), <http://www.mirror.co.uk/archive/2006/03/11/victim-of-a-vaccine-89520-16802227/>.

332. *Id.*

333. *See* Brady, *supra* note 324, at 3.

334. *Id.*

335. *Id.*

336. Pywell, *supra* note 6, at 247.

337. John G. Fleming, *The Pearson Report: Its "Strategy,"* 42 MOD. L. REV. 249, 249 (1979).

338. R. A. Hasson, *The Pearson Report- Something for Everyone?*, 6 BRIT. J. OF L. AND SOC'Y 119, 120 (1979).

339. Fleming, *supra* note 337, at 249.

340. *Id.* at 252.

Commission Report also endorsed strict liability for defective products, ultra hazardous activities, and vaccine injuries.³⁴¹ Shortly after publication of the Report, Parliamentary debates began on the Vaccine Damage Payments Act.³⁴²

E. The Long Way Home: The Vaccine Damage Payments Act

Vaccination in Great Britain, unlike the United States, is not mandatory.³⁴³ Nonetheless, after the thalidomide tragedy,³⁴⁴ the *Sunday Times* decision,³⁴⁵ the lobbying of members of Parliament, public pressure exerted by the Association of Parents of Vaccine Damaged Children,³⁴⁶ and the publication of the Royal Commission's Report,³⁴⁷ Parliament enacted the Vaccine Damage Payments Act in 1979.³⁴⁸

The Vaccine Damage Payments Act, as originally enacted in 1979, provided a one-time £10,000 (\$19,600)³⁴⁹ statutory payment³⁵⁰ to a vaccine injury victim who was at least eighty percent disabled³⁵¹ and could prove "on the balance of probability"³⁵² that the injury resulted from vaccination against one of the diseases listed in the Act.³⁵³ A claim under the Vaccine Damage Payments Act had to be brought before the vaccine injury victim's eighth birthday or six years from the date of vaccination, whichever was later.³⁵⁴ Agents for the Secretary of State conducted medical assessments and evaluated the vaccine injury victim's claims.³⁵⁵ The evaluations were then forwarded to the Vaccine Damage Payments Unit staff, which ultimately advised claimants of the decision.³⁵⁶ A claimant may appeal the initial decision to a Vaccine Damage Appeal Tribunal on questions of fact or law.³⁵⁷ A claimant may not appeal the decision of a Vaccine Damage Appeal Tribunal *per se*, but rejected claimants

341. Hasson, *supra* note 338, at 119.

342. See Pywell, *supra* note 6, at 248-49.

343. *Id.* at 247.

344. See *supra* notes 186-319 and accompanying text.

345. *Sunday Times v. United Kingdom*, 2 Eur. Ct. H.R. (ser. A) at 245 (1979).

346. See *supra* notes 320-332 and accompanying text.

347. See *supra* notes 333-339 and accompanying text.

348. Vaccine Damage Payments Act, 1979, c. 17 (U.K.).

349. Conversion, *supra* note 150.

350. Vaccine Damage Payments Act § 1(1A).

351. *Id.* § 1(4).

352. Vaccine Damage Payments Act § 3(5).

353. *Id.* § 1(2).

354. Vaccine Damage Payments Act § 3(1)(c).

355. Pywell, *supra* note 6, at 250.

356. *Id.*

357. *Id.*

can file a written application for reversal with the Secretary of State for Social Security, explaining why the claimant believes the decision is erroneous.³⁵⁸

Parliament rejected the Royal Commission's strict liability approach in favor of a causation approach.³⁵⁹ Some members of Parliament urged adoption of the Royal Commission approach and criticized the balance of the probability approach, emphasizing that it would be difficult for claimants to establish a causal link between inoculation and subsequent illnesses.³⁶⁰ The small £10,000 lump sum statutory payment was also criticized.³⁶¹ One member pointed out that if Parliament adopted the Royal Commission strict liability approach, an average vaccine injury claimant would receive £100,000 instead of the proposed paltry £10,000.³⁶²

The Vaccine Damage Payments Act was meant to be a temporary measure.³⁶³ Prior to the passage of the Act, the Secretary of State for Social Services told concerned members of Parliament that a more generous compensation scheme would ultimately be enacted, but time was needed to study the Royal Commission Report.³⁶⁴ However, after the general election of 1979, the Labour government was voted out of power and the Conservative party, led by Margaret Thatcher, came into power.³⁶⁵ In 1983, the Conservative government stated in unequivocal terms that the Royal Commission's strict liability approach would not be implemented.³⁶⁶ The conservative Secretary of State also indicated that the £10,000 lump sum statutory payment provided vaccine injured children a measure of relief, and that if they wanted additional compensation they should institute legal proceedings.³⁶⁷

358. *Id.*

359. *Id.* at 250-51.

360. *Id.* at 250.

361. Pywell, *supra* note 6, at 250.

362. *Id.*

363. *See id.*

364. *Id.* (quoting 962 PARL. DEB., H.C. (5th ser.) (1979) 35).

365. 10 Downing Street, Margaret Thatcher, <http://www.number-10.gov.uk/output/Page126.asp> (last visited Oct. 3, 2007).

366. Pywell, *supra* note 6, at 250-51 (quoting 49 PARL. DEB., H.C. (6th ser.) (1983) 417).

367. *See id.*

VI. THE GLASS IS HALF EMPTY

A. *Mission Accomplished? Adequate Supply, Litigation Reduction, and Payment*

1. Objectives of the National Childhood Vaccine Injury Act

Since the National Childhood Vaccine Injury Act was passed, vaccine prices have decreased,³⁶⁸ reports of large jury verdicts against vaccine manufacturers have disappeared,³⁶⁹ and no pharmaceutical company has ceased producing vaccines since 1990.³⁷⁰ However, twenty years after passage of the Act, only five major pharmaceutical companies manufactured the fourteen most widely used vaccines in the United States.³⁷¹ Prior to 2000, it could also be safely stated that vaccine supplies in the United States had stabilized since passage of the National Childhood Vaccine Injury Act³⁷² and that the Act had arguably achieved part of what Congress originally intended.³⁷³ However, in 2000, an unprecedented vaccine supply disruption began.³⁷⁴ Childhood immunization schedules had to be changed to reduce the number of doses administered because nine different vaccines routinely given were in short supply.³⁷⁵ The influenza vaccine shortage of 2004 further highlighted the fragility of the vaccine supply in the United States.³⁷⁶

2. Objectives of the Vaccine Damage Payments Act

The Vaccine Damage Payments Act was not passed to ensure adequate vaccine supplies in the United Kingdom.³⁷⁷ Further, unlike the situation in the United States, there have been no vaccine shortages or interruptions to the childhood vaccination program.³⁷⁸ The Vaccine Damage Payments Act was enacted simply to provide a statutory payment to vaccine injury victims.³⁷⁹

368. See Derry Ridgway, *No-Fault Vaccine Insurance: Lessons From the National Vaccine Injury Compensation Program*, 24 J. HEALTH POL. POL'Y & L. 59, 76 (1999).

369. *Id.* at 77.

370. *Id.* at 76.

371. See Orenstein et al., *supra* note 5, at 603.

372. See Ridgway, *supra* note 368, at 76.

373. *Id.* at 76-77.

374. Orenstein et al., *supra* note 5, at 607.

375. *Id.*

376. *Id.*

377. Vaccine Damage Payments Act, 1979, c. 17 (U.K.).

378. David M. Salisbury, *Development of Immunization Policy and Its Implementation in the United Kingdom*, 24 HEALTH AFF. 744, 749 (2004).

379. Pywell, *supra* note 6, at 246.

B. What About Us?

1. Uncompensated Victims in the United States

Despite the National Childhood Vaccine Injury Act and common law tort remedies, many vaccine injury victims, like Andrew Clements, remain uncompensated.³⁸⁰ In *Clements v. Sec'y of Dep't of Health & Human Servs.*,³⁸¹ Andrew Clements, a six-month-old child, began having seizures less than twenty-four hours after he received a DPT vaccination.³⁸² He was rushed to the hospital while suffering from an extremely high fever.³⁸³ The fever persisted for approximately forty hours after he was admitted to the hospital.³⁸⁴ Andrew continued to suffer seizures and in September 1995, while suffering from a 108 degree fever, he went into shock and his internal organs began to fail.³⁸⁵

The Clements family filed a timely petition under the National Childhood Vaccine Injury Act in 1995.³⁸⁶ Despite all of the evidence the Clements presented, on July 30, 1998, the special master assigned to their case denied their claim for relief stating, "petitioners may prevail solely on the evidence they present, not on the sympathy they engender."³⁸⁷ Andrew Clements' plight is not unique.³⁸⁸ As of October 2006, 11,916 vaccine injury victims or their estates have filed claims for compensation under the National Childhood Vaccine Injury Act.³⁸⁹ Of the 11,916 claims filed, only 2011 vaccine injury victims have received compensation under the Act.³⁹⁰ During the same period, 9445 claimants were denied compensation,³⁹¹ and 460 were awaiting a decision.³⁹²

380. See *Clements v. Sec'y of Dep't of Health & Human Servs.*, No. 95-484V, 1998 WL 481881 (Fed. Cl. July 30, 1998).

381. *Id.*

382. *Id.* at *1.

383. *Id.* at *1-*2.

384. *Id.*

385. *Id.* at *3.

386. See *Clements*, 1998 WL 481881 at *1.

387. *Id.* at *15.

388. See Leonard D. Pertnoy, *A Child's View of Recovery Under the National Childhood Vaccine Act or "He Who Hesitates is Lost,"* 59 MONT. L. REV. 275, 284 (1998).

389. U.S. Department of Health & Human Services, Health Resources & Services Administration, *National Vaccine Injury Compensation Program*, http://www.hrsa.gov/vaccinecompensation/statistics_report.htm (last visited on Oct. 3, 2007).

390. *Id.*

391. *Id.*

392. See *id.*

2. Uncompensated Victims in Great Britain

When the Vaccine Damage Payments Act was passed in 1979, vaccine injury victims were to be paid a one-time lump sum of £10,000.³⁹³ From 1979 to 2003, approximately 8808³⁹⁴ vaccine injury victims filed claims under the Vaccine Damage Payments Act. Of those 8808 claims filed, only 907 vaccine injury victims have received payment under the Act.³⁹⁵ Since no common law claim for vaccine damage has ever succeeded in England or Wales,³⁹⁶ and only one has succeeded in Ireland,³⁹⁷ it follows that more than 7900 vaccine injury victims were denied payment under the Act and have been left without compensation.³⁹⁸

VII. THERE IS ALWAYS ROOM FOR IMPROVEMENT

A. Improving the National Childhood Vaccine Injury Act

The National Childhood Vaccine Injury Act does not address all vaccine injury concerns.³⁹⁹ The Act has its weaknesses, but commentators do not appear to be calling on Congress to repeal the Act.⁴⁰⁰ Overall, vaccine injury victims appear to be better off with the National Childhood Vaccine Injury Act than they are with the tort system alone.⁴⁰¹

1. Reducing the Adversarial Nature of the Proceedings

Congress intended the National Childhood Vaccine Injury Act to be a no-fault alternative to litigation,⁴⁰² but it has deteriorated to a contentious battle between vaccine injury victims and government lawyers that is as adversarial as

393. Vaccine Damage Payments Act, 1979, c. 17, § 1(1A) (U.K.).

394. See MANITOBA LAW REFORM COMMISSION, REPORT NO. 104 ON COMPENSATION OF VACCINE-DAMAGED CHILDREN 29 (2000) (Can.), available at <http://www.gov.mb.ca/justice/mlrc/reports/104.pdf> (4217 claims from 1979 to 2000), [hereinafter MLRC]; *Vaccine Damage Payments*, 27.4(5) CONSUMER LAW TODAY 1 (2004) (U.K.) (4591 claims from 2000 to 2003).

395. See MLRC, *supra* note 391, at 29 (896 claims paid from 1979 to 2000); *Clinical Negligence Claims*, 25.10(4) CONSUMER L. TODAY 1 (2004) (U.K.) (eleven claims paid from 2000 to 2003).

396. Pywell, *supra* note 6, at 248.

397. *Id.*

398. See *supra* notes 391-92 and accompanying text (explaining the difference between the total number of filed claims and the total number of paid claims).

399. Bennett, *supra* note 103, at 770.

400. Keith M. Garza, *Administrative No-Fault Recovery for Transfusion-Related HIV Infection*, 60 DEF. COUNS. J. 384, 388 (1993).

401. *Id.*; see also Bennett, *supra* note 103, at 770.

402. H.R. REP. NO. 106-977, at 1 (2000).

the process it was meant to supplant.⁴⁰³ The government opposes compensation for vaccine injury victims on purely technical grounds.⁴⁰⁴ Justice Department lawyers have argued over expenses as slight as the projected cost of diapers⁴⁰⁵ and opposing counsel's taxi fares to court.⁴⁰⁶ Petitioners' attorneys also appear to be spending far more hours preparing cases than should be necessary.⁴⁰⁷ The intense preparation further reflects the adversarial nature of the proceedings.⁴⁰⁸ One solution to the problem is shifting the burden of showing an alternate cause of harm from the petitioner to the government.⁴⁰⁹ This would greatly benefit the victims and reduce the adversarial nature of the proceedings.⁴¹⁰

The adversarial nature of the proceedings can also be reduced by broadly interpreting the Vaccine Injury Table, rather than interpreting the Table as strictly as possible.⁴¹¹ An ambiguity in the table should favor the vaccine injury victim, not the government.⁴¹² Congress established the National Childhood Vaccine Injury Act under the presumption that some victims will be compensated even though vaccination was not the definitive cause of their injuries.⁴¹³ With that premise in mind, the Vaccine Injury Table should favor vaccine injury victims.⁴¹⁴

2. Increasing Compensation Amounts

Damages payable to a deceased vaccine injury victim's estate have been capped at \$250,000 since the Act's inception.⁴¹⁵ Congress should simply increase the damages cap.⁴¹⁶ A vaccine injury victim's estate should be allowed to seek recovery for costs related to the victim's death as well as the costs related

403. See Kristine M. Severyn, *Jacobson v. Massachusetts: Impact on Informed Consent and Vaccine Policy*, 5 J. OF PHARMACY & L. 249, 265 (1996).

404. Ridgway, *supra* note 368, at 83.

405. John Hanchette & Sunny Kaplan, *National Vaccine Compensation Program for Children Draws Fire*, GANNETT NEWS SERVICE (1998), <http://www.nvic.org/Articles/gnscompe.htm> (last visited Oct. 3, 2007).

406. *Id.*

407. Steel, *supra* note 12, at 162.

408. *Id.*

409. Elizabeth C. Scott, Comment, *The National Childhood Vaccine Injury Act Turns Fifteen*, 56 FOOD & DRUG L.J. 351, 364 (2001).

410. *Id.*

411. Steel, *supra* note 12, at 172.

412. *Id.*

413. *Id.*

414. *Id.*

415. National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-15(a)(2) (2000).

416. Jaclyn Shoshana Levine, *The National Vaccine Injury Compensation Program: Can It Still Protect an Essential Technology?*, 4 B.U. J. SCI. & TECH. L. 9, 77 (1998).

to preparing the vaccine injury petition for the Federal Claims Court.⁴¹⁷ Ironically, the compensation fund is operating with its largest surplus ever, but more and more vaccine injury victims are left uncompensated.⁴¹⁸

3. The Statute of Limitations and Equitable Tolling

The Vaccine Damage Payments Act in Great Britain allows claims to be filed under the Act up to the vaccine injury victim's twenty-first birthday or six years from the date of vaccination, whichever is later.⁴¹⁹ The National Childhood Vaccine Injury Act requires a claim to be filed within three years of the date the vaccine was administered.⁴²⁰ Vaccine injury victims in Great Britain have *eighteen* additional years to bring a claim under the Vaccine Damage Payments Act.⁴²¹

Equitable tolling is a doctrine that allows a plaintiff to avoid the statute of limitations.⁴²² The National Childhood Vaccine Injury Act must make allowances for parents of victims who were unaware of a causal connection between vaccination and their child's injury, as well as for incidents where health care providers do not detect or accept a causal connection between vaccination and a victim's injury.⁴²³ Many victims are denied recovery when the three-year statute of limitations is strictly enforced.⁴²⁴ The Court of Appeals for the Federal Circuit has noted that equitable tolling may be available to a petitioner under the Act.⁴²⁵

4. Changes to the Vaccine Injury Table Should Only be Made by Congress

The Secretary of Health and Human Services has the unilateral authority to change the scope of the Vaccine Injury Table.⁴²⁶ The Secretary has narrowed the scope of the Vaccine Injury Table, making it more restrictive and more difficult for vaccine injury victims to prevail.⁴²⁷ It was presumed that the Secretary had the power to expand the Table, but not to narrow its scope.⁴²⁸

417. *Id.*

418. Scott, *supra* note 409, at 362.

419. Vaccine Damage Payments Act, 1979, c. 17, § 3(c)(i)-(ii) (U.K.).

420. National Childhood Vaccine Injury Act of 1986, § 300aa-16(a)(2).

421. *Compare* Vaccine Damage Payments Act, § 3(c)(i)-(ii), *with* National Childhood Vaccine Injury Act, § 300aa-16(a)(2).

422. Pertnoy, *supra* note 388, at 296.

423. *Id.* at 299.

424. *Id.* at 297.

425. *Id.*

426. Scott, *supra* note 409, at 364.

427. *Id.*

428. *Id.*

Only Congress can add a vaccine to the Vaccine Injury Table,⁴²⁹ therefore, by analogy, only Congress should be able to make the Vaccine Injury Table more restrictive.⁴³⁰

5. Appoint Neutral Panels of Experts

A neutral panel of court-appointed experts might better represent both parties in a vaccine injury proceeding.⁴³¹ Justice Department lawyers routinely attack petitioners' expert witnesses.⁴³² Testimony given by petitioners' experts is frequently dismissed by the Justice Department as biased.⁴³³ Instead of dueling experts bickering about causation, the scientific decision would be made outside of the proceedings.⁴³⁴ This would reduce the costs to the petitioner (who would not have to hire expert witnesses) and reduce the adversarial nature of the system.⁴³⁵

B. Improving the Vaccine Damage Payments Act

Great Britain has a history of providing a system of social security⁴³⁶ for its citizens dating back to the industrial revolution.⁴³⁷ However, as demonstrated by the thalidomide tragedy and the plight of vaccine-injured children,⁴³⁸ the system has not served all members of society.⁴³⁹ A comprehensive compensation system for vaccine injury victims is still needed.⁴⁴⁰

1. Increasing the Statutory Sum

The Vaccine Damage Payments Act has improved since it was enacted; it was amended in 1985 to increase the one-time statutory payment from £10,000

429. *Id.*

430. *See id.*

431. *See id.* at 365.

432. Scott, *supra* note 409, at 362.

433. Severyn, *supra* note 403, at 266.

434. Scott, *supra* note 409, at 365.

435. *Id.*

436. William Beveridge, Great Britain's architect of modern Welfare State, defined social security as:

[T]he securing of an income to take the place of earnings when they are interrupted by unemployment, sickness or accident, to provide for retirement through age, to provide against loss of support by the death of another person, and to meet exceptional expenditures, such as those connected with birth, death and marriage.

Wikeley, *supra* note 21, at 183.

437. Freed, *supra* note 61, at 755.

438. *See supra* Part V.

439. *See* Wikeley, *supra* note 21, at 183.

440. Pywell, *supra* note 6, at 256.

to £20,000.⁴⁴¹ The statutory payment was again increased in 1991, from £20,000 to £30,000,⁴⁴² and increased from £30,000 to £40,000 in 1998.⁴⁴³ Vaccine injury victims are now paid a one-time lump sum of £100,000⁴⁴⁴ (\$196,000).⁴⁴⁵

The most significant changes to the Vaccine Damage Payments Act were announced on June 27, 2000.⁴⁴⁶ In addition to increasing the statutory sum to £100,000, the time limit for making claims was extended to allow claims to be filed up to the vaccine injury victim's twenty-first birthday or six years from the date of vaccination, whichever is later.⁴⁴⁷ The disability threshold has been lowered from eighty percent to sixty percent.⁴⁴⁸ Further, all previous claimants who received payment under the Vaccine Damage Payments Act prior to June 27, 2000, will collect additional retroactive payments of £58,000 to £67,000 in order to match the payments made to claimants who qualify for payment under the new £100,000 statutory sum.⁴⁴⁹

However, the new £100,000 statutory sum still compensates vaccine injury victims less favorably than other injury victims.⁴⁵⁰ The Vaccine Damage Payments Act has no provision for loss of future earnings and no provision for future medical care.⁴⁵¹ In *Stephens v. Doncaster Health Authority*,⁴⁵² the plaintiff, who suffered from a birth injury that rendered him quadriplegic, required twenty-four hour care and had a life expectancy of only twenty-five years, was awarded more than £1.3 million (\$2.5 million)⁴⁵³ at common law.⁴⁵⁴ A similarly situated vaccine injury victim would merely be entitled to the £100,000 (\$196,000)⁴⁵⁵ statutory sum.⁴⁵⁶

441. Vaccine Damage Payments Act, 1979, c. 17, § 1(1A) (U.K.).

442. Vaccine Damage Payments Act § 1(1A), n.1.

443. Pywell, *supra* note 6, at 249.

444. *Id.* at 251.

445. Conversion, *supra* note 150.

446. See Pywell, *supra* note 6, at 251.

447. Vaccine Damage Payments Act § 3(1)(c)(i)-(ii).

448. Vaccine Damage Payments Act § 1(1A)(4), n.2.

449. Pywell, *supra* note 6, at 251.

450. *Id.* at 254.

451. *Id.*

452. *Id.*; *Stephens v. Doncaster Health Authority* (1996) 7 MED.L.R. 357.

453. Conversion, *supra* note 150.

454. Pywell, *supra* note 6, at 255.

455. Conversion, *supra*, note 150.

456. Vaccine Damage Payments Act, 1979, c. 17, § 1 (U.K.).

2. Disability Thresholds and Sliding Scales

Members of Parliament have criticized the Vaccine Damage Payments Act's disability threshold.⁴⁵⁷ It has been noted that a child with a seventy-nine (or fifty-nine, after the June 2000 amendment) percent disability needs no less care than does a child who is eighty-one (or sixty-one, after the June 2000 amendment) percent disabled.⁴⁵⁸ These Parliamentary critics contend the absolute disability threshold should be replaced with a sliding scale that allows payment for multiple disability thresholds.⁴⁵⁹ The Act is inferior when compared to common law remedies.⁴⁶⁰ Common law remedies are available to compensate plaintiffs with minor disabilities,⁴⁶¹ but a vaccine injury victim who has minor disabilities may not be compensated.⁴⁶²

3. Increase the Number of Vaccines and Vaccine Injuries Covered

The Vaccine Damage Payments Act currently covers injuries caused by vaccination against polio, diphtheria, pertussis, tetanus, measles, rubella, tuberculosis, and smallpox.⁴⁶³ However, the British government also recommends that children be vaccinated against mumps, meningitis C, and Hib,⁴⁶⁴ but injuries caused by these vaccines are not covered under the Vaccine Damage Payments Act.⁴⁶⁵ Further, no vaccine injury victim has succeeded with a claim for injuries caused by measles, mumps, and rubella vaccines since 1989.⁴⁶⁶

4. Causation

Causation has been the most difficult hurdle for vaccine-injured victims to overcome in order to receive compensation under the Vaccine Damage Payments Act.⁴⁶⁷ It appears the causation issue is getting worse as vaccine injury victims are no longer given the benefit of the doubt.⁴⁶⁸ The Vaccine Damage Payments Unit informs victims who become ill within days of being vaccinated that their

457. Pywell, *supra* note 6, at 254.

458. *Id.*

459. *Id.*

460. *Id.*

461. *Id.*

462. *See Id.*

463. Vaccine Damage Payments Act, 1979, c. 17, § 1(2)(a)-(h) (U.K.).

464. Pywell, *supra* note 6, at 247.

465. Vaccine Damage Payments Act § 1(2)(a)-(h).

466. Pywell, *supra* note 6, at 256.

467. *See id.*

468. *Id.* at 254.

injury would probably have occurred anyway, and that the temporal proximity between the two events is merely coincidental.⁴⁶⁹

The small number of recent successful claimants is additional evidence of the causation problem: between 1979 and 1994, there were 880 successful petitions for payment under the Vaccine Damage Payments Act,⁴⁷⁰ compared to only twenty-four successful petitions for payment between 1995 and 2004.⁴⁷¹

VIII. CONCLUSION

Politicians agree that vaccine injury victims deserve preferential treatment.⁴⁷² The National Childhood Vaccine Injury Act and the Vaccine Damage Payments Act were established to provide preferential treatment to vaccine injury victims in their respective countries.⁴⁷³ However, both Acts fall short of adequately compensating vaccine injury victims.⁴⁷⁴ While vaccine injury victims in the United States and Great Britain are better off with the respective Acts than without,⁴⁷⁵ neither Act sufficiently compensates vaccine injury victims. A comprehensive, less adversarial compensation system is therefore required.⁴⁷⁶

469. *Id.* at 256.

470. *See Clinical Negligence Claims, supra* note 395, at 2.

471. *See id.*

472. Pywell, *supra* note 6, at 256.

473. *See generally* Vaccine Damage Payments Act, 1979, c. 17 (U.K.); *see generally* 473. National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-2 to -33 (2000).

474. *See* Pywell, *supra* note 6, at 256; *see* *Clements v. Sec'y of Dep't of Health & Human Servs.*, No. 95-484V, 1998 WL 481881 (Fed. Cl. July 30, 1998).

475. *See* Garza, *supra* note 400, at 388.

476. Pywell, *supra* note 6, at 256; *see* Steel *supra* note 12, at 173.