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DTP VACCINE RELATED INJURY: AN EXAMINATION OF PROPOSED VACCINE INJURY COMPENSATION LEGISLATION

I. INTRODUCTION

Each year an estimated 15,000,000 doses of diphtheria-tetanus-pertussis vaccine ("DTP" or "DPT") are administered to the children of this nation to immunize them from potentially fatal diseases.¹ Approximately one in 310,000, or sixty-one of the children immunized, die or suffer severe neurologic complications² including prolonged convulsions, encephalitis, or encephalopathy.³ The pertussis component of the vaccine causes these disorders; the pertussis disease, more commonly known as whooping cough, can be fatal. Prior to the availability of a vaccine, deaths in the United States resulting from pertussis were seventy per million in the 1920's.⁴ Vaccine use reduced this figure to seven per million by the mid 1950's.⁵ Two scientists at the Centers for Disease Control estimate that use of the DTP vaccine prevents approximately 322,000 cases of pertussis per year.⁶ An estimated four hundred fifty-seven persons per year would die from the disease without an immunization program, yet, use of the vaccine reduces this figure to forty-four.⁷ There is, then, a strong incentive to vaccinate. However, along with a mass immunization program comes the question of who should bear the burden of paying for vaccine related injuries.

1. This figure is based on multiplying the approximate number of children born each year (3,000,000) by the number of doses each child must receive (five). *National Childhood Vaccine-Injury Compensation Act of 1985: Hearings on S. 827 Before the Senate Comm. on Labor and Human Resources*, 99th Cong., 1st Sess. 327 (1985) [hereinafter *Hearings*] (statement of Martin H. Smith, M.D., F.A.A.P.).

2. Miller, Ross, Alderslade, Bellman & Rawson, *Pertussis Immunization and Serious Neurological Illness in Children*, 282 *BRIT. MED. J.* 1595-99 (1981). This figure is a source of controversy, however, because the study observed children who received a different vaccine than the one administered in the United States. An earlier UCLA study, published in 1980, suggested a much higher proportion of deaths or permanent injury; 1: 1750. H. COULTER & B. FISHER, *DPT: A SHOT IN THE DARK* 371-75 (1985).

3. Encephalitis is inflammation of the brain, encephalopathy is any disease of the brain. *STEDMAN'S MEDICAL DICTIONARY* 408, 410 (22d ed. 1972).

4. H. COULTER & B. FISHER, *supra* note 2.

5. *Id.*

6. Hinmon & Koplan, *Pertussis and Pertussis Vaccine: Reanalysis of Benefits, Risks and Costs*, 251 *J. A.M.A.* 3112, Table 5 (1984).

7. *Id.*

A compensation program for those who are injured as a result of vaccination does not currently exist in the United States on the federal level.⁸ Because childhood immunization is one of the most successful preventive public health programs,⁹ many people believe that society should provide support for those who have undertaken a risk and suffered adverse consequences for the benefit of all.¹⁰ A concerned group of parents, whose children were injured as a result of DTP vaccination, formed an organization called Dissatisfied Parents Together, to lobby for legislation authorizing a federal compensation program. Senator Paula Hawkins, in April 1985, proposed such legislation, which was endorsed by the American Academy of Pediatrics.¹¹ This measure directed the establishment of a compensation plan and also sought to guarantee parents the right to judicial relief. Because the Hawkins' bill availed parents of an opportunity to seek judicial relief, vaccine manufacturers opposed this legislation.¹²

Manufacturers have been held strictly liable by courts in vaccine injury cases.¹³ The Restatement (Second) of Torts § 402A¹⁴ imposes strict liability on the seller who markets a product unreasonably dangerous to the consumer. Comment k of that section, however, makes an exception to the rule providing:

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 The same is true of many other drugs, *vaccines*, and the like The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held strictly liable for the unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product,

8. The state of California has a compensation plan for those who are injured as a result of mandatory vaccination. CAL. HEALTH & SAFETY CODE § 429.35 (West 1979).

9. *Hearings, supra* note 1, at 118 (statement of Dr. James O. Mason, Acting Assistant Secretary for Health, and Director, Centers for Disease Control, Department of Health and Human Services).

10. *Id.* at 223, 248, 326 (statements of Robert L. Willmore, Deputy Assistant Attorney General, Civil Division; Robert B. Johnson, President, Lederle Laboratories Division, American Cyanamid Company; Martin H. Smith, M.D., F.A.A.P.).

11. S. 827, 99th Cong., 1st Sess. (1985). The bill died in committee.

12. *Hearings, supra* note 1, at 250, 273, 312-13 (statements of Robert B. Johnson, President, Lederle Laboratories Division, American Cyanamid Company; David J. Williams, Vice President, Connaught Laboratories, Inc.; Charles F. Hagan, Vice President, American Home Products Corporation).

13. *See infra* p. 235 & note 16.

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

attended with a known but apparently reasonable risk.¹⁵

This exception would appear to protect DTP manufacturers from liability; however, courts have not so held. A number of courts in the 1960's held the manufacturer responsible for vaccine related injury.¹⁶ Because many recent decisions are either unreported or sealed, a current statement as to why comment k does not protect manufacturers is unavailable.¹⁷

From 1978-1984 one hundred forty suits were filed against the three current manufacturers of DTP vaccine; more than half in 1984, with an average specified claim of \$46.5 million.¹⁸ Jury awards have been significant in DTP injury cases,¹⁹ and manufacturers are making increasingly large settlements with victims.²⁰ The current trend is for manufacturers to settle cases then request that the court records be sealed and the amount of the settlement kept secret.²¹

It is precisely because of these significant jury awards that some manufacturers have withdrawn from the market.²² The difficulty in obtaining liability insurance has prompted the withdrawals; the underwriters are no more willing to shoulder the expense for these claims than are the manufacturers themselves. As a result, the drug companies, like Dissatisfied Parents Together, have lobbied for a federal compensation program. In March of 1985,

15. *Id.* comment k (emphasis added).

16. *See, e.g.,* Tinnerholm v. Parke-Davis & Co., 285 F. Supp. 432 (S.D.N.Y. 1968), *modified*, 411 F.2d 48 (2d Cir. 1969); Stromsodt v. Parke-Davis & Co., 257 F. Supp. 991 (D.N.D. 1966), *aff'd*, 411 F.2d 1390 (8th Cir. 1969); Gottsdanker v. Cutter Laboratories, 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (1960).

17. The U.S. Court of Appeals recently certified a question construing the principles of § 402A comment k to the Idaho Supreme Court. *Toner v. Lederle Laboratories*, 779 F.2d 1429 (9th Cir. 1986).

18. *Hearings, supra* note 1, at 156 (statement of Dr. James O. Mason, Acting Assistant Secretary of Health, and Director, Centers for Disease Control, Department of Health and Human Services).

19. In the unreported case of *Toner v. Lederle Laboratories*, No. 80-1245 (D. Idaho Apr. 23, 1984), the parents of a child who developed a rare brain disorder after receiving a DTP shot alleged that the whole cell vaccine manufactured by Lederle was not as safe as the split cell vaccine manufactured by Eli Lilly. The jury awarded \$1.2 million to the plaintiff.

20. *See, e.g.,* Chickasuye v. Connaught & Lederle, No. 75439 (1st Cir. Haw. Sept. 24, 1985) (settlement with parents of child left with severe retardation and seizures following DTP shot of \$4.3 million guaranteed with \$1.65 million in cash and annuities); *Holcomb v. United States & Richardson-Merrell*, No. 79-2376 (S.D. W. Va. May 5, 1982) (settlement of \$600,000 with parents of infant who suffered encephalopathy after DTP shot).

21. *Dissatisfied Parents Together News* 3 (Winter 1986) (available from the editorial offices of J. CONTEMP. HEALTH L. & POL'Y, Catholic University of America, Columbus School of Law, Washington, D.C. 20064).

22. *Hearings, supra* note 1, at 271, 311 (statements of Robert B. Johnson, President, Lederle Laboratories Division, American Cyanamid Company; David J. Williams, Vice President, Connaught Laboratories, Inc.; Charles F. Hagan, Vice President, American Home Products Corporation).

Congressman Madigan proposed legislation which, unlike the Hawkins' initiative, would have empowered an independent panel to render compensation decisions.²³ The parents' group opposed this bill because it limited damage awards and deprived them of a right to sue in court.²⁴

The public interest in maintaining childhood vaccination programs led to yet another proposal.²⁵ Two drug companies, Wyeth and Connaught, withdrew from the production and supply market. Subsequently, in 1984, the third commercial source of DTP vaccine, Lederle, encountered production difficulties. The result was a vaccine shortage which threatened the public safety.²⁶ Compounding the problem was an announcement by Lederle that it was encountering difficulties in obtaining a renewal of its liability insurance.²⁷ These events led Health and Human Services Secretary Margaret Heckler to establish a Working Group on vaccine supply and liability.²⁸ The efforts of this group resulted in a proposal by the Administration which would protect the supply of childhood vaccines.²⁹ To that end, the bill proposed a cap on the damage recoveries for injuries due to certain vaccines. The bill, introduced by Congressman Tauke in March 1986, was not a compensation program; it would have simply regulated damage awards resulting from suits in federal and state courts.³⁰

All three proposals sought adequate compensation for vaccine related injuries and protection of the vaccine supply. The proposals of the parents and the manufacturers are similar to the indemnity plan established for the swine flu vaccine in 1976.³¹ This comment will examine the proposals in light of the swine flu model and will compare them for similarities and differences.

23. H.R. 1780, 99th Cong., 1st Sess. (1985). This bill died in committee.

24. *Hearings, supra* note 1, at 119 (statement of Jeffrey H. Schwartz, President, Dissatisfied Parents Together).

25. H.R. 4777, 99th Cong., 2d Sess. (1986). This bill died in committee.

26. *Hearings, supra* note 1, at 119 (statement of Dr. James O. Mason, Acting Assistant Secretary for Health, and Director, Centers for Disease Control, Department of Health and Human Services).

27. *Id.*

28. *Id.*

29. H.R. 4777, *supra* note 25.

30. A limitation on damage awards resulting from a nuclear accident involving nuclear energy was attempted in the Price Anderson Act, 42 U.S.C. § 2210(e) (1982). That portion limiting damages was held constitutional by the Supreme Court in *Duke Power Co. v. Carolina Env'tl. Study Group, Inc.*, 438 U.S. 59 (1978) (The court relied on a minimal scrutiny rational basis test to uphold the limitation on damages.). This would set a precedent for any challenge to congressional legislation limiting damage awards in vaccine injury cases.

31. National Swine Flu Immunization Program of 1976, Pub. L. No. 94-380, 90 Stat. 1115 (codified prior to amendment at 42 U.S.C. § 247b (1982)) [hereinafter Swine Flu Program].

Finally, it will estimate what problems might arise with each legislative scheme, if enacted, and suggest methods for resolving the problems.

II. THE SWINE FLU LEGISLATION

A. History

In February 1976, a number of soldiers at Fort Dix were infected by a New Jersey influenza ("swine flu").³² There was serious concern that this was the same type of influenza that caused the winter of 1918 pandemic. For this reason, then-President Gerald Ford encouraged development of a vaccine program to be implemented in the fall of that year, with the government appropriating money to test a vaccine.³³ The vaccine manufacturers developed a vaccine but opposed a mass immunization program because of the possibility of their exposure to liability for injuries that might occur.³⁴ The insurance companies agreed and either cancelled or greatly limited the liability coverage of the manufacturers.³⁵ The proposed National Swine Flu Immunization Program bill was accordingly stalled because Congress did not understand the hesitancy on the part of the insurance companies.³⁶ Due in large part to the efforts of President Ford, Congress finally passed the bill on August 10, 1976, implementing the program and providing compensation for vaccine related injuries.³⁷

Congress agreed that the United States would indemnify the manufacturers for strict liability, but not for negligence.³⁸ This is precisely what the manufacturers wanted because their concern was for claims arising under the Restatement (Second) of Torts § 402A.³⁹ The Swine Flu Act provided that the Federal Tort Claims Act ("FTCA")⁴⁰ would be the vehicle for asserting claims against the United States government arising out of the swine flu program.⁴¹ Under the FTCA, the United States is liable for injury "if a private person[,] would be liable to the claimant in accordance with the law

32. Shapo, *Swine Flu and Legal Policy*, 63 A.B.A. J. 51 (1977).

33. *Id.*

34. *Id.* at 52.

35. *Id.*

36. *Id.*

37. Swine Flu Program, *supra* note 31, 90 Stat. 1115 (codified prior to amendment at 42 U.S.C. § 247b).

38. *Id.*

39. *Proposed National Swine Flu Vaccination Program: Hearings on President's Proposal to Initiate National Immunization Program to Insure that Every Citizen may be Protected Against the Swine Flu Influenza, Before the Subcomm. on Health and the Environment of the House Comm. on Interstate and Foreign Commerce*, 94th Cong., 2d Sess. 9-14 (1976).

40. Federal Tort Claims Act, 28 U.S.C. §§ 2671-2860 (1982).

41. Swine Flu Program, *supra* note 31, at § 2(k)(2)(A), 90 Stat. at 1115 (codified prior to amendment at 42 U.S.C. § 247b).

of the place where the act or omission occurred.”⁴²

The Swine Flu Act provided further that the United States could be held strictly liable for the acts or omissions of a program participant.⁴³ A “program participant” was defined as any manufacturer or distributor of the vaccine, the public or private agency that provided inoculation, and medical and health personnel who assisted in providing inoculation without charge, in compliance with informed consent requirements.⁴⁴ This definition was important to the legislative liability scheme because the United States was not to be considered a program participant, therefore, actions based on its acts or omissions were governed by the normal procedures of the FTCA.⁴⁵

The Attorney General was required to defend any claim brought against the federal government, its employees, or a program participant.⁴⁶ Once the Attorney General certified the claim, the action would be against the United States.⁴⁷ If an action were brought in a district court of the United States, the United States would be substituted as a party defendant once the claim was certified;⁴⁸ if an action were brought in a state court, the Act provided for removal to a federal district court.⁴⁹ Finally, the Act stated that claims under it would be the exclusive remedy for all injuries arising from the swine flu program.⁵⁰ These provisions allowed the federal government to handle all claims which would arise due to injuries related to immunizations under the program.

B. Implementation

The swine flu immunization program continued to experience difficulties

42. 28 U.S.C. § 1346(b) (1982).

43. Swine Flu Program, *supra* note 31, 90 Stat. 1113 (codified prior to amendment at 42 U.S.C. § 247b). “The United States shall be liable with respect to claims submitted . . . for personal injury or death arising out of the administration of the swine flu vaccine under the swine flu program and based upon the act or omission of a program participant”

44. Swine Flu Program, *supra* note 31, at § 2(k)(4), 90 Stat. at 1116 (codified prior to amendment at 42 U.S.C. § 247b).

45. Baynes, *Liability for Vaccine Related Injuries: Public Health Considerations and Some Reflections on the Swine Flu Experience*, 21 ST. LOUIS U.L.J. 44, 67 (1977).

46. Swine Flu Program, *supra* note 31, at § 2(k)(4), 90 Stat. at 1116 (codified prior to amendment at 42 U.S.C. § 247b).

47. Swine Flu Program, § 2(k)(5)(A), 90 Stat. at 1116 (codified prior to amendment at 42 U.S.C. § 247b).

48. *Id.*

49. *Id.* at § 2(k)(5)(B), 90 Stat. at 1116 (codified prior to amendment at 42 U.S.C. § 247b).

50. *Id.* at § 2(k)(3), 90 Stat. at 1116 (codified prior to amendment at 42 U.S.C. § 247b). This provision was held constitutional in *Jones v. Wyeth Laboratories*, 457 F. Supp. 35 (W.D. Ark. 1978). The court held that the immunization program could not have proceeded without the swine flu legislation and the plaintiff’s right to equal protection was not violated because the Act was rationally related to a legitimate governmental goal.

after implementation. The public was aware of the vaccine, but failed to submit to the inoculation.⁵¹ Three vaccinees died immediately after the program began, heightening concern over its safety.⁵² The discovery that the neurologic disorder known as Guillian-Barre Syndrome ("GBS") was a possible side effect led to the termination of the program in December 1976.⁵³ By the summer of 1981, some 4,000 administrative claims had been filed.⁵⁴

Because of the massive amount of litigation which arose, the Judicial Panel on Multi-District Litigation ordered all of the cases consolidated for pre-trial discovery.⁵⁵ At the end of the discovery stage, the United States stipulated that it would concede liability in cases where GBS occurred a short time after receipt of the shot.⁵⁶ Thus, only causation and damages remained open issues at trial.⁵⁷ Once the cases were remanded after discovery, most district courts elected either to assign all the cases to one judge or to allow the cases to stay with the judge who was assigned when the case was filed.⁵⁸ A liaison office was opened in Washington, D.C. to handle communications between the courts, the plaintiffs, and the government attorneys.⁵⁹

C. Litigation

The 4,000 claims filed initially resulted in more than 1,500 cases in federal district courts.⁶⁰ By 1985 the amount of claims filed against the federal government totalled \$3,000,000,000.⁶¹ Examples of some recent cases will serve to illustrate how the program works.

With regard to diagnosis and causation the courts generally have not held the government liable for disorders other than GBS.⁶² When liability was

51. Baynes, *supra* note 45, at 69.

52. *Id.*

53. Rheingold & Shoemaker, *The Swine Flu Litigation*, 8 LITIGATION 28 (1981).

54. Huber, *Safety and Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 287 (1985).

55. Pursuant to the multi-district litigation rules in 28 U.S.C. § 1407 (1982). Rheingold & Shoemaker, *supra* note 53, at 29.

56. Stipulation and Final Pre-Trial Order, *In re Swine Flu Immunization Prods. Liab. Litig.*, 446 F. Supp. 244 (D.D.C. 1979).

57. Rheingold & Shoemaker, *supra* note 53, at 29.

58. *Id.*

59. *Id.*

60. *Id.*

61. *Id.* For further information on Swine Flu litigation contact Torts Branch, Civil Division, Department of Justice, Washington, D.C.

62. See, e.g., *Zeck v. United States*, 720 F.2d 534 (8th Cir. 1983) (A brain stem stroke following swine flu inoculation was found not a result of the shot when the victim smoked heavily, had a history of vascular disease, and was under great stress.); *Gaul v. United States*,

not stipulated, the plaintiff had to prove it.⁶³ In non-GBS cases the issue arose in connection with the informed consent requirement of the statute.⁶⁴ In one case, because the danger of serum sickness from the swine flu vaccine was known to the medical community prior to the 1976 immunization program, the government was held liable for failure to warn of this specific risk when the plaintiff contracted serum sickness subsequent to receipt of the vaccine.⁶⁵

The issue of damages was handled in the same manner as in any trial. Plaintiffs have been allowed to recover for past and future medical expenses, lost wages, future and past earnings, present and future pain, and suffering to the extent allowed under the applicable state law.⁶⁶

D. Swine Flu Legislation: A Good Model?

A report issued in March 1977 critiquing the swine flu model stated that the federal tort procedure of the Swine Flu Act was "inappropriate for a long-term national policy."⁶⁷ First, by requiring proof of fault for all claims under the law of the state in which an alleged act or omission occurred, the Act subjects liability to potentially different interpretations and standards in all the states.⁶⁸ The report found this inconsistent with the concept of a national policy on immunization. Second, the report indicated that the tort procedure actually served as a disincentive to immunization because of the expense of litigation and the burden of proof required.⁶⁹

The government assumed the role of principal defendant under the swine flu model. Whether this is essential to any compensation program is uncertain. Where, as with the swine flu, there is a possible threat of pandemic, the government may appropriately consider itself required to implement a vaccination program and accept the consequences of that decision by becoming

582 F. Supp. 1122 (D. Del. 1984) (Plaintiff failed to prove causation between vaccination and contraction of swine flu.)

63. See, e.g., *Zeck*, 720 F.2d 534; *Gaul*, 582 F. Supp. 1122.

64. Swine Flu Program, *supra* note 31, at § 2(j)(1)(F), 90 Stat. at 1113.

65. *Petty v. United States*, 740 F.2d 1428 (8th Cir. 1984). *Contra, In re Swine Flu Immunization Prods. Liab. Litig.*, 533 F. Supp. 703 (D. Utah 1982).

66. See, e.g., *McDonald v. United States*, 555 F. Supp. 935 (M.D. Pa. 1983) (Plaintiff's claim must be supported by a reasonable basis for calculation.); *Sulesky v. United States*, 545 F. Supp. 426 (S.D. W. Va. 1982) (Plaintiff permitted to recover damages to the extent that she was able to prove with reasonable degree of medical certainty that they were proximately caused by her condition.)

67. OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH, DEPARTMENT OF HEALTH, EDUCATION AND WELFARE, REPORTS AND RECOMMENDATIONS OF THE NATIONAL IMMUNIZATION WORK GROUP ON LIABILITY 35 (Mar. 11, 1977).

68. *Id.* at 37.

69. *Id.*

the principal defendant in cases where individuals are injured as a result of the program.⁷⁰ Given the increasing number of lawsuits pending against DTP manufacturers and the reluctance of the insurance industry to underwrite liability, the federal government may have to face the issue of a national compensation program in the near future.

Although a form of absolute liability has been developing in drug product liability suits, the swine flu model did not embrace that theory.⁷¹ The theory received attention particularly in the area of vaccines.⁷² The underlying policy of the theory is that compensation is justified for vaccine related injuries simply because society has received a great benefit.⁷³ Thus, the injury itself may establish proof of a defect.⁷⁴ The swine flu model, unwisely, did not address the issue of whether recovery should be contingent on the fact of injury or should be based on proof of defect.⁷⁵ In short, victims of swine flu vaccine injuries must litigate "within the context of a body of laws floundering in the grey area between strict liability and absolute liability."⁷⁶ These criticisms of the swine flu model are of considerable importance in developing a satisfactory compensation program for those persons injured by DTP vaccinations.

III. PROPOSED DTP VACCINE INJURY COMPENSATION LEGISLATION

A. History

Forty-four states currently require pertussis vaccination prior to school entry.⁷⁷ An exception is allowed in almost all of these jurisdictions if a physician determines that receipt of the vaccine would be detrimental to a child's health.⁷⁸ Some states permit an unvaccinated child to attend school based on an objection to the vaccine by a parent; in some cases only a religious objection is recognized,⁷⁹ while in others, a personal belief opposing

70. Shapo, *supra* note 32.

71. 2 DIXON, DRUG PRODUCT LIABILITY § 9.08(1) (1974).

72. *Id.*

73. Baynes, *supra* note 45, at 70.

74. *Id.*

75. *Id.* at 74.

76. *Id.*

77. Hinmon, *The Pertussis Vaccine Controversy*, 99 PUB. HEALTH REP. 255 (1984).

78. See, e.g., DEL. CODE ANN. tit. 14, § 131(a)(5) (1981) ("Provisions for exemption from any or all of the immunization programs . . . upon a written statement from a physician . . . stating that the enrollee should not receive the prescribed immunization . . . because of the reasonable certainty of a reaction detrimental to that person . . .") See also CAL. HEALTH & SAFETY CODE § 3385 (West 1979).

79. See, e.g., MD. HEALTH-GEN. CODE ANN. § 18-403(a)(2) (1982) ("the Department may not require the immunization of an individual if . . . the individual's parent or guardian

immunization is also permitted.⁸⁰ In January 1985, Maryland passed a model bill on pertussis.⁸¹ Among other provisions, the bill places a duty on health care providers to warn of problems which may result from receipt of the vaccine.⁸²

To date, California is the only state which has legislation providing compensation to victims with vaccine related injuries.⁸³ It is not clear, however, that this is the best method for handling such injuries. Although immunization is made mandatory through state laws, federal legislation has been proposed to handle the problem of compensating vaccine related injuries.

In order to ascertain the policy disincentives to the enactment of individual state compensation plans, it is necessary to examine the policy and purpose underlying the three federal proposals. Protection of the childhood vaccine supply, establishment of predictability for the insurance companies, and compensation for victims with vaccine related injuries motivate the federal plans.⁸⁴ Policy concerns include public health protection, an adequate supply of vaccine and attraction of additional suppliers coupled with the realization that continuing punitive damage awards may drive all suppliers out of the market.⁸⁵

Punitive damages are designed to deter and to punish egregious conduct and unacceptable behavior;⁸⁶ it has been suggested that this deterrent is unnecessary in vaccination cases.⁸⁷ Vaccines are regulated by the Food and Drug Administration ("FDA") and provide a significant reduction in public risk.⁸⁸ Additionally, the federal government encourages states to promote immunization programs. To that end, the government provides grants to

objects to immunization because it conflicts with the parent or guardian's bona fide religious beliefs and practices."'). See also CAL. HEALTH & SAFETY CODE § 3385 (West 1979); DEL. CODE ANN. tit. 14, § 131(a)(5) (1981).

80. See, e.g., COLO. REV. STAT. § 25-4-903(2)(b) (1973) ("a child shall be exempt from receiving the required immunizations: Upon submitting a statement . . . that the parent . . . has a personal belief that is opposed to immunizations.'). See also CAL. HEALTH & SAFETY CODE § 3385 (1979); IND. CODE § 20-8.1-7-2(a) (1981); OKLA. STAT. tit. 70, § 1210.192 (1972).

81. MD. HEALTH-GEN CODE ANN. §§ 18-328 - 18-322 (1982).

82. *Id.*

83. CAL. HEALTH & SAFETY CODE § 429-35 (West 1979). This statute provides compensation for vaccine related injury and grants immunity from liability in the administration of the vaccine. The grant of immunity does not, however, protect vaccine manufacturers. In *Flood v. Wyeth Labs.*, 183 Cal. App. 3d 1272, 228 Cal. Rptr. 700 (1986), the court held that manufacture of a vaccine could not be equated with administration of a vaccine.

84. S. 827, *supra* note 11; H.R. 1780, *supra* note 23; H.R. 4777, *supra* note 25.

85. *Hearings*, *supra* note 1, at 223 (statement of Robert L. Willmore, Deputy Assistant Attorney General, Civil Division).

86. *Id.* See also BALLANTINE'S LAW DICTIONARY 1027 (3d ed. 1969).

87. *Id.*

88. Huber, *supra* note 54, at 285, 288.

states "for preventive health service programs to immunize children against immunizable diseases." A report to Congress by the Department of Health, Education & Welfare ("HEW") noted that:

[W]hile each vaccinee benefits from immunization, there is also a substantial benefit to the public at large Containment of disease and consequent reduction of morbidity and the complications of disease are the control objectives of immunization programs. Thus, the extent of public benefit depends on the breadth of public participation.⁸⁹

Injury sustained by submission to vaccination arguably occurs in the public interest. There are several justifications for a compensation system. First, the injured individual has benefitted society; the derived benefits should be sufficient to cover the costs of injury.⁹⁰ Second, the traditional tort method for compensation may not cover the full cost of the program because injury has occurred without fault.⁹¹ Finally, the government has intervened directly into individual lives by promoting or requiring immunization with resulting changes that otherwise would not have occurred, especially in mandatory programs.⁹²

Still the question arises — why not let the states compensate victims? Several compelling answers have been suggested. One is that childhood immunization is in the national interest and national immunization programs have been the most successful programs.⁹³ Further, Americans are mobile and vaccinations are needed in all states.⁹⁴ Finally, uniformity of compensation would be difficult to achieve in fifty states.⁹⁵

B. Eligibility

All three proposals cover, at a minimum, the currently mandated vaccines, DTP, poliomyelitis ("OPV") and measles-mumps-rubella ("MMR"). The administration bill and the parents' bill⁹⁶ limit compensation to these vaccines. The manufacturers' proposal would apply compensation and tort limits to any vaccine listed by Health & Human Services ("HHS"), as well as

89. DEPARTMENT OF HEALTH, EDUCATION AND WELFARE, LIABILITY ARISING OUT OF IMMUNIZATION PROGRAMS, FINAL REPORT TO CONGRESS 4 (May 1978).

90. *Id.* at 99.

91. *Id.*

92. *Id.* at 100.

93. AMERICAN ACADEMY OF PEDIATRICS, TASK FORCE ON COMPENSATION FOR VACCINE RELATED INJURIES REPORT (Apr. 1981).

94. *Id.*

95. *Id.*

96. H.R. 4777, *supra* note 25, at § 312(b)(1); S. 827, *supra* note 11.

any presently mandated vaccines.⁹⁷

Eligibility for compensation varies under the plans. The swine flu model did not in any way change the eligibility of an individual to go to court.⁹⁸ The Administration bill is the same in this respect.⁹⁹ The manufacturers' bill would have allowed anyone injured by a vaccine to file for a hearing.¹⁰⁰ The parents' proposal determined eligibility by use of a Vaccine Injury Table.¹⁰¹ An individual must have received a vaccine listed in the Table,¹⁰² sustained an injury listed in the Table,¹⁰³ and suffered a disability which lasted more than one year after receipt of the vaccine,¹⁰⁴ or died, his death due in whole or part to injuries sustained as a result of vaccination.¹⁰⁵ Further, the plaintiff may not have previously collected an award from a civil action, nor filed an action in tort.¹⁰⁶ There was some concern with the Vaccine Injury Table included in the Hawkins' proposal, since it amounted to legislation of causality and would not allow for easy revision as new scientific knowledge became available.¹⁰⁷ An alternative method would be similar to that adopted under the swine flu model whereby the government stipulated to liability in certain GBS cases.¹⁰⁸ DTP vaccination can cause several illnesses.¹⁰⁹ Defendants (i.e., manufacturers) could stipulate to liability in those instances in which a known illness occurs.¹¹⁰

C. *Dispute Resolution Process*

As in the swine flu model, the nature of the process remains adversarial under the Administration's bill; the plaintiff simply goes to court.¹¹¹ The parents' bill would have allowed parents to go to court,¹¹² but offered a non-adversarial alternative: compensation determined in an *ex parte* civil action

97. H.R. 1780, *supra* note 23.

98. Swine Flu Program, *supra* note 31, 90 Stat. at 1113 (codified prior to amendment at 42 U.S.C. § 247b).

99. H.R. 4777, *supra* note 25, at § 312(a).

100. H.R. 1780, *supra* note 23, at § 2103(a).

101. S. 827, *supra* note 11, at § 2103.

102. *Id.*

103. *Id.*

104. *Id.*

105. *Id.*

106. *Id.*

107. *Hearings, supra* note 1, at 161 (statement of Dr. James O. Mason, Acting Assistant Secretary for Health, and Director, Centers for Disease Control, Department of Health and Human Services).

108. *See supra* note 56.

109. *See supra* p. 233 & note 3.

110. *See supra* note 55 and accompanying text.

111. H.R. 4777, *supra* note 25, at § 2103(a).

112. *Id.*

in the United States District Court for the District of Columbia.¹¹³ The alternatives presented, however, serve only to increase the liability of manufacturers. Thus, given the present hesitancy of the insurance companies to underwrite liability, it is likely that they would refuse to do so if plans such as these were adopted.

The manufacturers' bill contemplated an adversarial process, but provided for one that is less formal than a tort suit. A hearing panel, composed of people selected by Secretary of HHS and remunerated by the United States to perform such specified duties, would review claims.¹¹⁴ Both the plaintiff and the defendant would be permitted to select one member to be on the panel from a list of persons the Secretary would provide.¹¹⁵ The two members would then meet and select a third.¹¹⁶ At this point, the defendant would have the option to either consent to be bound by the decision of the panel or to refuse.¹¹⁷ Only if the defendant refuses to be bound will the plaintiff be allowed to go to court on the basis of traditional tort theories. The manufacturers' bill further relieved the manufacturer of all liability without regard to negligence.¹¹⁸ An alternative method would be to make the manufacturer liable for its negligent acts, as in the swine flu model and thereby provide incentives for vaccine improvement and assurance that vaccines are manufactured in a proper manner.

D. Administrative Requirements

Administrative requirements vary under each proposal. The applicable state or federal statute of limitations for filing a claim would have remained the same under the administration bill.¹¹⁹ The parents' bill would require that a claim be filed within five years of the occurrence of the injury or two years after enactment of the bill, whichever is later.¹²⁰ This would not apply if the claimant did not know that the injury was compensable.¹²¹ That provision was designed to ensure that all those injured as a result of vaccination have the opportunity to be compensated. The parents' bill also allowed the district court 270 days to make a decision.¹²² Thus, the problem of pro-

113. S. 827, *supra* note 11, at § 2104.

114. H.R. 1780, *supra* note 23, at § 2103.

115. *Id.* at § 2101.

116. *Id.*

117. *Id.* at § 2104.

118. *Id.*

119. H.R. 4777, *supra* note 25, at § 2103(a).

120. S. 827, *supra* note 11, at § 2106.

121. *Id.*

122. *Id.* at § 2104.

tracted litigation which was present with the swine flu model would be avoided.

The manufacturers' bill required that the claim be filed within two years after the injury first manifested itself or two years after the date of enactment, whichever is later.¹²³ This limit applied regardless of when the causal link between injury and vaccination was discovered.¹²⁴ Under this scheme no deadline for a decision is provided; thus, the possibility of protracted litigation exists.

E. Limitation On Awards

Both the parents' and the manufacturers' proposals established compensable damages; the latter placed a limit on them. The Administration's bill simply placed a limit on the amount of damages which a court may award. The parents' bill made payment of damages mandatory if the claimant is found eligible for compensation.¹²⁵ Compensable damages would include health, education, custodial care and service expenses, and rehabilitation necessary for the person "to achieve the maximum potential and enjoyment of life of such person."¹²⁶ In addition, compensation would be available for death,¹²⁷ as well as for pain and suffering of the injured person. Compensation amounts would be paid from a fund to which both the federal government and the manufacturers would contribute, the latter by way of a surcharge on vaccines.¹²⁸

Under the manufacturers' proposal, the hearing panel would compensate for health, education, custodial care and expenses, loss of earnings, and pain and suffering up to an aggregate amount of \$1,000,000. Also, awards for pain and suffering would not exceed \$100,000.¹²⁹ The bill provided for compensation to be paid by vaccine manufacturers.¹³⁰ A concern with those provisions is the ceiling placed on compensable damages. In cases where a child becomes severely handicapped, the medical expenses alone often leave families on the brink of financial disaster.¹³¹ It may be better to allow for payment of all reasonably incurred medical expenses without limit.

The Administration's bill places no limit on damages which the court may

123. H.R. 1780, *supra* note 23.

124. *Id.*

125. S. 827, *supra* note 11, at § 2104(f)(1).

126. *Id.* at § 2107.

127. *Id.*

128. *Id.*

129. *Id.*

130. H.R. 1780, *supra* note 23, at § 2111.

131. *Hearings, supra* note 1, at 326 (statement of Martin H. Smith, President, American Academy of Pediatrics).

award for past and future economic loss including expenses of health and custodial care, rehabilitation, loss of earnings, loss of homemaker expenses and burial expenses.¹³² No other damages may be awarded in excess of \$100,000.¹³³ These limits would be applied to all actions filed in state or federal courts and pre-empt any state law with inconsistent provisions.¹³⁴ This bill would not change the existing tort system: if found liable, the defendant in the suit would pay damages.

All three proposals would eliminate punitive damages. The only exception to this is under the parents' bill if a parent decides to go to court. In that case, punitive damages would be allowed to the extent permitted by state tort law.¹³⁵ The elimination of punitive damages is an idea which must be considered in the area of vaccine injury compensation because punitive damage awards are forcing manufacturers out of the market. This type of limitation would certainly establish predictability for the insurance underwriters. It could also be argued that manufacturers should not be punished for injuries which occur from vaccines which the federal government has approved for use. On the other hand, the elimination of punitive damage awards may remove any incentive which manufacturers have for the improvement of vaccines with potentially dangerous side effects, such as pertussis.

F. Model Legislation

Arguably, the best means of compensating injured vaccinees may be through federal government action.¹³⁶ This would eliminate the problem of trying to establish a uniform system of compensation in fifty states. The plan must be carefully drawn, however, so as to adequately compensate in a timely manner those who are injured. The best means of doing this would be to take the positive aspects of each proposal and combine them, while keeping in mind the pitfalls to be avoided from the swine flu model.

The current budget problems must be considered before the implementation of any compensation plan. Given the cuts that all departments face, it would be unwise to expect the federal government to assume liability as in the swine flu model.¹³⁷ Similarly, setting up a hearing panel would be too costly.¹³⁸

132. H.R. 4777, *supra* note 25, at § 312(b)(2).

133. *Id.*

134. *Id.*

135. S. 827, *supra* note 11, at § 2102.

136. *See supra* notes 9 & 10 and accompanying text.

137. Swine Flu Program, *supra* note 31, 90 Stat. 1115 (codified prior to amendment at 42 U.S.C. § 247b).

138. This was proposed in H.R. 1780, *supra* note 25.

First and foremost, national legislation is needed requiring health care providers to inform parents when the DTP vaccine is contraindicated and what side effects may occur if the vaccine is given. Many times, parents are either misinformed or not informed about those facts and their children suffer injuries as a result.¹³⁹

For suits brought, use of the existing court system is the wisest choice.¹⁴⁰ The problems which remain to be considered are time limits on decisions and limitations on awards. Whether or not a time limit for decisionmaking by the court is practical, it is necessary to avoid the possibility of protracted litigation.¹⁴¹ Compensable damages should include those for health, education, custodial care, rehabilitation, loss of earnings and death expenses.¹⁴² Damages should be allowed for pain and suffering although there is a debate as to whether or not a ceiling should be placed on them.¹⁴³

The remaining issue is whether punitive damage awards should be eliminated. If the argument that society should bear the cost of injuries which result when individuals are innoculated with federally approved vaccines for the public good is accepted, then the elimination of punitive damages is an acceptable premise.¹⁴⁴ However, a total elimination would prevent the punishment of manufacturers who are negligent in producing the vaccine.¹⁴⁵ Also, manufacturers would have no incentive to improve their products.¹⁴⁶

IV. CONCLUSION

Immunization programs are certainly vital to national public health policies. While each vaccinee benefits from immunization, there is a great benefit to society as a whole. It is indisputable, however, that some individuals are going to be injured as a result of vaccination. It may be argued that since the general public benefits, the cost of compensating those who are injured should be borne by society. The best means of accomplishing this may be through federal action, although the problems which arose with the swine flu legislation indicate that careful consideration must be given before any federal legislation is enacted.

139. *Hearings, supra* note 1, at 37-40 (statement of Jeffrey H. Schwartz, President, Dissatisfied Parents Together).

140. This is one of the methods contemplated in S. 827, *supra* note 11, and the only method available in H.R. 1780, *supra* note 23.

141. *See supra* pp. 246-47.

142. All three bills provide awards for these damages. *See* S. 827, *supra* note 11, at § 2105; H.R. 1780, *supra* note 23, at § 2107; H.R. 4777, *supra* note 25, at § 312(b)(2).

143. *See supra* note 142.

144. *See supra* notes 9-10 and accompanying text.

145. *See supra* p. 245-46.

146. *Id.*

National legislation would establish uniformity and eliminate the problems evident in coordinating legislation in the fifty states. The plan must provide timely, adequate compensation for those who are injured, while at the same time taking into account the current budget climate. To accomplish this, one must consider the positive aspects of each of the three proposals, while keeping in mind the difficulties with the swine flu model. The result should be a plan which will compensate victims adequately and will protect the national childhood vaccine supply.

V. EPILOGUE

On September 18, 1986, subsequent to submission of this comment for publication, Senator Waxman introduced H.R. 5546, The National Childhood Vaccine Injury Act of 1986.¹⁴⁷ The Act was passed by Congress on October 18, 1986, as a part of S. 1744, an Omnibus Health Package,¹⁴⁸ and signed into law by President Reagan on November 14, 1986. The measure will not go into effect, however, until a funding mechanism is enacted. It is anticipated that funding will be accomplished by enactment of an excise tax on each dose of vaccine given.¹⁴⁹

The program provides a national program for compensating victims of vaccine injury. It represents a combination of the three proposals heretofore discussed. For that reason, the arguments for and against those bills are equally applicable to the newly enacted legislation.

A. Eligibility

Persons suffering an injury after the program begins may not file suit in court until they have resorted to the no-fault compensation system established by the legislation.¹⁵⁰ Coverage is limited in a Vaccine Injury Table to the three currently mandated vaccinations; DTP, OPV and MMR.¹⁵¹ The Table further limits coverage to certain injuries, disabilities, illnesses and conditions caused by each vaccine.¹⁵²

The injuries listed in the Table are presumed to be vaccine-related. However, the presumption may be overcome if a vaccine manufacturer or HHS

147. H.R. 5546, 99th Cong., 2d Sess. (1986).

148. The House passed the measure by a voice vote on October 17, 1986. 132 CONG. REC. H11,614 (daily ed. Oct. 17, 1986). The Senate passed the measure on October 18, 1986 by voice vote. 132 CONG. REC. S17,348 (daily ed. Oct. 18, 1986).

149. National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, tit. 3, § 323(a), 100 Stat. 3755, 3784 (1986) [hereinafter Vaccine Injury Act].

150. *Id.* at § 2121, 100 Stat. at 3772.

151. *Id.* at § 2114(a), 100 Stat. at 3764-65.

152. *Id.*

submits evidence that a particular injury is not vaccine-related.¹⁵³ Also, upon the petition of any person, the Secretary of HHS may promulgate regulations to modify the Table.¹⁵⁴ This provision will permit claimants to seek to prove that an injury not listed in the Table is nevertheless vaccine-related.

B. Dispute Resolution Process

The no-fault system established is to be administered by the federal district courts.¹⁵⁵ Each court must designate a special master who is to make an initial determination as to whether or not a claimant is entitled to compensation.¹⁵⁶ The special master will use the Vaccine Injury Table to make this determination.

If a claimant is not awarded compensation he may elect to accept the judgment or to sue.¹⁵⁷ If he receives an award, he must irrevocably choose whether to accept the award or to sue.¹⁵⁸ If he chooses to sue, the suit will be governed by the applicable state law,¹⁵⁹ with three modifications. The modifications involve the liability of manufacturers.

First, a manufacturer cannot be held liable for unavoidable side effects if the vaccines are prepared and packaged pursuant to FDA directions.¹⁶⁰ The manufacturer will be held liable if the claimant can show wrongful conduct or a failure to exercise due care even though the manufacturer complied with FDA requirements.¹⁶¹ Second, vaccine manufacturers cannot be held liable for failure to provide direct warnings to the injured party.¹⁶² Finally, the cases are to be tried in three stages; the first to determine liability, the second to determine compensation and damages, and the last to determine punitive damages.¹⁶³ All of these restrictions on the liability of manufacturers will serve to provide predictability in the estimation of costs for compensating those who are injured as a result of vaccination.

C. Administrative Requirements

The legislation is to apply to all claims for damages in excess of \$1,000

153. *Id.*

154. *Id.* at § 2114(c), 100 Stat. at 3766.

155. *Id.* at § 2112(a), 100 Stat. at 3761.

156. *Id.*

157. *Id.* at § 2121, 100 Stat. at 3772.

158. *Id.*

159. *Id.*

160. *Id.*

161. *Id.*

162. *Id.*

163. *Id.* at § 2123, 100 Stat. at 3774.

arising after the effective date.¹⁶⁴ In addition, any person who filed a civil action prior to the effective date may, at any time within two years after the effective date or before judgment, whichever comes first, withdraw the action without prejudice and file a petition under the program.¹⁶⁵ Also, if the injured party brought suit prior to the enactment of the program and was denied relief he may file a petition under the program.¹⁶⁶

There is no limitation on the retroactivity of the program. This will permit claims by persons who were injured prior to the enactment date. There are, however, limitations on the amount of compensation for pre-enactment claims.¹⁶⁷

D. Limitations on Awards

Compensation under the program includes the following: actual unreimbursable medical expenses,¹⁶⁸ remedial care, rehabilitation, special education, vocational training, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment and certain related travel expenses.¹⁶⁹ Recovery may be obtained for lost wages; for children under the age of eighteen, compensation is to be determined on the basis of the average earnings of workers in the private non-farm sector.¹⁷⁰ Damages for pain and suffering are not to exceed \$250,000.¹⁷¹

Two types of compensation are prohibited under the program. The first is punitive damages.¹⁷² The second is compensation to a person other than the injured vaccinee for expenses other than health, education and welfare, with two exceptions.¹⁷³ An award may be made to the estate of a deceased and, as aforementioned, payments may be made for lost wages.¹⁷⁴ These measures will serve to keep down the costs of administering the program.*

Patricia Carmen Murray

164. *Id.* at § 2111(a), 100 Stat. at 3758-59.

165. *Id.*

166. *Id.*

167. *Id.* at § 2115(b), 100 Stat. at 3769.

168. *Id.* at § 2115(a), 100 Stat. at 3767.

169. *Id.*

170. *Id.* at § 2115(a), 100 Stat. at 3768.

171. *Id.*

172. *Id.* at § 2115(d), 100 Stat. at 3768.

173. *Id.*

174. *Id.* at § 2115(a), 100 Stat. at 3767.

* On Thursday March 5, 1987 the Reagan Administration told Congress that it favors a total overhaul of last year's childhood vaccine protection law. *Administration Attacks Vaccine Law*, Wash. Post, Mar. 6, 1987, at A6, col. 1.

