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THE NECESSARY COMPLEMENT TO MANDATORY IMMUNIZATIONS: A NATIONAL VACCINATION COMPENSATION PROGRAM

Children required by state law to attend school[1] must first be immunized against vaccine-preventable diseases.[2] The impetus for

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[1] E.g., Cal. Educ. Code § 48200 (West 1978) ("Each person between the ages of 6 and 16 years not exempted under the provisions of this chapter is subject to compulsory full-time education."); Fla. Stat. Ann. § 232.01(1)(a) (West Supp. 1986) ("All children who have attained the age of 6 years . . . but who have not attained the age of 16 years, except as hereinafter provided, are required to attend school regularly during the entire school term."); N.J. Stat. Ann. § 18A:38-25 (West 1968) ("Every parent, guardian or other person having custody and control of a child between the ages of six and 16 years shall cause such child regularly to attend the public schools of the district or a day school . . . ."); N.Y. Educ. Law § 3205(1)(a) (McKinney 1981) ("In each school district of the state, each minor from six to sixteen years of age shall attend upon full time instruction.").

[2] All 50 states have school immunization laws. See Hinman & Jordan, Progress Toward Achieving the 1990 Immunization Objectives, 98 Pub. Health Rep. 436, 438 (1983).

> The governing authority shall not unconditionally admit any person as a pupil of any private or public elementary or secondary school, child care center, day nursery, nursery school, or development center, unless prior to his or her first admission to that institution he or she has been fully immunized against diphtheria, pertussis (whooping cough), tetanus, poliomyelitis, measles, mumps, and rubella in the manner and with immunizing agents approved by the state department, except that all students who have reached the age of seven shall not be required to be immunized against pertussis or mumps.

Cal. Health & Safety Code § 3381(a) (West Supp. 1986).

> The school board of each district and the governing authority of each nonpublic school shall establish and enforce as policy that, prior to admittance to or attendance in a public or nonpublic school, grades kindergarten through 12, or a public preschool, each child present or have on file with the school a certification of immunization for the prevention of those communicable diseases for which immunization is required by the Department of Health and Rehabilitative Services . . . .

Fla. Stat. Ann. § 232.032(2) (West Supp. 1986).

> Any body having control of a school may, on account of the prevalence of any communicable disease, or to prevent the spread of communicable diseases, prohibit the attendance of any teacher or pupil of any school under their control and specify the time during which the teacher or scholar shall remain away from school.

N.J. Stat. Ann. § 26:4-6 (West Supp. 1985).

> No principal, teacher, owner or person in charge of a school shall permit any child to be admitted to such school, or to attend such school . . . without the certificate provided for in subdivision five . . . or some other acceptable evidence of the child's immunization against poliomyelitis, mumps, measles, diphtheria and rubella . . . .

N.Y. Pub. Health Law § 2164(7)(a) (McKinney 1985).

> According to the Centers for Disease Control, as of December 1983, nine states [did] not have laws requiring pertussis vaccination as a precondition for school entry: Arizona, Kentucky, Missouri, Montana, New York, Oregon, Pennsylvania,

these mandatory preschool immunization laws, enforced at the state level, comes from the federal government.[3] By awarding essential grant funding to states that comply with national objectives such as the "vigorous enforcement of school immunization laws,"[4] the federal government effectively compels the vaccination of American children.[5] While comprehensive immunization programs have been successful in decreasing childhood illness and mortality due to vaccine-preventable diseases,[6] the unavoidably unsafe nature of these vaccines is problematic; they may cause such serious side effects as local and systemic allergic responses, fever, convulsions, paralysis, encephalitis, and death.[7]

Because vaccines are incapable of being made completely safe,[8] under traditional tort law, a child suffering from an adverse reaction to a properly prepared and administered vaccine has no "legal in-

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> Rhode Island, and Washington. Twenty-two states . . . permitted parents to object to mandated vaccine on the grounds of "personal conviction" or "philosophical objection": Arizona, California, Colorado, Delaware, Idaho, Indiana, Louisiana, Maine, Michigan, Minnesota, Missouri, Montana, Nebraska, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, Utah, Vermont, Washington, and Wisconsin. In addition, a child may be able to be exempted from the vaccine requirement if the parent can obtain a written statement from a physician stating that the vaccine would be detrimental to the child's health. Most states also will exempt a child from the vaccine requirement if the parent objects on the grounds of religious conviction.

Dissatisfied Parents Together, Pertussis and Pertussis Vaccine—Information for Parents 2 (1985) (available from DPT, 128 Branch Rd., Vienna, Va. 22180).

[3] Immunization grants are awarded to states and local governments, 42 U.S.C. § 247-247b (1982 & Supp. II 1984), "to assist in establishing integrated and comprehensive immunization delivery systems capable of making immunizations for vaccine-preventable childhood diseases available to every child in the United States." Centers for Disease Control, Dep't of Health & Human Servs., Project Grants for Preventive Health Services—Childhood Immunization—Program Announcement 1 (Apr. 1983) [hereinafter Project Grants].

[4] 42 C.F.R. § 51b.204(4)(vi) (1985). The federal regulations regarding the award of "Grants for Childhood Immunization Programs" are codified at id. § 51b.201-206.

[5] While the statutory mandate is by the states, see supra note 2, the federal government initiates the compulsory preschool immunization laws by incorporating them into the federal funding program as requirements. See infra notes 43-45 and accompanying text.

[6] "Widespread use of [seven] vaccines in childhood has brought about dramatic reductions in the occurrence of" diphtheria, measles, mumps, pertussis, poliomyelitis, rubella, and tetanus. See Hinman & Jordan, supra note 2, at 437.

[7] See Adverse Events Following Immunization, 34 Morbidity & Mortality Weekly Rep. 43 passim (1985).

[8] Vaccines are considered to be unavoidably unsafe products. See Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1273 (5th Cir.) (living virus in polio vaccine makes it an "unavoidably unsafe product"), cert. denied, 419 U.S. 1096 (1974); Davis v. Wyeth Laboratories, Inc., 399 F.2d 121, 128 (9th Cir. 1968) (Sabin polio vaccine is an unavoidably unsafe product). These courts relied heavily on, and quoted at length, Restatement (Second) of Torts § 402A comment k (1965); see infra note 52 and accompanying text.

jury,"[9] and thus, has no recourse against the manufacturer. Nonetheless, in a few cases, courts permitted recovery under a strict liability theory when sufficient warning of the vaccine's risk was not given.[10] However, the general utility of such a recovery route is effaced by the existence of such mandatory preschool immunization laws.[11] For even if sufficient warning of the vaccine's inherent dangers is given, it is unlikely that the parental decision to have the child vaccinated is a decision of informed consent. Parents who consent to preschool immunization of their children are hardly making a decision of choice; rather, they are acting in response to state and local mandates. Once a legally sufficient warning of the dangers is given, the vaccine recipient bears the risk of any adverse effect. If the injured vaccinee seeks to recover against the government that mandated the immunization,[12] another roadblock is encountered: sovereign immunity.[13]

The pertussis (whooping cough) vaccine is a dramatic example of the benefits and risks involved in immunization.[14] Use of the vaccine prevents an estimated 322,000 cases of whooping cough per year[15] and saves approximately 413 lives,[16] reducing the annual mortality from 457 to 44.[17] At the same time, however, the incidents of brain

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9 As long as there has been no malpractice in the manufacture, distribution, or administration of a vaccine and the vaccine has been accompanied by adequate warning and directions, there is no compensable "legal injury." See infra notes 51-62 and accompanying text.

10 The failure of a drug manufacturer to give adequate warning of the risk involved in a vaccine may render the drug unreasonably dangerous as marketed and permit recovery under a strict liability theory. See Givens v. Lederle, 556 F.2d 1341, 1345-46 (5th Cir. 1977); Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1276 (5th Cir.), cert. denied, 419 U.S. 1096 (1974); Davis v. Wyeth Laboratories, Inc., 399 F.2d 121, 127-29 (9th Cir. 1968). For further discussion, see infra note 56 and accompanying text.

11 See supra note 2 and accompanying text.

12 The federal government mandates through the instrumentality of grants-in-aid. See infra notes 42-50 and accompanying text.

13 Sovereign immunity precludes one injured by a preschool vaccination from bringing suit against the government that mandated the immunization. See infra notes 81-89 and accompanying text.

14 Before recommending and instituting an immunization program, medical scientists and public health officials must estimate the benefit-risk ratio for every vaccine and conclude that the benefits of the immunization far outweigh the risks. For a discussion of the use of the ratio to justify standard childhood immunizations, see Mortimer, Problems With Immunization Against Infectious Diseases, 13 Pediatric Resident 684, 684-87 (1979). As early as 1905, the Supreme Court utilized the benefit-risk ratio to uphold vaccination programs. Jacobson v. Massachusetts, 197 U.S. 11, 24 (1905) (accepting the argument that medical experts generally have considered the risk of an injury from improper vaccinations "too small to be seriously weighed as against the benefits").

15 Hinman & Koplan, Pertussis and Pertussis Vaccine: Reanalysis of Benefits, Risks, and Costs, 251 J. A.M.A. 3109, 3112 (1984).

16 Id.

17 Id.

damage increase by twenty-five.[18] Thus, in accordance with the premise that the benefits of immunization outweigh the risks involved,[19] the pertussis vaccine slightly increases the risk of one particular form of injury, yet drastically reduces the risk of another.

The one child in hundreds of thousands who suffers inevitable injury or death from a mandatory vaccine has no effective legal remedy. This Note argues that because the impetus for childhood vaccination programs is provided by the federal government, there is a need for, and a responsibility to institute, a national compensation system for those injured by compulsory vaccinations.[20] The government provides the incentive for such preschool immunizations, and therefore, it should waive the barrier of sovereign immunity—as it has previously done for those injured by the swine flu vaccine[21]—and provide an effective remedy for persons injured by mandatory childhood vaccines.

Part I of this Note delineates the federal involvement in vaccine programs, specifically by means of the Vaccination Assistance Act of 1962.[22] This section explores how the federal government utilizes the state-run programs to carry out the national goal of mandatory preschool immunizations.[23] Part II illustrates why the traditional fault-

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18 Id. at 3111-12.

19 See supra note 14.

20 In establishing mandatory childhood immunization programs at the state and local levels, the integral role played by the federal government has been primarily the distributor of financial grants-in-aid. See infra notes 42-50 and accompanying text.

21 The National Swine Flu Immunization Program of 1976, Pub. L. No. 94-380, 90 Stat. 1113 (originally codified at 42 U.S.C. § 247b(j)(1) (1976)), provided a mechanism for bringing suit against the federal government for vaccine-related injuries. See infra notes 90-97 and accompanying text.

The Swine Flu Program no longer appears in title 42. See Health Services and Centers Amendments of 1978, Pub. L. No. 95-626, § 202, 92 Stat. 3551, 3554 (Section 317, "Project Grants for Preventative Health Services," has been completely revised and no longer provides for appropriations for the 1978 and 1979 Swine Flu Immunization Program.).

22 Pub. L. No. 87-868, § 2, 76 Stat. 1155 (codified as amended at 42 U.S.C. § 247b (1982 & Supp. II 1984)), provided for special project grants to states and local communities to pay part of the costs of intensive vaccination programs against polio, diphtheria, pertussis, and tetanus. The Act has been expanded and remains in effect. See infra notes 35-41 and accompanying text.

23 The national program goals for immunization espoused by the states are:

1. Reduce morbidity and mortality due to vaccine-preventable diseases of childhood.

2. Maintain interruption of indigenous measles transmission.

3. Maintain 90 percent immunization levels for school children under age 15 against measles, poliomyelitis, diphtheria, tetanus, and rubella. Maintain 95 percent immunization levels for school enterers and 90 percent immunization levels for children enrolled in licensed day-care centers against measles, poliomyelitis, diphtheria, tetanus, pertussis, rubella, and mumps.

based tort system is an ineffective mechanism for compensating faultless immunization injuries.[24] The solution advocated in Part III is the institution of a comprehensive federal vaccine injury compensation program.[25]

I. FEDERAL INVOLVEMENT IN VACCINATION PROGRAMS

Although the individual states legislate preschool immunization,[26] the federal government uses the states as agents to carry out the national policy of communicable disease control through the administration of grants-in-aid.[27] Through this system the federal government has, in effect, mandated the vaccination of American children. This justifies the support of a federally instituted system that provides a remedy for those injured by mandatory childhood vaccines.

A. *The Vaccination Assistance Act*

Over the years, Congress has enacted programs that bolster the states' efforts to eradicate communicable diseases.[28] The rationale behind such involvement is that communicable diseases, knowing no state boundaries,[29] are a national problem and the federal government has a continuing responsibility for their control.[30]

Federal programs designed to control the spread of disease through interstate commerce[31] were first introduced in the nineteenth

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4. Develop, test, and implement systems for use in the States to ensure that 90 percent or more of children complete basic immunizations by age 2.

Project Grants, supra note 3, at 1.

24 In the majority of cases where there has been neither malpractice nor a failure to warn in vaccine administration, an injured vaccinee has no legal recourse. See infra notes 51-56 and accompanying text.

25 The solution is modeled on the unenacted Senate bill introduced in Congress in 1985 which would amend the Public Health Services Act to establish a National Childhood Vaccine Injury Compensation Program. S. 827, 99th Cong., 1st Sess., 131 Cong. Rec. S3843 (daily ed. Apr. 2, 1985); see infra notes 100-11 and accompanying text.

26 See supra note 2.

27 See infra notes 42-45 and acompanying text.

28 See infra notes 31-41 and accompanying text.

29 McKray & McKray, Federal Health Law in the United States, in Legal Aspects of Health Policy: Issues and Trends 33, 35 (1980).

30 S. Rep. No. 825, 92d Cong., 2d Sess. 6, reprinted in 1972 U.S. Code Cong. & Admin. News 3430, 3434. Further incentive for federal involvement is that vaccines remain one of the great bargains of health care. Child immunization programs result in enormous savings in medical costs. It has been estimated that every dollar invested in vaccination results in a savings of $11 in reduced costs of treatment. Hinman & Koplan, supra note 15, at 3109.

31 Historically, the legal justification for federal involvement in health matters has been based upon a broad construction of the Constitution's interstate commerce clause and the power to tax and spend for the general welfare. See McKray & McKray, supra note 29, at 36

century[32] and greatly expanded over the years to include tuberculosis, venereal disease, and vaccination programs.[33] When the polio vaccine became available, Congress approved the Poliomyelitis Vaccination Assistance Act of 1955[34] that was "instrumental in dramatically reducing the incidence of polio in the United States."[35] However, once federal aid was curtailed, epidemics again broke out[36] and the critical need for continued federal financing to combat polio led to the passage of the Vaccination Assistance Act of 1962.[37] Congress recognized the decline in illnesses and deaths from polio, diphtheria, and pertussis since the vaccines against these diseases became available.[38] At the same time, Congress realized that the failure to vaccinate the total United States population constituted a public health threat.[39] In order to benefit the nation by raising immunization levels, federal assistance was required to effectively implement vaccination programs at the state level.

Since 1970, the Communicable Disease Control Amendment to

("The interstate commerce clause was the constitutional provision that provided the 'foot in the door' for federal involvement in health maintenance. Through use of the general welfare clause, the door swung wide open."); U.S. Const. art. I, § 8, cl. 1, 3.

For an historical survey of federal health law in the United States, see id. at 33-45; Litman, Government and Health: The Political Aspects of Health Care—A Sociopolitical Overview, in Health Politics and Policy 3-31 (1984).

32 In 1890, the threat of a cholera epidemic led to the enactment of a federal quarantine law which is still in effect. See McKray & McKray, supra note 29, at 34-35.

33 See 42 U.S.C. § 247b (1982 & Supp. II 1984).

U.S. Const. art. I, § 8, cl. 1 provides that Congress "shall have Power To lay and collect Taxes . . . and provide for the . . . general Welfare of the United States." Through the exercise of this power, Congress has the authority to give grants to individual states in order to carry out federally designed programs. In Steward Mach. Co. v. Davis, 301 U.S. 548 (1937), the Supreme Court relied on this general welfare clause to uphold the constitutionality of forcing employers to pay Social Security taxes on behalf of their employees. The significance of this decision was that the principle of "providing for the general welfare" applied as readily to health care matters as it did to Social Security. See McKray & McKray, supra note 29, at 35.

The specific state challenge to the constitutionality of federal grants-in-aid was defeated fourteen years earlier in Massachusetts v. Mellon, 262 U.S. 447 (1923), where the Court dismissed the challenge that the federal government violated the 10th amendment in requiring the states to abide by certain regulations in return for health care grants-in-aid.

34 Poliomyelitis Vaccination Assistance Act of 1955, ch. 863, §§ 1-10, 69 Stat. 704 (codified as amended at 42 U.S.C. § 247b (1982 & Supp. II 1984)).

35 H.R. Rep. No. 1114, 91st Cong., 2d Sess. 3, reprinted in 1970 U.S. Code Cong. & Admin. News 4135, 4136.

36 See id.

37 Pub. L. No. 87-868, § 2, 76 Stat. 1155 (codified as amended at 42 U.S.C. § 247b (1982 & Supp. II 1984)). For the legislative history, see S. Rep. No. 1907, 87th Cong., 2d Sess. 3, reprinted in 1962 U.S. Code Cong. & Admin. News 3970, 3970-71.

38 See S. Rep. No. 1907, 87th Cong., 2d Sess. 3, reprinted in 1962 U.S. Code Cong. & Admin. News 3970, 3971.

39 Id.

the Vaccination Assistance Act of 1962[40] has provided for assistance to the states in sustaining effective efforts against communicable diseases. A 1972 amendment authorized a program of project grants to "make it possible for States and communities to undertake a coordinated national immunization program against measles, poliomyelitis, and diphtheria, as well as rubella."[41]

B. *Federal Regulation of State Immunization Programs*

The federal government has allocated substantial sums of money to the individual states in order to effectuate the goal of nationwide childhood immunization.[42] To be eligible for a grant of funds, the state must comply with federal mandates;[43] to receive immunization program money, the responsible state agency must include and describe in its application "[a] plan to systematically immunize susceptible children at school entry through *vigorous enforcement of school immunization laws*."[44] Since state and local governments rely heavily on federal grants to run childhood immunization programs,[45] they are compelled to effectuate the national objectives and mandates.

The award of grants-in-aid illustrates the dependence of state- and local-level immunization programs on federal moneys. Approximately one-third to one-half of the states' total program costs are met with federal funding.[46] However, this ratio is deceptive in that it suggests that local programs are dependent on federal funds for almost

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40 The 91st Congress enacted the Communicable Disease Control Amendments of 1970, Pub. L. No. 91-464, § 2, 84 Stat. 988 (codified as amended at 42 U.S.C. § 247b (1982 & Supp. II 1984)), to assist the states in sustaining effective efforts against communicable diseases. H.R. Rep. No. 1114, 91st Cong., 2d Sess. 1, reprinted in 1970 U.S. Code Cong. & Admin. News 4135, 4135-36.

41 S. Rep. No. 825, 92d Cong., 2d Sess. 2, reprinted in 1972 U.S. Code Cong. & Admin. News 3430, 3438.

42 In fiscal years 1982, 1983, and 1984, Congress authorized $29.5 million, $32 million, and $34.5 million respectively for programs to immunize children against vaccine-preventable disease. 42 U.S.C. § 247b(j)(1) (1982). The appropriations for 1985, 1986, and 1987 are considerably higher: $34.5 million, $59 million, and $65 million. See Act Amendment of Oct. 30, 1984, Pub. L. No. 98-555, 98 Stat. 2854. The difference is accounted for by the inclusion of Swine Flu Immunization Program applications in these figures. Id.

43 See Project Grants, supra note 3, at 1. Under the Public Health Services Act, 42 U.S.C. § 247b (1982 & Supp. II 1984), grant applications for programs to immunize children against vaccine-preventable diseases are made to the Secretary of Health & Human Services. See general application procedure at 42 C.F.R. § 51b.101-206 (1985).

44 42 C.F.R. § 51b.204(a)(4)(vi) (1985) (emphasis added).

45 See infra notes 46-50 and accompanying text.

46 This figure is based on estimates made by the Centers for Disease Control. See letter from Alan R. Hinman, M.D., Director, Division of Immunization, Center for Prevention Services, to Barbara J. Connolly (Sept. 30, 1985) (discussing federal funding for state immunization programs).

Federal appropriations for "preventive health service programs to immunize individuals

half of their total costs. This is not the case. For example, during fiscal years 1972-73 through 1975-76, the "New York City Region" received ten percent of its immunization funding from the federal government[47] in contrast to the "Upstate New York Region" that received eighty-six percent of its funding from the federal government during the same four-year period.[48] In the absence of federal moneys, heavily dependent programs such as those in "Upstate New York," would undoubtedly collapse. And if one sector of society—such as the children of "Upstate New York"—is inadequately immunized, a substantial increase in the cases of vaccine-preventable diseases is likely to occur.[49] This would result in disastrous public health consequences since the control of communicable diseases through vaccination requires universal immunization.[50]

II. PROBLEMS OF THE CURRENT SYSTEM

A. *Traditional Tort Theory*

The seller or manufacturer of a defective product that is unreasonably dangerous to an ultimate consumer whose person or property

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against vaccine-preventable diseases" were $34.5 million, $52 million, and $59 million for the fiscal years 1984, 1985, and 1986 respectively. 42 U.S.C. § 247b(j)(1) (Supp. II 1984).

47 State of N.Y. Legislative Comm'n on Expenditure Review, Immunization of Children 17 (May 27, 1977). As this program audit has not been updated to reflect actual current figures, its utility is limited to demonstrating the dependence of state and local programs on federal funds.

48 Id. at 12.

49 The current rarity of diphtheria, tetanus, pertussis, measles, mumps, rubella, and poliomyelitis is due primarily to the high level of child immunization. Most cases occur among unimmunized or inadequately immunized persons. Thus, it appears that failure to immunize against vaccine-preventable childhood diseases will inevitably result in an increase of such cases. See generally Hinman & Jordan, supra note 2, at 436 ("*Dramatic progress has been made in reducing morbidity due to infectious diseases of childhood through programs of universal immunization of children.*") (emphasis in original).

With a childhood vaccination program in effect whereby 90-95% of children have received their basic immunization series, unvaccinated persons are benefitted by the effect of herd immunity. The immunized population has worked to reduce vaccine-preventable diseases dramatically. In the face of low incidence of vaccine-preventable diseases, one may conclude that the chance of incurring injury from the immunization is greater than the likelihood of incurring the disease. On an individual level, one may choose to defer immunization because the vaccine is more likely to result in an injury than in the disease it is intended to prevent, and thus, the herd immunity effect provides the necessary protection. However, should a substantial number of persons refuse vaccinations on this basis, herd immunity would no longer exist to protect the unvaccinated; the number of vaccinated persons would decrease, and the disease incidence would rise. A balance would then be struck in favor of vaccination, because the risk of injury from the disease would outweigh the likelihood of vaccine-related adverse effects.

50 "Universal immunization" means that 90% of children under age 2 and 95% of children through grade 12 are fully immunized. See Hinman & Jordan, supra note 2, at 438.

is physically harmed by the product may be held strictly liable for such harm.[51] Despite the risk involved, a vaccine which inevitably causes some harm is not considered "defective" or "unreasonably dangerous"; it is an "unavoidably unsafe product"[52]—a product "which, in the present state of human knowledge, [is] quite incapable of being made safe for [its] intended and ordinary use."[53] The rabies vaccine is an outstanding example because the rabies treatment itself commonly leads to "serious and damaging consequences."[54] However, use of the vaccine is fully justified "[s]ince the disease itself . . . leads to a dreadful death."[55] Notwithstanding that vaccines are unavoidably unsafe products, the manufacturer may be held strictly liable if there has been a failure to warn of the inherent dangers.[56]

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[51] E.g., Greenman v. Yuba Power Prods., Inc., 59 Cal. 2d 57, 377 P.2d 897, 27 Cal. Rptr. 697 (1963); Goldberg v. Kollsman Instrument Corp., 12 N.Y.2d 432, 191 N.E.2d 81, 240 N.Y.S.2d 592 (1963); see Restatement (Second) of Torts, supra note 8, § 402A.

[52] See Givens v. Lederle, 556 F.2d 1341, 1345 (5th Cir. 1977) (applying Florida law); Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1273 (5th Cir.) (applying Texas law), cert. denied, 419 U.S. 1096 (1974); Davis v. Wyeth Laboratories, Inc., 399 F.2d 121, 128 (9th Cir. 1968) (applying Montana law); Restatement (Second) of Torts, supra note 8, § 402A comment k.

[53] Restatement (Second) of Torts, supra note 8, § 402A comment k.

[54] 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. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous.

Id.

[55] Id.

[56] Failure to give such a warning where it is required constitutes a "defect" in the product, and will, without more, cause the product to be "unreasonably dangerous as marketed." E.g., Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1274-78 (5th Cir.) (unavoidably unsafe trivalent oral polio vaccine unreasonably dangerous as marketed since there was a failure to warn parents of its unreasonably dangerous properties), cert. denied, 419 U.S. 1096 (1974); accord Givens v. Lederle, 556 F.2d 1341, 1345-46 (5th Cir. 1977) (duty to warn each individual consumer of polio vaccine dangers imposed on manufacturers even if individual medical attention has been provided); Davis v. Wyeth Laboratories, Inc., 399 F.2d 121, 130-31 (9th Cir. 1968) (liability imposed upon manufacturer of polio vaccine for failure to warn ultimate consumer of dangers in live-virus vaccine notwithstanding that warning had been given to medical society that purchased vaccine). But cf. Cunningham v. Charles Pfizer & Co., 532 P.2d 1377, 1381-83 (Okla. 1974) (verdict against manufacturer for failure to warn of dangers inherent in live-virus vaccine reversed and remanded to determine whether reasonable person in plaintiff's position would have refused vaccine had adequate warning been given).

Where malpractice has occurred in the manufacture or administration of the vaccine, a suit is justified against the manufacturer, physician, or government. E.g., Wilson v. United States, No. C.80-1325A, slip op. (N.D. Ga. Sept. 28, 1982) (air force pediatrician held liable for negligence); Griffin v. United States, 351 F. Supp. 10 (E.D. Pa. 1972) (United States gov-

Those injured by a failure to warn of inherent dangers are not adequately compensated in tort. A recipient who has been injured by an improperly marketed vaccine has the burden of pursuing compensation through litigation. While all tort plaintiffs face the powerful disincentives of high legal costs, long delays, and the uncertainty of recovery, the injured vaccinee presents the strongest case for bypassing the tort system.[57] There is general agreement that injured vaccinees deserve compensation for their participation in a public health measure mandated by law and public policy.[58] In this "special context of immunization, it is inequitable and irresponsible to force the injured vaccinee to pursue the parties at fault through the courts."[59]

The real problem is that "in most cases, warnings are adequate," and therefore, "there is no one at fault, and dyspractice, not malpractice has occurred."[60] "Dyspractice" refers to the unavoidable adverse reactions to vaccine administration caused by neither failure to warn nor malpractice.[61] However, the one person in tens of thousands who suffers an adverse reaction has no legal recourse. The drug company is not at fault when producing and offering an approved product with proper instructions; neither is the physician at fault in administering

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ernment held liable for negligently releasing a batch of live-virus vaccine after test results showed batch did not meet safety standards imposed by administrative regulation), aff'd in part and rev'd in part, 500 F.2d 1059 (3d Cir. 1974); Tinnerholm v. Parke Davis & Co., 285 F. Supp. 432 (S.D.N.Y. 1968) (manufacturer negligence), aff'd, 411 F.2d 48 (2d Cir. 1969); Stromsodt v. Parke-Davis & Co., 257 F. Supp. 991 (D.N.D. 1966) (manufacturer negligence), aff'd, 411 F.2d 1390 (8th Cir. 1969).

[57] It is inappropriate and unfair to require innocent victims, injured in the course of serving the public interest in controlling communicable disease, to seek compensation through the judicial process. That elaborate, unwieldy mechanism, premised on an adversarial relationship between the parties and directed at allocation of fault between them, is ill-equipped to serve as a compensation vehicle.

McIntosh, Liability and Compensation Aspects of Immunization Injury: A Call for Reform, 18 Osgoode Hall L.J. 584, 609 (1980).

[58] See id. at 609-13; see also Baynes, Liability for Vaccine Related Injuries: Public Health Considerations and Some Reflections on the Swine Flu Experience, 21 St. Louis U.L.J. 44, 75 (1977) ("the unfortunate victims of vaccine injuries should not be expected to pay the full price for a benefit shared by all"); Franklin & Mais, Tort Law and Mass Immunization Programs: Lessons from the Polio and Flu Episodes, 65 Calif. L. Rev. 754, 775 (1977) ("[t]he case for assuring compensation to all injured [immunization] participants is uniquely strong").

[59] McIntosh, supra note 57, at 609-10.

[60] Krugman, Immunization "dyspractice": The need for "no fault" insurance, 56 Pediatrics 159, 159 (1975) (acknowledging existence of challenge to DTP's (diphtheria-tetanus-pertussis vaccine) safety). See Tarr, DTP Vaccine Injuries: Who Should Pay?, 7 Nat'l L.J., Apr. 1, 1985, at 1, col. 1. A major battle over the DTP vaccine has erupted between plaintiffs' lawyers and drug manufacturers. However, the underlying premise of this Note is that vaccines are manufactured in the safest possible manner; thus this discussion is limited to such vaccines.

[61] Krugman, supra note 60, at 159 (comparing unavoidable "dyspractice" with malpractice which implies ignorance, negligence, or criminal intent).

or directing the immunization in accordance with the instructions. Tort law is, therefore, an inadequate vehicle for the compensation of these childhood immunization injuries caused by dyspractice.

Once a vaccine recipient is warned of the dangers, the recipient assumes the risk of any loss incurred as a consequence of the immunization.[62]

B. *Issues Faced by Vaccine Manufacturers and Resulting Public Health Concerns*

The adequacy of the required warnings is problematic. Courts have held drug manufacturers strictly liable for injuries resulting from live-virus polio vaccines when individual vaccinees were inadequately warned of the risks.[63] This duty was imposed upon the manufacturers because the vaccines were not dispensed as prescription drugs; rather, they were "dispensed without the sort of individualized medical balancing of the risks to the vaccinee that is contemplated by the prescription drug exception."[64] Exactly what constitutes "adequate" warning is not clear. When immunizations are dispensed at clinics without individualized balancing of the risks, the manufacturer has a duty to see that warnings reach the consumer.[65] However, in the mass immunization context, manufacturers may never be sure that a warning sufficient to exempt them from liability will ultimately reach the consumer.[66]

The rationale behind the requisite warning is that individuals receiving childhood immunizations have the right to receive information sufficient to give an "informed consent."[67] The warnings given

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62 See supra note 56 and accompanying text.

63 See supra note 52.

64 Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1277 (5th Cir.), cert. denied, 419 U.S. 1096 (1974).

65 Id. at 1277-79; Davis v. Wyeth Laboratories, Inc., 399 F.2d 121, 130-31 (9th Cir. 1968); Cunningham v. Charles Pfizer & Co., 532 P.2d 1377, 1381 (Okla. 1974).

66 This is primarily due to the fact that the manufacturer is not in face-to-face contact with the vaccinee and must rely on the health officials to give the manufacturer's warnings. In Davis v. Wyeth Laboratories, Inc., 399 F.2d 121, 125 (9th Cir. 1968), because the warnings given by the manufacturer to the medical society were not passed on to the patients, the manufacturer was held liable. Id. at 131.

67 See Givens v. Lederle, 556 F.2d 1341, 1345-46 (5th Cir. 1977); *Reyes*, 498 F.2d at 1277; *Davis*, 399 F.2d at 128-29.

> 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 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.

Restatement (Second) of Torts, supra note 8, § 402A comment k.

must fully caution the recipient of qualitative and quantitative risks of the vaccine.[68] However, in mandatory immunization cases these warnings are merely a fiction. A parent has no choice but to subject his child to immunization or face possible criminal violations for failing to send his child back to school.[69]

As well as being a complex and inequitable solution,[70] the tort-based compensation system has adversely affected public health. The few victims who are successful in winning large liability awards consume the profits of the manufacturer either through the award itself or by way of legal costs and higher insurance fees. Confronted with these high liability costs[71] and the problem of designing a warning sufficient to avoid strict liability,[72] manufacturers have reacted by restricting manufacture and distribution of vaccines by raising the

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[68] Givens v. Lederle, 556 F.2d 1341, 1345-46 (5th Cir. 1977); *Reyes*, 498 F.2d at 1276-78; *Davis*, 399 F.2d at 130-31.

[69] In the event that any such parent, guardian, or other person continually and willfully fails to respond to directives of the school attendance review board or services provided, the school attendance review board shall direct the school district to make and file in the proper court a criminal complaint against the parent, guardian, or other person, charging the violation, and shall see that the charge is prosecuted by the proper authority.

Cal. Educ. Code § 48291 (West Supp. 1986).

"In each case of nonenrollment or of nonattendance upon the part of a child who is required to attend some school, when no valid reason for such nonenrollment or nonattendance is found, the superintendent shall institute a criminal prosecution against the child's parent." Fla. Stat. Ann. § 232.19(2) (West Supp. 1986).

A parent, guardian or other person having charge and control of a child between the ages of 6 and 16 years, who shall fail to comply with any of the provisions of this article relating to his duties, shall be deemed to be a disorderly person and shall be subject to a fine of not more than $25.00 for a first offense and not more than $100.00 for each subsequent offense, in the discretion of the court.

N.J. Stat. Ann § 18A:38-31 (West Supp. 1985).

Except as otherwise provided, a violation of part one of this article shall be punishable for the first offense by a fine not exceeding ten dollars or ten days imprisonment; for each subsequent offense by a fine not exceeding fifty dollars, or by imprisonment not exceeding thirty days, or both such fine and imprisonment.

N.Y. Educ. Law § 3233 (McKinney 1981). See State v. Vaughn, 44 N.J. 142, 207 A.2d 537 (1965) (penal complaint need only allege that parent or guardian did not cause the child to attend school). But see *In re* Richards, 166 Misc. 359, 2 N.Y.S.2d 608 (Children's Ct.) (refusal of parent must be willful and defiant and accompanied by an unlawful intent), aff'd, 255 A.D. 922, 7 N.Y.S.2d 722 (1938).

[70] If there has been a failure to warn, the vaccinee may be able to recover up to several million dollars for damages incurred. See Boffey, Vaccine Liability Threatens Supplies, N.Y. Times, Jun. 26, 1984, at C13, col. 1. Yet, another child who suffers precisely the same injury, will receive nothing if adequate warning has been given, notwithstanding that preschool immunizations are mandatory and there is no true alternative.

[71] In 1984, the New York Times reported on a document submitted to a congressional committee in that year citing "11 recent court awards or settlements in which victims won between $150,000 and $5.5 million." Id.

[72] See supra note 65 and accompanying text.

prices,[73] or withdrawing from the market.[74] The result is that the nation's vaccine supply is threatened by the small number of remaining manufacturers. In cases where there is a single manufacturer of a vaccine, the chief concern is that the supply could be disrupted by an unanticipated manufacturing problem, a bad batch of vaccine, a strike by employees, or the ultimate exigency—a decision by the last manufacturer to abandon the market.[75]

With this dwindling supply come the public health concern of an inability to maintain adequately high immunization levels[76] and the threat of vaccines costing more than local and state public health departments can afford.[77] Finally, there is a danger that manufacturers may overemphasize vaccine risks purely to avoid liability rather than truly to warn.[78] Such a scare tactic could result in a national threat of

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[73] Lederle Laboratories, the remaining major retailer of pertussis vaccine—and the sole manufacturer of the oral polio immunization—recently doubled its prices in response to mushrooming legal costs. Since the summer of 1984, Lederle has raised the price for fifteen doses of DTP vaccine from $17.90 to $42.00 ($1.20 to $2.80 per dose). Tarr, supra note 60, at 27. "Dr. Martin Smith, a vice president of Academy of Pediatrics, said that dependence on single companies would likely mean a continued rise in the price of all vaccines." Engelberg, Maker of Vaccine Quits the Market, N.Y. Times, Dec. 12, 1984, at A21, col. 1.

[74] Wyeth Laboratories, the same company that was involved in the polio vaccine cases, see Reyes v. Wyeth Laboratories, 498 F.2d 1264 (5th Cir.), cert. denied, 419 U.S. 1096 (1974); Davis v. Wyeth Laboratories, Inc., 399 F.2d 121 (9th Cir. 1968), recently decided to withdraw from the pertussis vaccine market because of the " 'dramatic increases in the cost of participating in this market,' chiefly due to liability insurance and the costs of litigation." Boffey, supra note 70, at Cl, col. 1.

> The Wyeth defection continued a trend that has been under way for the past decade or two . . . . During the 1960's . . . there were eight manufacturers of the combined vaccine that is used to immunize children against diphtheria, whooping cough, and tetanus; now, after Wyeth's withdrawal, there are two, Lederle Laboratories . . . and Connaught Laboratories.

Id. at Cl, col. 1, C13, col. 1.

Wyeth's departure left only one major U.S. seller—Lederle Laboratories—in the whooping cough vaccine market. One other smaller supplier of the vaccine, Connaught Laboratories, abandoned the market some months after Wyeth. "[T]he concern's insurers demanded higher premiums and deductibles. . . . 'It just wasn't economically feasible to continue production,' [a Connaught vice president for marketing and sales] said." Engleberg, supra note 73, at A21, col. 1.

[75] Boffey, supra note 70, at Cl, col. 1. This is precisely the problem public health officials confronted in December 1984. The Federal Centers for Disease Control, acting in response to a perceived shortage of whooping cough vaccine caused by the withdrawal of two manufacturers and production problems at the remaining maker, advised doctors to postpone giving booster shots to children older than one year. Engelberg, Official Explains Gaffe on Vaccine Shortage, N.Y. Times, Dec. 19, 1984, at A21, col. 1.

[76] See supra note 49.

[77] See, e.g., Hinman & Jordan, supra note 2, at 436 (the rising costs of vaccines may influence immunization programs in the future; the measles, mumps, and rubella vaccines rose more than 40% in cost during 1981-1982).

[78] See Baynes, supra note 58, at 61; Franklin & Mais, supra note 58, at 774; McIntosh, supra note 57, at 610.

epidemic if sizable numbers refused the vaccine despite the state immunization laws. One court has responded to this by declaring that the warning need be only simple enough to be understood in order to meet the duty to warn, phrased in a way that would not stifle immunization efforts.[79] Yet, it is doubtful that such a warning could be devised.[80]

C. *Sovereign Immunity*

The doctrine of sovereign immunity prohibits an injured vaccinee from bringing suit against the federal government that mandated the immunization[81] unless the government so consents.[82] The sovereign consents by enacting legislation that permits a suit against the government. In 1946, through the passage of the Federal Tort Claims Act (the "Act"),[83] the federal government consented to a general abrogation of the rule that precluded tort suits.[84]

The Act, however, sets forth two qualifications that bar suit against the government for immunization injuries. Although the government's liability is determined generally in accordance with local law—with the government treated as though it were a private defend-

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79 Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1293-94 (5th Cir.), cert. denied, 419 U.S. 1096 (1974).

80 See Baynes, supra note 58, at 61.

81 See infra notes 82-89 and accompanying text.

82 See, e.g., United States v. Sherwood, 312 U.S. 584, 586 (1941) ("The United States, as sovereign, is immune from suit save as it consents to be sued.") (quoting United States v. Thompson, 98 U.S. 486 (1878)).

The concept of sovereign immunity has been expressed in two maxims: "the king can do no wrong" and "the sovereign cannot be sued without his consent." E.g., Kawananakoa v. Polyblank, 205 U.S. 349, 353 (1907) ("A sovereign is exempt from suit . . . on the logical and practical ground that there can be no legal right as against the authority that makes the law on which the right depends.").

Such a rationale, based upon notions of royal supremacy, has been criticized as having no application in this country. See Note, Suits Against Government Officers and the Sovereign Immunity Doctrine, 59 Harv. L. Rev. 1060, 1060 (1946). Thus, the only rationale given due regard by "courts and commentators alike is that official actions of the Government must be protected from undue judicial interference." Cramton, Nonstatutory Review of Federal Administrative Action: The Need for Statutory Reform of Sovereign Immunity, Subject Matter Jurisdiction, and Parties Defendant, 68 Mich. L. Rev. 387, 397 (1970) (footnotes omitted).

83 Originally title IV of the Legislative Reorganization Act of 1946, Pub. L. No. 79-601, 60 Stat. 812, 842 (codified as amended in scattered sections of 28 U.S.C.).

84 The central provisions of the Act are sections 1346(b) and 2674 of title 28. Section 1346(b) gives the district courts jurisdiction over any civil action against the United States for

> personal injury or death caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment, under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred.

28 U.S.C. § 1346(b) (1982).

ant—there is no liability for claims based on strict or absolute liability.[85] As the Act requires a "negligent or wrongful act or omission" by a government employee,[86] there is no liability for the inevitable faultless vaccine injuries.[87] Additionally, the Act exempts "[a]ny claim . . . based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty . . . whether or not the discretion involved [was] abused."[88] This clause, therefore, works to bar suit for immunization injuries since the government may not be held liable for policy determinations made by its officials—such as the decision to support certain childhood vaccines at local levels. Rather, governmental liability exists only when officials fail to conform to preexisting statutory and regulatory requirements in carrying out their duties.[89]

Liability under the Act was altered significantly when the United States waived its immunity from liability for injuries related to the National Swine Flu Immunization Program (the "Swine Flu Program").[90] The manufacturers of the vaccine found their insurers un-

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85 See 28 U.S.C. § 1346(b) (1982).

86 Id.

87 See Laird v. Nelms, 406 U.S. 797 (1972); Dalehite v. United States, 346 U.S. 15, 44-45 (1953) (construing 28 U.S.C. § 1346(b)).

88 28 U.S.C. § 2680(a) (1982).

89 See Dalehite v. United States, 346 U.S. 15, 42 (1953). This conclusion is based partly on Griffin v. United States, 500 F.2d 1059 (3d Cir. 1974), where the court held that the decision of the Division of Biologic Standards of the Department of Health, Education, and Welfare to release a large amount of oral polio live-virus vaccine did not fall within the "discretionary function" provision of the Federal Tort Claims Act. The Court stated: "We do not hold that the Government may be liable for policy determinations made by its officials. Rather, we hold only that the Government may be liable where its employees, in carrying out their duties, fail to conform to pre-existing statutory and regulatory requirements." Id. at 1069.

Thus, where the nature of the judgment calls for a policy consideration and decision, there is discretion. See *Dalehite*, 346 U.S. at 35; *Griffin*, 500 F.2d at 1064-65. Although no case has squarely addressed the point, the decision to financially support childhood immunization programs would likely be held to be a discretionary decision. But see Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1294 n.57 (5th Cir.) ("It can . . . be argued . . . that since all society benefits from universal immunization against infectious disease, the loss should be borne by the local, state or federal government. Unless the doctrine of sovereign immunity is significantly altered, however, such a loss distribution scheme does not appear to be likely."), cert. denied, 419 U.S. 1096 (1974).

The rationale underlying this discretionary provision is that judicial control of legislative or executive activities of the government would disrupt the balance of powers. See Prosser and Keeton on the Law of Torts 1039 (W. Keeton 5th ed. 1984) (judicial review of executive policies regarding negligence might place the judiciary in the position of supreme arbiter in government).

90 National Swine Flu Immunization Program of 1976, Pub. L. No. 94-380, 90 Stat. 1113 (originally codified at 42 U.S.C. § 247b(j)(1) (1976)).

In 1976, in response to an occurrence of swine flu among U.S. Army recruits at Fort Dix, New Jersey, President Ford proposed a national program through which every American would be immunized. Ford delivered a message to Congress concerning "a serious potential

willing to accept the risk of claims based on vaccination injuries, and the manufacturers would not proceed without insurance protection.[91] The Swine Flu Program[92] was the necessary solution. The legislation, inter alia, relieved the vaccine manufacturers from primary liability and created an exclusive remedy against the United States for any injuries resulting from the immunization program.[93] Liability was accepted by the federal government

> for personal injury or death arising out of the administration of swine flu vaccine under the swine flu program and based upon the act or omission of a program participant in the same manner and to the same extent as the United States would be liable in any other action brought against it [under the Federal Tort Claims Act].[94]

The Swine Flu Program abrogated the rule that under the Federal Tort Claims Act the government cannot be held liable on strict liability theory,[95] and forced the government to agree not to invoke the "discretionary function" provision[96] of the Act that would otherwise bar liability.[97]

III. THE SOLUTION

In light of the ineffectiveness of the tort-based system, there is a widely recognized need for a federally run vaccine-injury compensation program[98] for vaccinees injured by mandatory immunization.[99]

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public health threat this winter from [this] strain of virus known as swine influenza." 122 Cong. Rec. 8049 (1976) (message from President Ford). Congress responded promptly to the President's request and the appropriations measure became law on April 15. See H.R.J. Res. 890, Pub. L. No. 94-266, 90 Stat. 362 (1976).

91 122 Cong. Rec. 26,008-09 (1976). It was not the possibility of manufacturer negligence liability that concerned the insurance companies, but rather, the risk of strict products liability and the anticipated cost of defending meritless suits. See id. at 26,796, 26,799-800, 26,808-09 (1976) (remarks of Rep. Rogers).

92 See Pub. L. No. 94-380, § 2, 90 Stat. 1113 (originally codified at 42 U.S.C. § 247b(j)(1) (1976)). The legislation was whisked through both houses in a single day, Tuesday, August 10, 1976, and enacted in unparalleled haste. See 122 Cong. Rec. 26,625-40 (1976) (Senate); id. at 26,793-817 (House).

93 Pub. L. No. 94-380, § 2, 90 Stat. 1113 (originally codified at 42 U.S.C. § 247b(K)(1)(A) (1976)).

94 Id. (originally codified at 42 U.S.C. § 247b(K)(2)(A) (1976)).

95 Id. (originally codified at 42 U.S.C. § 247b(K)(2)(A)(i) (1976)).

96 Id. (originally codified at 42 U.S.C. § 247b(K)(2)(A)(ii) (1976)).

97 See supra note 88 and accompanying text.

98 The need for such a compensation program has the support of many observers. Dissatisfied Parents Together, a parents group concerned with childhood vaccination injuries, and the American Academy of Pediatrics helped develop and support the "National Childhood Vaccine-Injury Compensation Act" which was introduced in similar form in both the House of Representatives and the Senate in 1985. The proposals provide for a no-fault program, federal compensation, and recovery by the federal government from negligent manufacturer-providers. The bills provide that the programs would be an alternative to the traditional tort remedy.

In 1985, the National Childhood Vaccine-Injury Compensation Act was introduced in Congress to amend the Public Health Services Act.[100] Although the bill has not been enacted to date,[101] it reflects a workable approach to compensating vaccine-related injuries. Con-

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See S. 827, 99th Cong., 1st Sess., 131 Cong. Rec. S3843 (daily ed. Apr. 2, 1985); H.R. 1780, 99th Cong., 1st Sess., 131 Cong. Rec. H1587 (daily ed. Mar. 27, 1985).

Several countries—Denmark, Hungary, Japan, Monaco, Switzerland, and West Germany—have already enacted laws to compensate persons who experience vaccine-associated disability. See Ladimer, Legal and Regulatory Perspectives in Mass Immunization Programs, Ins. L.J., Aug. 1976, at 459, 469. See also McIntosh, supra note 57, at 613 (in Britain, flat payment of £ 10,000 to any person severely injured as a result of vaccination).

Baynes, supra note 58, points out a number of advantages of a no-fault model for vaccine injuries, including an increase in the number of persons compensated, recovery guaranteed for "injuries due to unavoidably unsafe vaccines regardless of whether there was an adequate warning, a defect, or an assumption of risk," lower administration costs, and a decrease in personal injury costs by eliminating damages for pain and suffering. Id. at 72-73.

Other supporters of a nontort compensation scheme based on a social policy rationale include: AMA offers recommendations for vaccine injury compensation, 252 J. A.M.A. 2937, 2944 (1984) (It is the position of the Centers for Disease Control and the American Academy of Pediatrics that "social justice demands that society compensate those persons who suffer as a result of a program from which society as a whole benefits."); Franklin & Mais, supra note 58, at 754-55 ("the public interest in encouraging citizens to participate in mass immunization programs justifies a non-tort compensation system for those injured by the vaccine or its administration"); Krugman, supra note 60, at 159 ("[i]f society is to benefit from immunization practice, as it obviously does . . . then society . . . should logically be responsible for immunization dyspractice"); McIntosh, supra note 57, at 609 ("[t]he public's interest in and benefit from the vaccinee's 'private' decision to submit to immunization must be accompanied by public responsibility for the compensation of the victim"); Merrill, Compensation for Prescription Drug Injuries, 59 Va. L. Rev. 1, 87 (1973) ("consumers should not bear the cost of adverse drug reactions that are not attributable to their own carelessness"); Comment, Immunization Injuries: Proposed Compensatory Mechanisms—An Analysis, 11 Conn. L. Rev. 147, 179 (1978) ("[t]he ultimate beneficiary of immunization programs is not so much the individual vaccine recipient as society as a whole[;] . . . compensatory justice demands that society, through its government, assume the obligation, when no one is at fault, of redressing injuries incurred by the few for the benefit of the many").

[99] Commentators have long advocated abolishing tort law as a compensation vehicle for immunization injuries. E.g., Baynes, supra note 58, at 72 ("The basic argument advanced in favor of turning to no-fault compensation systems is that the tort-litigation system is outdated."); Franklin & Mais, supra note 58, at 775 ("The tensions between the private and public interests in mass immunization programs lead one to question the utility of tort law in this context."); McIntosh, supra note 57, at 612 ("private tort law, which is fault-oriented and rooted in the adversarial litigation process, is a fundamentally inappropriate approach to this public health issue").

[100] S. 827, 99th Cong., 1st Sess., 131 Cong. Rec. S3843 (daily ed. Apr. 2, 1985). Another compensation bill was introduced in the House of Representatives by Representative Madigan of Illinois. H.R. 1780, 99th Cong., 1st Sess., 131 Cong. Rec. H1587 (daily ed. Mar. 27, 1985). The House bill, however, is not as comprehensive as the Senate bill and has been opposed by groups such as Dissatisfied Parents Together. See supra note 98.

[101] To date, 15 senators have joined Senator Paula Hawkins in cosponsoring S. 827, 99th Cong., 1st Sess., 131 Cong. Rec. S3843 (daily ed. Apr. 2, 1985). The bill is being endorsed by the American College of Physicians, American Nurses Associations, Association of Retarded Citizens, Association of Schools of Public Health, Epilepsy Foundation of America, Health Department of the State of Michigan, National Association of Children's Hospitals and Re-

gressional findings supporting the bill include the "long-standing effort by the Federal Government to promote childhood vaccinations,"[102] the "injury, illness, disability, or even death of some innoculated children,"[103] as well as the fact that the "traditional fault-based system offers no effective mechanism for compensating injured individuals."[104]

Under the proposed scheme, any recipient of enumerated childhood vaccines who suffers vaccine-related injuries may elect to seek a remedy under the program as an alternative to judicial action.[105] It sets an aggregate, per person award limit that provides compensation for damages arising from pain, suffering, and emotional distress.[106] Additionally, there is a subrogation provision whereby the United States Secretary of Health and Human Services may bring a civil action to recover damages against any responsible party.[107] Therefore, the scheme does not eliminate fault; if a physician, health care provider, or manufacturer has proximately caused the recipient's injury, ultimate liability will be imposed on the responsible party.

Financing such a compensation plan may be effectuated in a number of ways.[108] Under the Senate version of the bill, a national

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lated Institutions, and the National Foundation on Birth Defects (March of Dimes). See Dissatisfied Parents Together News, Winter 1986, at 10.

Opponents of the bill include both the American Medical Association and vaccine manufacturers. These groups want to eliminate the lawsuits altogether either by making a federal compensation system the "exclusive remedy" for vaccine-damaged children or by restricting access to the courts as well as by placing caps on amounts that could be awarded in court. Id.

Several major obstacles are thought to be blocking the passage of S. 827. For example, vaccine manufacturers, the Reagan Administration, and the AMA are lobbying in an effort to persuade senators to adopt amendments to the bill which would place a cap on awards, as well as limit access to the courts. In addition, the federal budget deficit and the passage of the Gramm-Rudman Act make the enactment of new federal compensation programs particularly difficult. See id. at 5-6.

102 S. 827, 99th Cong., 1st Sess., § 2101(a)(1), 131 Cong. Rec. S3843 (daily ed. Apr. 2, 1985).

103 Id. § 2101(a)(2).

104 Id. § 2101(a)(3).

105 Id. § 2102(b). Although the bill provides for an alternative to traditional tort remedy, without a program which is the exclusive remedy of claimants, goals such as the continued availability of vaccines, development of improved vaccines, and the participation of health care providers in the immunization programs may not be met.

106 Id. § 2107(a)(3).

107 Id. § 2108(a). This is a critical provision since "[g]overnment liability, unless coupled with some form of direct levy against manufacturers and physicians, would reduce the economic incentives for both of these parties to reduce accident costs." Merrill, supra note 98, at 106.

108 Proponents of a national compensation scheme have advocated different methods for financing such a program, including support through taxation, an annual surcharge on vaccine manufacturers, insurance pools, and federal appropriations necessary for each fiscal year. See

trust fund would be established[109] that would include amounts received from surcharges on vaccine manufacturers, and amounts recovered in subrogation, as well as federal appropriations necessary for the fiscal year.[110] The proposal also advocates a vaccine insurance plan for manufacturers that includes an insurance pool.[111]

With the establishment of a national compensation system for vaccine-related injuries, there will be no general need to sue for redress. A no-fault, nonadversarial national program will assure expedited, just compensation, at low transaction costs for those who have sustained vaccine-related injuries.[112] This scheme is particularly desirable because it eliminates the victim's need to establish fault or negligence as a prerequisite to recovery.[113] Therefore, when inevitable faultless injury is caused by the inherently dangerous properties associated with the vaccine, the victim will have a legal remedy that is not currently available.[114]

In addition to effectuating simple, equitable compensation, such a scheme has positive public health effects. First, a national compensation program helps ensure the continued supply of vaccines at reasonable costs, and funds research for new and improved vaccines. The Senate bill provides for a broad study of the risks associated with childhood vaccines.[115] Furthermore, the Secretary of the Department of Health and Human Services would have an affirmative duty to "promote the development or refinement of substitute childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market"[116] and "make or assure improvements in . . . the licensing, manufacturing, processing, testing, labeling, warning, use instructions . . . and research on vaccines, in order to reduce the risks of adverse reactions to vaccines."[117] Second, such a scheme would improve the type of information distributed by health care

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S. 827, 99th Cong., 1st Sess., §§ 2110, 2122, 2124, 2126, 131 Cong. Rec. S3843 (daily ed. Apr. 2, 1985).

109 Id. § 2110 ("National Vaccine Injury Compensation Trust Fund").

110 Id. § 2110(b), (c).

111 Id. §§ 2122-2126.

112 These are the objectives of the National Childhood Vaccine-Injury Compensation Act, S. 827, 99th Cong., 1st Sess., 131 Cong. Rec. S3843 (daily ed. Apr. 2, 1985); H.R. 1780, 99th Cong., 1st Sess., 131 Cong. Rec. H1587 (daily ed. Mar. 27, 1985); see supra note 98.

113 Although a vaccine recipient need not establish fault in order to recover, the nontort compensation scheme does not completely eliminate fault. The federal government would maintain the right to file an action for contribution or indemnification against an alleged negligent manufacturer or program provider. See supra note 107 and accompanying text.

114 See supra notes 51-56 and accompanying text.

115 S. 827, 99th Cong., 1st Sess., § 2142, 131 Cong. Rec. S3843 (daily ed. Apr. 2, 1985).

116 Id. § 2144(a)(1).

117 Id. § 2144(a)(2).

providers to the parent of any child receiving a vaccine. Such material would include information concerning the disease to be prevented by the vaccine, reactions to the vaccine, precautionary measures to reduce the risk of adverse reaction, early warning signs and symptoms, when and how to report adverse reactions, the contraindications to administration of the vaccine, and a summary of relevant state and federal laws concerning the vaccine requirements.[118] Finally, participants would be informed that should they suffer an adverse reaction there is a concurrent remedy. This informational material would reduce the alarm and confusion that currently exists in the public sector.[119] The availability of such information will increase the likelihood of public participation in the nationwide vaccination program.

An effective national vaccination compensation program that takes the manufacturer's risk costs and places them on the public as a whole, through a tax-generated compensation system, is the necessary complement to mandatory immunization of children. Such a system was implemented by the Swine Flu Program[120] and was a sound political response to the pharmaceutical manufacturers' refusal to supply the vaccine without protection against liability. The statute was the first nontort compensation system for those suffering adverse reactions to vaccine, and although initiated in response to manufacturers' demands, provides a guide for future legislation in this area. Moreover, the mass immunization of young children presents a stronger case for a nontort compensation scheme than does the Swine Flu Program. The adverse reaction rate for routine childhood immunizations is far greater than that for swine flu vaccines.[121] In the case of child-

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118 Id. § 2143(c).

119 "As a matter of attaining public health goals, the argument can be made that public participation in immunization programs would increase if the public learned that anyone hurt by the vaccine or its administration would be compensated for the injury." Franklin & Mais, supra note 58, at 773.

120 See supra notes 90-97 and accompanying text.

121 Between 1979 and 1982, 78 deaths were reported among children who received publicly funded vaccines. Adverse Events Following Immunization, supra note 7, at 25. All except one of the sudden infant death syndrome (SIDS) cases were reported in temporal association with DTP vaccine administration. Id. The rate of SIDS from DTP vaccine administration was reported to be 1.5 cases per million doses administered. Id. at 44. Less severe complications, such as local reactions and fever, were reported at 30.4 and 45.8 cases per million doses. Id.

Flu vaccines generally have been associated with three types of systemic reactions: fever and malaise lasting up to one to two days after vaccination, rare allergic responses, and Guillain-Barré Syndrome. See Influenza Vaccines 1983-84, Recommendation of the Immunization Practices Advisory Committee, 99 Annals Internal Med. 497, 497-99 (1983). The most severe reaction of Guillain-Barré Syndrome, a neurological disease characterized by evolving paralysis of unestablished cause, was noted in 1976 after an administration of a New Jersey swine

hood vaccines, not only is the likelihood of injury greater, but the victim is apt to be younger;[122] hence, the effect of the injury may be borne throughout the lifetime of the child. Furthermore, the possible injuries from childhood vaccines are usually more severe than those injuries resulting from swine flu vaccine.[123] Finally, swine flu vaccinations are not mandatory; each individual may independently decide whether or not to be immunized.[124] However, preschool immunization of children is mandatory[125] and individuals are, in effect, compelled to bear the risk of a noncompensable adverse vaccine reaction.

There is no justifiable rationale for denying a federal compensation program to persons injured by mandatory preschool vaccinations when sovereign immunity was waived in the Swine Flu Program[126] and a compensation program was instituted for those immunization victims. The Swine Flu Program specified three underlying reasons in support of actions against the United States. One rationale—"to achieve the participation in the program of the agencies, organizations, and individuals who will manufacture, distribute, and administer the swine flu vaccine"[127]—was undoubtedly based on the underlying insurance problems which threatened the existence of the

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influenza vaccine. Id. at 499. The frequency of the rate of such reaction was approximately 10 cases per million persons vaccinated. The incidence of this syndrome was five to six times higher than in unvaccinated persons. However, in the subsequent seasons of 1978-79 through 1980-81 no significant excess risk of Guillain-Barré Syndrome was found for recipients of the influenza vaccine. Id.

122 DTP immunization is routinely given first at six weeks of age, followed by a second dose in four to eight weeks, a third dose in another four to eight weeks, and the fourth dose approximately one year after the third. A booster is then given prior to the child's entering kindergarten or elementary school. Recommendation of the Immunization Practices Advisory Committee, Diphtheria, Tetanus and Pertussis: Guidelines for Vaccine Prophylaxis and Other Preventive Measures, 34 Morbidity & Mortality Weekly Rep. 405, 405-14, 419-26 (1985).

Influenza vaccination is most strongly recommended for older persons, particularly those over 65 years, because the risk of death during influenza outbreaks generally increases with age. See Morbidity and Mortality Associated with Influenza B in the United States, 1979-1980. A Report from the Centers for Disease Control, 142 J. Infectious Diseases 360, 362 (Sept. 1980). It is also recommended that the chronically ill receive the vaccination. Id.

123 The significant clinical categories of adverse reactions to DTP, measles, mumps, and rubella vaccinations are local reaction, fever, allergic reactions, arthritis, febrile and nonfebrile convulsions, encephalitis, SIDS, and death from other causes. Adverse Events Following Immunization, supra note 7, at 44; cf. supra note 121 (adverse reactions to swine flu vaccine).

124 Individuals participating in swine-flu immunization programs are given forms which warn them of possible adverse reactions to the vaccine. The individual must sign the consent form in order to be vaccinated. Pub. L. No. 94-380, § 2, 90 Stat. 1113 (originally codified at 42 U.S.C. § 247b(j)(1)(F) (1976)).

125 See supra note 2 and accompanying text.

126 See supra notes 90-97 and accompanying text.

127 Pub. L. No. 94-380, § 2, 90 Stat. 1113 (originally codified at 42 U.S.C. § 247b(K)(1)(A)(i) (1976)).

program.[128] Today, manufacturers' refusals to participate in vaccine distribution are no longer a threat, but a reality.[129] In view of the current crisis of decreased vaccine production, there is an urgent need for a national compensation program to ensure continued availability of childhood vaccines from the manufacturers.

The second rationale—"to establish an orderly procedure for the prompt and equitable handling of claims"[130]—is provided because, as was the case with the Swine Flu Program, the federal government has played an instrumental role in the "initiation, planning, and administration"[131] of mandatory childhood immunization programs. This element of relationship common to both immunization programs sufficiently justifies waiver of sovereign immunity. Finally, Congress premised the solution on a need "to be prepared to meet the potential emergency of a swine flu epidemic . . . that a procedure be instituted for the handling of claims."[132] The explicit purpose of assuring an orderly procedure for the prompt and equitable handling of claims—implicitly based on the instrumental role of the federal government in the Swine Flu Program—analogously supports a similar compensation scheme for childhood immunization injuries. The federal government should, therefore, reconcile the inapposite responsibility taken and provide the necessary remedy to redress inevitable childhood vaccine injuries.

CONCLUSION

Immunization against communicable diseases plays a significant role in this country's national health policies. Since the 1900's, major reductions in childhood illness and mortality have resulted from communicable disease control through immunization. Through the years, the federal government has become deeply involved in promoting national childhood immunization programs run locally at the state level. Such effort is commendable, for immunization programs are less expensive than the unnecessary cost of human lives and well-being brought about in the absence of such control measures. However, as long as immunization is necessary, unavoidable adverse reactions to vaccines will remain.

Persons who incur illness as a result of receiving required immu-

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128 See supra note 91 and accompanying text.

129 See supra notes 74-75 and accompanying text.

130 Pub. L. No. 94-380, § 2, 90 Stat. 1113 (originally codified at 42 U.S.C. § 247b(K)(1)(A)(ii) (1976)).

131 Id.

132 Id. (originally codified at 42 U.S.C. § 247b(K)(1)(a)(iii) (1976)).

nization should be entitled to compensation. By promoting and requiring the immunization of children, the federal government has intervened directly into individual lives, causing injuries that otherwise would not have occurred. As President Lincoln stated, "it is as much the duty of government to render prompt justice against itself, in favor of citizens, as it is to administer the same, between private individuals."[133] In the case of childhood vaccinations, the federal government has the duty to create the much needed compensation system for persons injured by mandatory immunizations.

Barbara J. Connolly

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[133] This quote is inscribed in the Claims Court Building, Lafayette Square, Washington, D.C.