Federal Compensation for Vaccination Induced Injuries

Arnold W. Reitze, Jr.
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I. INTRODUCTION

In January 1976, Private Lewis reported to sick call at Fort Dix, New Jersey. He had an upper respiratory infection and was told to remain in bed for 48 hours. Instead, he went on a march, collapsed, was taken to the infirmary where he died on February 4, 1976. Shortly after Private Lewis became ill, many other soldiers began to report to sick call with upper respiratory disorders. The New Jersey Department of Public Health laboratory evaluated throat cultures from the sick soldiers and found A/Victoria flu virus and another unidentifiable virus. The specimens were then sent to the federal Centers for Disease Control (CDC) in Atlanta where some were found to contain swine flu virus. Thus began the largest public health vaccination program in history, to be followed by one of the largest collections of tort law suits. 2

Almost a decade after Private Lewis died, the litigation continues. 3 The number of suits, and the cost of this litigation have had substantial influence on the development of public policy concerning vaccination programs. To understand the policy and legal issues arising from inoculation programs requires some understanding of how and why such programs develop.

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1 The Centers for Disease Control is an agency of the Public Health Service within the Department of Health and Human Services. It is headquartered in Atlanta, Georgia.


3 One hundred sixty seven cases were pending in April, 1985. TORTS BRANCH, CIVIL DIV., DEPT. OF JUSTICE, SWINE FLU STATISTICS, 1985 [hereinafter cited as DEPT. OF JUSTICE].
This article explores the legal and public policy issues surrounding recent government vaccination programs. The second and third sections discuss the swine flu epidemic and concludes that the federal acceptance of tort liability creates a system of compensation that is simply too expensive for general use where claims might be very numerous. The fourth and fifth sections discuss the DPT controversy and the proposed federal legislation and concludes that the approach has merit but, a dual tort/compensation system is also too expensive. The article concludes with a recommendation for a program, broad in scope, to cover injuries from vaccination, but with reduced benefits to cover medical costs and lost earnings.

II. THE SWINE FLU EPIDEMIC

Influenza is a family of viruses that continually change molecular makeup. They produce an acute contagious respiratory infection characterized by sudden onset, chills, headache, myalgia (muscle tenderness) and sometimes prostration. The severity of the illness is dependent upon the molecular structure of the organism. The disease affects birds and animals as well as humans (the first flu virus, for example, was isolated from a pig in 1930). It can also reside in one specie without much effect and then seriously affect a different specie. A small change in molecular structure can create a deadly hybrid that will sweep through a population. The capacity of a virus to change molecular structure can make vaccines obsolete. These molecular changes can also change a nuisance disease (one with little effect on humans) into a killer. In the 1918–1919 influenza pandemic, twenty million people died world-wide, and two billion people suffered from the disease. In the United States approximately 500,000 people died. What makes a virus deadly? No one seems to know.

In January 1976, when a number of United States Army recruits came down with respiratory ailments at Fort Dix, laboratory cul-
tures completed by the state turned up Victoria virus, which had been the dominant type of human influenza since 1968. However, the CDC discovered four cases, including the one fatality, that were identified as swine flu. These swine flu cases created great concern among public health professionals. They realized that the recruits could have been infected through human-to-human transmission without contact with pigs, and that this type of virus could affect the American populace which lacked the specific antibodies necessary to protect itself. The Fort Dix virus differed from the established influenza circulating in the human population because its surface proteins ("antigens") had changed. The experts believed that antigenic shifts were likely to be followed by pandemics similar to the swine flu pandemic in 1918.

A. The Federal Governmental Response

The national public health apparatus became active: CDC's parent entity, the Department of Health, Education and Welfare (HEW) (now HHS), responded through the Public Health Service (PHS); the Food and Drug Administration responded through the Bureau of Biologics (BoB), whose responsibility it is to license and test vaccines; and the National Institutes of Health responded through its National Institute for Allergy and Infectious Diseases (NIAID).

Flu viruses fall into three types: A, B, and C. Type A, the most variable, causes pandemics as well as the more common seasonal outbreaks; type B causes smaller outbreaks; and type C rarely causes serious health problems. A flu virus has two surface proteins, hemagglutinin (HA) and neuraminidase (NA). The HA breaks into the host cell where the virus can replicate. The NA permits all the viral offspring to break free of the host cell once replication is complete. The HA and NA structures allow viruses to be classified. A-type viruses can be classified into 13 HA subtypes and 9 NA subtypes. The two surface proteins seem to be the reason that flu can change from year to year. An antigenic drift develops when a genetic change occurs in the gene code for the 550 or so amino acids in the HA or NA molecule. When sufficient changes develop, the drift becomes a shift. This usually results in a major pandemic. In the twentieth century, we have had the 1918 flu pandemic, the Asian flu of 1957, and the Hong Kong flu of 1968. But accurate prediction of when shifts will occur is very difficult and creates problems for public health policy makers.

Id.

When Joseph Califano became Secretary of HEW at the end of the swine flu program in 1977 he decided that a scholarly study of the entire program would be useful to policy makers. He asked Richard E. Neustadt and Harvey V. Fineberg, M.D. of Harvard University to make a study. This study was published as a book. Neustadt & Fineberg, The Swine Flu Affair, Decision-Making on a Slippery Disease GPO #017-000-00210-4 (1978) [hereinafter cited as Neustadt & Fineberg]. This book is the seminal study on this subject, and, unless otherwise footnoted, is the source of this article's material on the evolution of the swine-flu program. Nothing inconsistent with the Neustadt and Fineberg book was found in the many sources cited in this article that would effect my legal analysis.
On February 20, 1976, the media covered a CDC press conference on the swine flu cases. The Army, continuing its own investigation at Fort Dix, found many new influenza cases, but none were swine flu. Analysis of every civilian case of flu near the Fort showed no swine flu. By the end of February, the Army had found one death, perhaps thirteen sick men, and up to 500 recruits who had caught and resisted the disease. This latter group showed a rise in swine flu antibodies, but had no apparent illness.

On March 10, 1976, the federal group of agencies met to consider its options. The flu season ends in the Northern Hemisphere in March, but decisions had to be made before the next flu season. The four active vaccine manufacturers had produced about 20 million doses of Victoria vaccine for the civilian market that year. The vaccine is grown in eggs, and time is required to produce large amounts. A new vaccine would also require immunization trials and extensive testing. For a large immunization program, manufacturers would have to substantially increase production.

A major participant in swine flu policy making was David J. Sencer, M.D., Director of CDC. He was faced with a no-win situation. If a pandemic did not occur and the government prepared for one, it would be criticized for wasting money. If the government did prepare and there was a pandemic, it would be blamed if the program did not work well. Furthermore, the government had never before attempted to provide effective protection to millions of people in a short time. The all-out effort to respond before the next flu season would interrupt other work and divert resources from the many other CDC health research projects. The public health professionals were aware of the severity of the 1918 flu pandemic and knew that immunity was not present in the existing population. Since the infection brings on the disease within a few days, and inoculation brings about immunity in two weeks, an individual must receive the vaccine before the disease becomes established. Therefore, stock piling the vaccine would not be a viable option. The federal agencies’ recommendation was sweeping: a federal government purchase of the vaccine for the entire population. It would be produced by the private sector, field tested through NIAID, and licensed by BoB. States would be involved in planning an inoculation program to use

11 NEUSTADT & FINEBERG, supra note 10, at 8.
12 See Wecht, supra note 2, at 428.
13 See NEUSTADT & FINEBERG, supra note 10, at 9.
14 Domestic producers of influenza virus vaccine are: Lederle Laboratories; Merck Sharp & Dohme; Parke-Davis; and Wyeth Laboratories, Inc. NATIONAL ACADEMY OF SCIENCES INSTITUTE OF MEDICINE, VACCINE SUPPLY AND INNOVATION 162 (1985).
a mix of public and private services. The CDC would supervise the operations. The estimated cost was $134 million, $100 million for vaccine, and the rest for administration, surveillance and research. Dr. Sencer submitted the recommendation to the Secretary of HEW on March 15, 1976. The HEW hierarchy, aware that people travelling by jet aircraft could move the disease throughout the country in a few weeks, supported CDC, even though the risk was unknown. It was a risk where inaction was politically unacceptable.

On March 22, President Ford held a meeting on this subject. He, too, was aware it was a no-win issue. If there was a pandemic, no matter what the government did, it would not be enough. If the pandemic did not materialize, the government would be criticized for its expensive response. But the more important problems that actually developed were not called to President Ford's attention. He was not warned about side effects of the vaccine, children's dosage problems, the difficulties in obtaining liability insurance, and the problems of public relations.

President Ford decided to consult experts outside the government before deciding to proceed. On March 24, the experts, including both Doctors Salk and Sabin of polio vaccine fame, assembled. Doctor Salk strongly urged mass immunization. Doctor Sabin, who had previously indicated his support, ratified his position. President Ford asked the assembled experts for a show of hands on whether to proceed. All hands went up. He asked whether there were any dissents or objections. There were none. President Ford immediately held a press conference and, with Doctors Salk and Sabin flanking him, announced he was asking Congress for $135 million to inoculate every person in the United States. The media suspected the decision was a political one and covered it cynically; the cynicism was apparently fed by dissent from within CDC.

Congress responded with alacrity to the President's request for money. On April 9, 1976 the Senate acted. On April 12, the House followed and the appropriation bill became law on April 15.\textsuperscript{15} The Federal government was committed to inoculating 95 percent of the population — about 200 million people.

CDC staff specialists, however, considered the task to be impossible. Once allergic persons, infants, and the very ill were excluded, then perhaps 150 million inoculations would be a realistic target.

\textsuperscript{15} The appropriation was tacked on to a pending supplemental bill. There was therefore no authorization bill but rather an appropriation under Title III of the Public Health Service Act. The substantive health subcommittees wanted authorizing legislation which did come in August of 1976. NEUSTADT & FINEBERG, supra note 10, at 31 and 128.
However, a power struggle developed almost immediately to see who in HEW would run the program and CDC quickly lost. While CDC remained a participant and was involved in the important surveillance work, CDC in Atlanta failed to muster the Washington presence necessary to run the program. Theodore Cooper, M.D., Assistant Secretary for Health of HEW emerged as the director of the combined federal task force.\(^{16}\) Cooper, unfortunately, had no authority over the Office of General Council (OGC). This flaw became important as legal issues began to dominate the program during the summer of 1976.\(^{17}\)

On March 25, the key organizations within HEW met to determine program targets. The aim was to begin vaccination by August (in 1918, the virulent phase of the pandemic began in August). The government wanted 200 million doses to be manufactured, to be delivered beginning in June. There would be no further production of Victoria vaccine. Existing Victoria vaccine would be made bivalent\(^{18}\) by adding swine flu vaccine. This would provide 30 million doses for high risk groups — mainly the elderly. The rest of the vaccine would be a single dose, monovalent\(^{19}\) vaccine.

Dissent surfaced early in the program. On April 2, 1976, CDC hosted a meeting to acquaint state health officials and private sector medical representatives with the program targets and planning needs. During this meeting there was disagreement as to the need for such a program. A few state officials spoke out against the program, but there was tremendous professional pressure to close ranks and to support the government’s decision. The New York Times, however, editorialized against the swine flu program on February 23, and again on April 6.\(^{20}\) Furthermore, while other countries of the world took steps to inoculate high risk groups, none attempted to imitate the United States response.

The planning for field trials involved NIAID, BoB, and CDC. Vaccine from each manufacturer had to be tested as well as “whole” and “split” vaccine,\(^{21}\) because two different methods of preparing the

\(^{16}\) Despite Cooper’s power, the program was later criticized for having no clear line of command and no single lead. Id. at 36.

\(^{17}\) See NEUSTADT & FINEBERG, supra note 10, at 34.

\(^{18}\) The bivalent vaccine would provide protection from both swine flu and Victoria flu. Id. at 37.

\(^{19}\) Monovalent vaccine would provide protection only from swine flu.

\(^{20}\) See NEUSTADT & FINEBERG, supra note 10, at 40.

\(^{21}\) A “split” vaccine involves the process of taking the whole virus cell vaccine and separating out the toxic components from the protective ones.
killed-virus vaccine were used. One criticism of the trials was that children, who ordinarily need either stronger, or more, doses, for inoculations to be effective, were not tested with two doses.

While field trials progressed, CDC worked with state and local governments to develop implementation plans. Some jurisdictions dragged their feet because they did not support the inoculation program. By June, 1976, problems began to develop. Dr. Sabin publicly disagreed with the government’s program and advocated active stockpiling rather than immediate immunization. The field trials indicated single doses worked poorly on children. The whole cell vaccine did work but caused reactions ranging from sore arms to high fever. The “split” vaccine did not cause reaction problems, but it did not work. If more than one dose was needed, the production facilities, already strained, would probably not have the capacity to produce enough vaccine. Finally, CDC announced that the program would not initially vaccinate children. To most health professionals this decision did not make sense because children are usually the major targets for immunization; in previous pandemics, children were the primary disease spreaders. While critics cautioned and suggested a slower pace, CDC’s leadership advocated a full speed ahead approach. CDC’s approach was the one adopted.

B. The Legal System’s Response

1. Insurance Coverage

The first major crisis in the inoculation program occurred in June, 1976. The insurance industries refused to continue coverage for the manufacturers of vaccine; existing coverage expired on June 30. An indemnification bill went to Congress on June 16, but Congress was not in any hurry to agree to pay the prospective legal costs of the swine flu program. Thus, the manufacturers refused to bottle the vaccine, and the program slammed to a halt.

The primary reason for industry’s fear concerning the supplying of swine flu vaccine was the Fifth Circuit’s 1974 decision in the case of *Reyes v. Wyeth Laboratories*. In this case, the court upheld a jury award of $200,000 to an eighteen month old child who had contracted polio after receiving the Sabin live-virus oral vaccine. The vaccine carried a warning of its danger, but the warning was not

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conveyed to those receiving the vaccine. The court found the manufacturer strictly liable for the child’s injuries. The court used a two step analysis for defining an “unavoidably unsafe product”. A product is defective if it is unreasonably dangerous. However, a product is not unreasonably dangerous per se when the benefits from its use outweigh the potential harm. While the polio vaccine was not unreasonably dangerous per se, it was unreasonably dangerous as marketed because it was not marketed with an adequate warning. The court held that, when the manufacturer has reason to know that the drug will not be administered with an individualized medical judgment regarding the risk of treatment, a warning that reaches only the physician is insufficient. The manufacturer must give recipients sufficient information to enable them to balance risks and benefits.

When Mrs. Reyes, the mother of the infant plaintiff, took her daughter to the Hidalgo County Department of Health Clinic in Mission, Texas, she signed a standard release liability form used in Texas. The form conveyed no warning. She had a seventh grade education, and her primary language was Spanish. The vaccine had been purchased by the Texas Department of Public Health. Included with each vial of ten doses was a circular provided by the defendant Wyeth Laboratories that warned of potential dangers. The public health nurse who administered the shot had read the directions on the package insert but had not conveyed the warnings to the mother.

In products liability cases, the plaintiff must prove: (1) that the product caused the injury; and, (2) that a warning would have caused the plaintiff to act differently. In Reyes, the court paid little attention to the causation issue, despite expert testimony that estimated the child’s risk of contracting polio was one in 3,000, and the risk of contracting this type of polio from the vaccine was one in 5.88 million. The court did not require the plaintiff to show that a warning would have caused her to act differently. Instead, it held that there was a rebuttable presumption that the consumer would have read any warning and acted to minimize the risk.

24 Id. at 1273.
25 Id. at 1276.
26 Id. at 1277.
27 Id. at 1294.
28 Id. at 1270.
29 Id.
31 498 F.2d at 1264.
32 See Franklin &Mais, supra note 30, at 758.
33 498 F.2d at 1281.
The Reyes court’s reasoning is not persuasive. Polio existed in the community; indeed that is probably how Anita Reyes contracted polio. The mother’s choice was either to not vaccinate her child, which would be both dangerous for the child and illegal under Texas law, or to pay a private physician to administer the killed Salk vaccine\textsuperscript{34} to the child. The Salk vaccine, however, has disadvantages; it must be injected by hypodermic needle, and a separate inoculation is required for each of the three types of polio virus.\textsuperscript{35} Booster shots are also necessary. Since the killed virus Salk vaccine does not immunize the intestinal tract of the vaccinee the virus can be passed to others.\textsuperscript{36} Thus, under the circumstances it was irrational to argue that a warning would have changed the mother’s conduct.

The American Academy of Pediatrics (AAP) and the Conference of State and Territorial Epidemiologists (CSTE) had submitted amici briefs to the Fifth Circuit arguing that individual warnings, if required, would undermine immunization programs.\textsuperscript{37} These arguments were rejected, just as the trial court had rejected similar arguments by the defendant’s experts.\textsuperscript{38}

What is disturbing about the court’s decision is that the manufacturer was held liable, not the government agency that was supervised by physicians and supported by a legal system that mandates vaccination. Other courts have followed the Reyes court’s reasoning, and have required the manufacturer to warn consumers even though it is the medical personnel in the clinics that have the real opportunity to convey warnings.\textsuperscript{39} In one case, however, the court at least required the plaintiff to establish that he would have refused to take the vaccine if an adequate warning had been given.\textsuperscript{40}

It was, therefore, not unreasonable for the industry to conclude that the meaning of the Reyes case was that the plaintiff would win.

\textsuperscript{34} Killed Salk vaccine is one in which the pathogen has been killed or inactivated, whereas the Sabin attenuated vaccine is one in which the pathogen’s virulence has been decreased. The virus remains infectious for man but loses the ability to induce clinical disease. Both vaccines retain the ability to stimulate protective antibodies when the host is subsequently exposed to the disease.

\textsuperscript{35} \textit{THE MERCK MANUAL OF DIAGNOSIS AND THERAPY} 211 (Berkow 14th ed. 1982) [hereinafter cited as Berkow].

\textsuperscript{36} 498 F.2d at 1296.

\textsuperscript{37} Neal Nathanson, Professor of Epidemiology at The Johns Hopkins University School of Public Health, was an expert witness for Wyeth. Professor Nathanson testified that a great majority of vaccinees receive their inoculations in mass administrations or county clinics manned at least in part by volunteers. 498 F.2d at 1277.

\textsuperscript{38} 498 F.2d at 1294-95.

\textsuperscript{39} See, e.g., Davis v. Wyeth Laboratories, Inc., 399 F.2d 121 (9th Cir. 1968); Stahlheber v. American Cyanamid Co., 451 S.W.2d 48 (Mo. 1970).

\textsuperscript{40} Cunningham v. Charles Pfizer & Co., Inc., 532 P.2d 1377 (Okla. 1974).
This view was buttressed by other, less publicized, polio vaccine decisions that have almost always found the industry liable using a variety of legal theories.\(^{41}\) In *Grinnell v. Charles Pfizer & Co.*, liability was based on express warranty.\(^{42}\) In *Gottsdanker v. Cutter Laboratories*,\(^{43}\) the basis of liability was implied warranty. Negligence was the basis of liability in *Griffin v. United States*.\(^{44}\) Failure to warn, however, remains the legal theory most likely to succeed. The developing case law made the industry very jittery and unwilling to produce the swine flu vaccine without a substantial, government supplied, liability umbrella.

The government had expected to accept the duty to warn requirement in the contracts it made with manufacturers. The government would then avoid liability by providing a legally adequate warning, as well as a legally adequate release from those being vaccinated. The manufacturers did not believe they could avoid liability, let alone the expense of defending law suits, through contract. The pharmaceutical industry wanted indemnification through legislation, but HEW was not amenable to such a plan. The insurance industry was concerned with liability, but it was even more concerned with the overhead costs of adjusting and adjudicating individual claims. The uncertainties about the program, such as who would get what type of vaccine, further complicated underwriting and made the risks unacceptable. While the government was optimistic over the swine flu program, and was negotiating with four drug companies to produce the vaccine, the government was not negotiating with the pessimistic insurance companies.

Congress responded to the insurance industry as if it was trying to cheat the public. In June, 1976, the indemnification bill seemed unlikely to move. The insurance industry was adamantly against providing any insurance without it. On July 23, President Ford publicly advocated the passage of the legislation. On August 1, fate intervened. A new disease, named "Legionnaire’s Disease", was discovered in Philadelphia. Press coverage was extensive. While this disease was not swine flu, it created a climate that allowed the swine flu bill to become law.\(^{45}\) The bill sought to amend the Federal Tort

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\(^{43}\) 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (1960).


\(^{45}\) NEUSTADT & FINEBERG, supra note 10, at 135.
Claims Act to permit suits against the federal government by those who might be injured by the vaccine. Manufacturers would be liable in subsequent indemnification suits by the government, but only if negligence was proved.

The bill passed the Senate by voice vote. It was sent to the House and voted on with a no-amendment rule. There was not time to even give the members copies of the bill they were voting to pass. It passed easily and was signed by President Ford on August 12, 1976. The so-called “Swine Flu Act” became effective on October 1, 1976. Until then, the manufacturers and insurers refused to allow anyone to be vaccinated. On October 1, the mass vaccination program commenced in the states that had vaccine. In the first ten days, over a million Americans, not including children, received shots.

On October 11, 1976, in Pittsburgh, Pennsylvania, three people over age 70, with diagnosed cardiac problems, died shortly after receiving swine flu shots. The county suspended flu shots, and nine states followed its lead. The deaths received critical media attention despite CDC’s explanation that, among people 70 to 74 years old, about 10 to 12 deaths per 100,000 occur every day. Thus, elderly people dying the day after vaccination is to be expected. On October 14, President Ford was televised receiving his flu shot. Allegheny County and five states announced resumption of inoculations.

By December 16, 1976, more than 40 million swine flu shots had been given. This was twice the number of inoculations ever given previously for an influenza virus in a single season. By November, it had been decided that children would receive two doses of the split vaccine, but there was only enough vaccine to vaccinate one child in twelve. Some small states immunized 80 per cent of their adults; other states only reached 10 per cent.

It was in Minnesota, where nearly two-thirds of the eligible adults were immunized, that Guillain-Barre syndrome first appeared. Within a week, three more cases, one fatal, were discovered in the state. By then, CDC had learned of three more cases in Alabama and one in New Jersey. The unknown statistical relationship quickly led to the halting of the swine flu program. The decision to halt the program was made easier by the fact that swine flu had never appeared. On December 16, 1976 the program died, followed by a

47 NEUSTADT & FINEBERG, supra note 10, at 135.
48 Id. at 61.
49 See infra notes 61–69 and accompanying text.
barrage of critical media commentary. Many in the media blamed politics, but after more thorough analysis, it was the government's professional health bureaucracy leadership, not politicians, that deserved complete responsibility for the swine flu program.

In January 1977, Jimmy Carter became President, and Joseph Califano, a Washington attorney, was appointed Secretary of HEW. At the end of January, Victoria flu appeared in Miami, Florida. Mr. Califano had to decide whether to release the existing stock of bivalent vaccine that protected against both swine flu and the common Victoria influenza. By then the risk of developing Guillain-Barre syndrome appeared to be eleven times greater for recipients of swine flu shots. The overall risk of developing Guillain-Barre was a remote one chance in 105,000 and the risk of death was 1 in 2 million among those vaccinated. However, there was no swine flu epidemic anywhere in the world, and, until the end of January, not even Victoria influenza in the United States. Mr. Califano assembled an advisory group, with members from outside the flu medical establishment, to present their conclusions. On February 7, 1977 they recommended the suspension of bivalent vaccine be lifted for high-risk groups facing possible Victoria flu. The Secretary accepted the recommendation immediately. In March, a similar decision-making process ended the mass-inoculation swine flu program.

The swine flu program left a continuing legacy. National commissions made immunization policy. The federal government assumed most legal liability, and it played the major role in the immunization program. This program diminished the credibility of health professionals, and demonstrated their limited ability to perform accurate risk assessment. It also taught us that when the members of scientific or medical professions play politics, their well-intentioned zeal does not guarantee desirable results.

2. Tort Liability

When the immunization program ended, the tort battle began. The National Swine Flu Immunization Program of 1976 made the United States the defendant in cases arising from swine flu vaccine. The swine flu vaccine was legally defined as vaccine against A/New Jersey/76 (Hsw 1N1) influenza, or such a vaccine in combination with vaccine directed at A/Victoria/75. The Act provided a remedy for

51 Id. at § 2 (j)(3).
claims brought within two years after the date the claim arose. Several provisions, however, provided for a tolling of the statute of limitations. The Act gave protection to: (1) the manufacturers and distributors of swine flu vaccine; (2) public and private agencies or organizations that provided inoculations without charge for such vaccine or its administration and in compliance with the informed consent form and procedures; and (3) medical and other health personnel who provided or assisted in providing inoculations without charge. The United States had an indemnification right against the program participants based on contract or negligence. Suits could be brought in state or federal district court, but state court actions could be removed to the federal district court by the United States government. The liability of the United States could be based on any theory of liability provided by the law of the state where the act or omission occurred, including negligence, strict liability in tort, and breach of warranty. The United States could also be liable under the Federal Tort Claims Act (FTCA) if the government was negligent. The act made more than fifty sets of state product liability and malpractice laws applicable as well as FTCA law.

The Act was upheld despite constitutional challenges based on claims alleging denial of due process, infringement of equal protection, violation of the right to jury trial, and intrusion on the Tenth Amendment. By the summer of 1981, approximately 4,000 administrative claims had been filed, resulting in more than 1,500 suits in federal district courts. The basis for most cases was Guillain-Barre syndrome, but other cases claimed a wide variety of injuries, including neurological diseases and allergic reactions.

III. GUILLAIN-BARRE SYNDROME LITIGATION

Since the decline of poliomyelitis, Guillain-Barre Syndrome (GBS) has emerged as the most frequent cause of acute or subacute severe,

52 Id. at § 2 (k)(2).
53 Id. at § 2 (k)(1).
54 Id. at § 2 (k)(7).
55 Id. at § 2 (k)(4)(B).
56 Id. at § 2 (k)(2)(A).
57 Id. at § 2 (k)(1)(B).
59 Rheingold & Shoemaker, The Swine Flu Litigation, 8 Litigation 28 (Fall 1982) [hereinafter cited as Rheingold & Shoemaker].
60 Id.
generalized human paralytic disease. In the 1970's the etiology of this disease was unknown. More recently, it is presumed to be the result of an immunologic attack on the peripheral nerves. GBS is thought to be either a primary virus infection or a form of neuro-allergy caused by either an antecedent illness or an immunizing injection. It has followed diarrhea caused by water pollution, but GBS usually occurs after recovery from an infectious disease. Experts have also noted that it has occurred as a rare complication of immunization with influenza vaccine.

Diagnosis of GBS is difficult, and the criteria are not universally established. Over the years the criteria, originally proposed by Dr. Guillain and others in 1916, have been expanded to include manifestations which other authors have thought belonged in this syndrome. The syndrome involves bilateral muscle weakness.

The severity of the illness varies considerably. If the patient survives the acute phase, the prognosis is good, and recovery is usually rapid and complete. During its acute phase, GBS mortality rates may reach 25 percent. Death is usually caused by respiratory and vasomotor paralysis. The treatment is symptomatic and supportive, with emphasis on complete nursing care in an intensive hospital setting.

When the swine flu inoculation program began, the consent forms did not mention Guillain-Barre Syndrome as a risk. The syndrome

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62 LUCKMANN & SORENSEN, MEDICAL-SURGICAL NURSING 680 (2d ed. 1980) [hereinafter cited as LUCKMANN & SORENSEN].
63 Berkow, supra note 35, at 1386. But see THE MERCK MANUAL OF DIAGNOSIS AND THERAPY 1361 (Holvey 12 ed. 1972) (concluding that the etiology was unknown) [hereinafter cited as Holvey].
65 Silman, Outbreak of Guillain-Barre Syndrome Associated with Water Pollution, 1 BR. MED. J. 751 (1978).
66 MEDICAL DICTIONARY, supra note 6 (N.B. the 5th ed. did not define Guillain-Barre syndrome).
68 The syndrome involves bilateral muscle weakness of the lower motor neuron type, with or without cranial nerve or sensory abnormalities, acute or subacute onset and evolution of signs and symptoms, and absence of other conditions such as diabetes mellitus, alcoholism, neoplasia, etc. Holvey, supra note 63, at 1361.
69 Vasomotor paralysis involves the failure of the nerves having muscular control of the blood vessel walls.
70 See LUCKMANN & SORENSEN, supra note 62, at 680–81.
was a disease whose cause was unknown, and no causal relationship between the vaccine and GBS had been demonstrated. Although nearly twenty million doses of influenza vaccine had been given in the United States each year for twenty years, the reported incidence of GBS following influenza vaccination was almost nonexistent.\(^{71}\) One report reviewing 1,100 cases of GBS found one case related to vaccination.\(^ {72} \) Another study reported one case of GBS following vaccination by a different vaccine, but concluded that there was no way to prove or to disprove the etiologic relationship.\(^ {73} \) Moreover, analysis of the small number of cases of GBS following any type of vaccination would be inadequate without reference to the fact that fifty-eight to eighty percent of GBS patients had some type of infection prior to the onset of the syndrome. Prior to 1976, the incidence rate of GBS was one or two cases per 400 million vaccinations and, therefore, statistically insignificant.\(^ {74} \)

When the swine flu program began, CDC established a surveillance system that was more sophisticated than anything ever before attempted by the public health community. A center, operational 24 hours a day, used the best technology and the best computer hardware available to track the program.\(^ {75} \) Later, the program was criticized for being set up more to collect data than to rapidly deal with the dangers created by the vaccine.\(^ {76} \) The careful collection of data did permit useful post-mortem analysis of the program.

By December 15, 1977, preliminary data indicated that the incidence of GBS among those who received the swine flu vaccine was approximately seven times greater than among those not vaccinated. These apparent associations were what ultimately resulted in the suspension of the swine flu program on December 16, 1976 and the expansion, nation-wide, of GBS surveillance.\(^ {77} \) The period of primary increased risk of GBS lasts five weeks after vaccination, although cases can occur for nine or ten weeks. The surveillance uncovered 532 GBS patients who had recently received influenza vaccinations and fifteen patients who had been vaccinated after the onset of GBS.

\(^{72}\) Id.
\(^{73}\) Id.
\(^{74}\) Id.
\(^{75}\) See Neustadt \& Fineberg, supra note 10, at 34.
\(^{76}\) Id. See also supra note 1.
The attack rates for recipients of monovalent and bivalent vaccines were not significantly different. The elevated attack rate existed in every age group. Furthermore, no single manufacturer's vaccine was related to a significantly different rate of GBS. The estimated attributable risk of vaccine-related GBS was one case per 100,000 vaccinations. There were fifty-eight fatalities reported during the time of surveillance.\(^{78}\) During the six-week risk period, the number of cases that can be attributed to the vaccine ranged from 211 to 246; the number is slightly higher if the risk period is considered to run for eight weeks.\(^{79}\) At the termination of the vaccination program in December 1976, approximately 40 million Americans had participated.

By early 1977, the cases became so numerous that the Judicial Panel on Multi-District Litigation ordered the consolidation of all the swine flu cases for pretrial discovery in the District Court for the District of Columbia.\(^{80}\) Since the government produced 50,000 documents during pretrial discovery, the thousands of plaintiffs elected fourteen law firms to serve as a Swine Flu Litigation Steering Committee.\(^{81}\)

By April 1985, the number of claims had climbed to 4,165; 278 of these were already settled, and the government considered 413 of these “denied and settled”.\(^{82}\) The settled cases cost the government $6,715,519 and the cases deemed denied and settled cost the government $35,208,225.\(^{83}\) The total cost was $41,923,744 for the swine flu claims.\(^{84}\) Approximately two thirds (2,813) of the claims have been denied.\(^{85}\)

In all, 1,604 law suits were filed, and 706 have been dismissed. The government settled 372 cases for $35,208,225. There have been judgments in 52 cases, where liability was stipulated, that have totaled $16,999,856. Where liability was contested, the government won 259 out of the 307 cases tried, resulting in an 84 percent win

\(^{78}\) Id.

\(^{80}\) Rheingold & Shoemaker, supra note 59.

\(^{81}\) Id.

\(^{82}\) DEPT. OF JUSTICE, supra note 3.

\(^{83}\) Id.

\(^{84}\) Id.

\(^{85}\) Id.
rate for the government. The 48 cases, which the government lost, cost $24,310,114, resulting in an average cost of over half a million dollars per case. There are 167 cases still pending. The total amount paid by the government, as of April 1985, was $83,233,714 plus the costs of administering the claims and law suits and the judicial costs of handling the law suits. The original cost of the swine flu program was estimated at $134 million, of which $100 million was for vaccine. The legal costs appear to have almost reached the vaccine cost.

The GBS litigation provides an important lesson for health policy makers. Epidemiological analysis, even well after the end of the swine flu program, showed an increase in GBS of at most twelve times the incidence in those not vaccinated. However, because the incidence was low, even among those vaccinated, only one person for each 83,000 Americans would get GBS due to the swine flu program. However, much of this evidence, from a legal perspective, is of little value in avoiding tort liability. Significant evidence indicates that, for ten weeks after receiving a swine flu inoculation, the occurrence of GBS in the vaccinee is more likely to be due to the vaccine than to other factors. A more conservative estimate is that for five weeks after vaccination, the vaccine is the most likely cause of GBS. This lower estimate is derived from the argument that the background rate of thirty-two cases per week, that was used in the earlier studies, was too low, and that fifty-six cases per week is a more accurate background rate. This change in assumptions results in a much lower number of GBS cases that can be related to vaccine.

For plaintiffs' lawyers, the chance of recovering for a GBS case occurring within five weeks after vaccination is nearly absolute. For cases occurring within ten weeks of vaccination, the chance of recovery is almost as high, because the government has been willing to settle almost all cases where GBS was contracted within ten weeks of a swine flu shot. Such settlement offers were based on a study

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86 Id.
89 Without a swine flu program, there will be thirty-two new cases per week in the United States from other causes.
by Schonberger and others. Thus, the swine flu statute provides for recovery for nearly all persons, regardless of individual causality who have had GBS within ten weeks following an inoculation.

While causation can be a significant problem for a plaintiff’s attorney, it was not a major problem for GBS victims who developed GBS during the appropriate time period. Occasionally courts have disregarded scientific evidence and awarded damages for GBS which developed more than ten weeks after the vaccination. For example, in Sulesky v. United States, a victim of GBS recovered damages even though the disease first manifested three months after the injection. In Cook v. United States, the GBS plaintiff first exhibited the disease twelve weeks after the inoculation.

Although the plaintiff who becomes ill within 10 weeks of inoculation avoids one causation problem, there are other medical and legal causation problems which must be addressed. In fact, proof of causation is often the biggest headache for plaintiffs’ attorneys in toxic tort cases. The major causation issue found in GBS cases is whether the disease is in fact GBS and therefore subject to being caused by an inoculation. The problem is created because the symptoms of the disease are amorphous. A diagnosis may be a physician’s judgment that would not be universally accepted. It has been pointed out in a swine flu context what most litigators know all too well: witnesses can be found to testify to almost anything. This permits nonmeritorious cases to go forward, and if in the hands of a fuzzy-minded judge, bizarre decisions can follow.

Only 16 percent of the litigated cases have been won by plaintiffs. However, the stakes are high, and the uncertain outcome is enough of a crap-shoot to encourage the gamble of a trial to verdict. Furthermore, given the uncertainty surrounding swine flu reactions, some of the more peculiar swine flu decisions that favor plaintiffs may have been correctly decided. But the legal literature is replete with swine flu cases that strain scientific credulity.

92 See Schonberger & Bergmann, supra note 77.
93 See supra note 50 and accompanying text.
95 545 F. Supp. 306 (N.D. Cal. 1982).
97 See Black & Lilienfeld, supra note 91.
98 See supra note 3 and accompanying text.
99 In Grubbs v. United States, 581 F. Supp. 536 (N.D. Ind. 1984), a GBS onset five months after inoculation resulted in a $721,040 damage award. In Unthank v. United States, 732 F.2d 1517 (10th Cir. 1984), an award of $333,431 was given for transverse myelitis. In Heath v.
The swine flu litigation is coming to an end, but its legal legacy threatens the many inoculation programs upon which public health — world wide — is dependent. The ability of our society to develop new vaccines to fend off current and emerging diseases is also threatened. Furthermore, the increasing legal requirements imposed on those giving vaccinations, such as the warning requirements,100 are only one aspect of the overall trend in products liability favoring plaintiffs. The decline of the state-of-the-art defense could remove the ability of vaccine manufacturers to avoid liability for unknowable side effects. 101 While this affirmative defense may still be more applicable in a drug case than in most product liability cases,102 few vaccine manufacturers today would be willing to believe that courts would not hold them strictly liable. 103 However, in the swine flu context, the overwhelming majority of courts seem to have compensated GBS victims who were made ill by the swine flu vaccine (at least, to the extent that our limited knowledge of the etiology and incidence of the GBS disease allows). The outer limits of product liability theory were not considered because recovery was based on statute.

The costs of the swine flu program, while substantial, were not unreasonable on a per shot basis. The $134 million federal program, with some locally incurred costs, provided 40 million vaccinations. 104 The cost was under $4 per shot. The compensation costs to date of

United States, No. 77F1113 (D. Colo. 1980), a structured settlement with an estimated payment of $1.2 million was made to a plaintiff who contracted encephalomyelitis (a viral inflammation of the brain) after receiving a swine flu injection. In Titchnell v. United States, No. 78-86 (W.D. Pa. 1981), a 71 year old man suffered a stroke within one day of receiving a swine flu vaccination. Medical experts testified that, if a medical history had been taken, the clinic personnel would have known that, because of his prior history of stroke, the plaintiff should have been lying down when he received the shot. The plaintiff received $147,400 plus $22,158 for medical expenses. His wife received $50,000 for loss of consortium. In Hasler v. United States, 517 F. Supp. 1262 (E.D. Mich, 1981), a woman suffered crippling arthritis ten days after receiving a swine flu inoculation. Defendant's expert testified that the plaintiff suffered from Still's disease (juvenile rheumatoid arthritis) the cause of which is not known. Plaintiff's experts testified she suffered from a rheumatoid disorder, with symptoms additional to those found in a normal case of Still's disease, and that they arose as an immunological reaction to the swine flu shot. She recovered $1.5 million. In another case involving rheumatoid arthritis, however, the court rejected the claim and stated that the overwhelming weight of medical literature opposed a theory that associated swine flu vaccine with the plaintiff's injuries. Gicas v. United States, 508 F. Supp. 217 (E.D. Wis. 1981).

100 See e.g., Petty v. United States, 740 F.2d 1428 (8th. Cir. 1984).
104 NEUSTADT & FINEBERG, supra note 10, at 68.
$83,233,714 are approximately $2 per inoculation. If legal, administration costs and the costs to complete the pending 167 cases are included, the total compensation costs are likely to range between $2 to $5 per inoculation. The most probable figure is about $3 per shot. Thus, the federal government spent approximately $7 per shot.

Should society accept the public health benefit of inoculations and not compensate its victims? In a just society, the answer should be no. The difficult issue, however, is whether a better compensation system can be developed. The controversy continues today, and is focused on the DPT program.

IV. THE DIPHTHERIA, PERTUSSIS, TETANUS PROGRAM

The Diptheria, Pertussis, Tetanus ("DPT") controversy arises amidst claims that the United States manufacturers do not produce the best or safest vaccines; that information concerning their safety is sometimes withheld from the public; and that the federal monitoring of immunization reactions is unlikely to detect a bad batch of vaccine. That this controversy should arise over such an "apple pie and motherhood" program causes significant concern. In the United States, diptheria and tetanus toxoid are usually incorporated with pertussis vaccine to produce DPT vaccine. It is the pertussis component, aimed at preventing whooping cough, that is the subject of the current concern.

In the 16th century in Europe, whooping cough was responsible for thousands of deaths. Until the last few decades, it remained a major cause of early childhood mortality. Today, recovery is common due to better medical care, but the disease is still considered a severe one. Some victims have serious sequelae including central nervous system damage. After vaccination for this disease became widespread, there was a sharp decrease in the disease. In recent years, the disease incidence has been increasing in England and other developed countries where vaccination rates declined due to widely publicized accounts of brain damage believed to have been caused by the vaccine.

105 See DEPT. OF JUSTICE, supra note 3.
108 The reported serious reactions fall into three groups: (1) shock that is occasionally lethal
The reaction of the medical community to the DPT controversy has been to stress that the medical complications from whooping cough, in the absence of an immunization program, would be far greater than the medical problems traceable to the vaccine. However, rational medical judgment is hampered by the scarcity of reliable data. Neither the incidence of the disease pertussis, nor the rates of adverse reactions, are established by reliable information. Cases of pertussis go unrecognized by physicians because the disease can be difficult to identify from clinical symptoms, and, even if recognized, it is not always reported. Verification of the infection by isolation of the organism requires culture methods not used routinely in many diagnostic laboratories; serologic testing is not feasible for routine diagnosis. For children who have been vaccinated, the disease may be diagnosed as bronchitis because the characteristic “whoop” will often not be present, and physicians assume that vaccination will have prevented whooping cough.

The incidence of vaccination complications is also subject to uncertainty because of the questionable nature of available data. Private physicians, who administer half the DPT shots in the United States, are not required to report adverse reactions. Even if a physician wishes to report a reaction, there is no single data collection agency. If such information is sent to the vaccine manufacturer, it must be maintained in a complaint file for one year. The file must be accessible to the FDA. The doctor might send a report to the state’s health department, which is supposed to forward it to CDC’s Monitoring System for Illness Following Immunization (MSIFI) or the information might be sent directly to CDC. However, the only doctors who are required to use the MSIFI system are doctors in public health clinics. Even this system fails to generate accurate data because the system depends on voluntary reporting by parents.

Furthermore, some states only forward reports to CDC if

and similar to the sudden infant death syndrome (SIDS) (though a relationship between SIDS and the vaccine has not been established); (2) febrile seizures which seem to appear at a elevated rate in the first two weeks after a DPT immunization; (3) infantile spasms, noninfectious encephalopathy, prolonged convulsions and possibly Reye's syndrome (this last problem, however, is not generally accepted as a DPT reaction. Severe brain damage can result, followed by death in many cases). See Miller, Alderslade & Ross, supra note 106.


110 NAT'L ACADEMY OF SCI., INSTITUTE OF MEDICINE, NEW VACCINE DEVELOPMENT ESTABLISHING PRIORITIES, 172, (1985) [hereinafter cited as NAT'L ACADEMY OF SCI.].

111 Parents seeking vaccination for their children receive a consent form. At the bottom of the form is a telephone number and instructions to call if the child gets sick in the four weeks
the child is hospitalized. Thus, the extent of under reporting is unknown. Though half of the DPT shots are administered by private physicians, less than ten percent of the MSIFI data comes from this source.\textsuperscript{112}

The ubiquitous DPT vaccination program has been subject to almost no studies to evaluate adverse reactions. The studies that have been undertaken are flawed. The medical establishment usually claims an incidence of adverse reaction as 1 case per 110,000 injections and the incidence of serious disorders, such as encephalopathy with persistent neurological dysfunction one year later as 1 case in 310,000 injections.\textsuperscript{113} Fatal reactions are established to be 1 to 2 cases per 10 million injections.\textsuperscript{114} Most estimates are based on the work of Miller in Great Britain\textsuperscript{115} and the federally funded study made by UCLA School of Medicine in 1978 and 1979.\textsuperscript{116} The British studies involve a different vaccine than is used in the United States as the British vaccine has a potency of about one half of the World Health Organization standard.\textsuperscript{117} The British sacrificed vaccine effectiveness in order to obtain increased safety.\textsuperscript{118} As Miller states,

\begin{quote}
[b]ecause of the broad nature of both the underlying assumptions and the wide confidence limits of the derived risk ratios, these estimates must be interpreted with extreme caution and cannot be regarded as precise measures.\textsuperscript{119}
\end{quote}

The United States' study\textsuperscript{120} is addressed to the American vaccine, but it is also flawed. The study did not include children who had previously experienced adverse reactions to DPT shots. Yet, as the cases discussed later will show, in the real world many children with contraindications are vaccinated. The study also fails to identify the number of children involved. Instead all data is given in terms of shots. Since the recommended immunization schedule is to get four

\textsuperscript{after vaccination. If the parent telephones, clinic personnel are supposed to fill out a form and send it to CDC.}

\textsuperscript{112} COULTER & FISHER, DPT: A SHOT IN THE DARK, 149 (1985) [hereinafter cited as COULTER & FISHER].

\textsuperscript{113} See NAT'L. ACADEMY OF SCI. supra note 110, at 173.

\textsuperscript{114} Id.

\textsuperscript{115} See Miller, Alderslade & Ross, supra note 106.

\textsuperscript{116} Cody & Baraff, Nature and Rate of Adverse Reactions Associated with DPT and DT Immunizations In Infants and Children, 68 PEDIATRICS 650 (Nov. 1981) [hereinafter cited as Cody & Baraff].

\textsuperscript{117} See Miller, Alderslade & Ross, supra note 106, at 6.

\textsuperscript{118} In addition, the number of children participating in the British field trials was insufficient to detect rare reactions.

\textsuperscript{119} See Miller, Alderslade & Ross, supra note 106, at 19.

\textsuperscript{120} See Cody & Baraff, supra note 116.
DPT inoculations between the age of two months and eighteen months, with a booster shot before entering school, risk statistics based on shots significantly underestimate the risk to children who receive multiple shots. Thus, the UCLA study underestimates the risk to children by a factor greater than two, assuming about 7000 children were involved. The study placed a forty-eight hour limit within which reactions had to occur to be included in the study. Two infants died within four days of the shot, but the 48 hour restriction allowed the report to state, “no sequelae were detected following reactions”. Eighteen children had convulsions or hypotonic hyporesponsive episodes, but there was no follow-up to determine whether long-term damage resulted. Unusual high-pitched crying was not considered a major reaction, yet children with that reaction were not given further pertussis vaccine. Cases that follow show that public health workers or physicians frequently vaccinate and injure such children. One must recognize that since most American children have had DPT shots, it is very difficult to get a baseline against which to evaluate the effect of the vaccine. It is also difficult to run clinical studies in light of ethical concerns for the human involved. Nevertheless, it seems apparent that any national policy that emerges concerning the DPT vaccination program will be based upon poor data concerning both the incidence of the disease and the adverse reactions to its vaccine.

The UCLA study concluded that local reactions to the vaccine occurred in 64 percent of the DPT vaccine recipients, and minor systemic reactions occurred in 50 percent. A control group that received only DT immunization experienced less-frequent and less-severe reactions. Convulsions and hypotonic hyporesponsive episodes occurred in one of every seventeen hundred and fifty immunizations, though no one in the study developed encephalopathy or permanent brain damage within the forty-eight hour period used in the study.

A strong public reaction to the perceived adverse effects of DPT vaccination has been developing, despite continued assurances from the medical community that the benefits of vaccination far outweigh

121 See Holvey, supra note 63, at 61.
122 See COULTER & FISHER, supra note 112, at 245.
123 Id.
124 Id.
125 See Cody & Baraff, supra note 116.
126 Id.
the risks. These reactions have led to an increase in the frequency of law suits and efforts to change the laws mandating vaccination. In Sweden, England, Wales, and Japan the rate of DPT vaccination has decreased, or the vaccine's potency has been reduced, because of the public's fear of severe reactions. In these countries the incidence of the disease pertussis has been increasing. Health professionals in the United States fear a similar pattern could develop in this country.

Law suits following DPT vaccine have become common. Such suits are brought against the vaccine manufacturer, the health care provider, or both. Suits against the manufacturer can only be prosecuted with great difficulty based on a claimed defect in the vaccine. One explanation, discussed above, is the lack of good data to demonstrate the risk of injury. Another explanation is that existing data is held by the government or by the manufacturers, and neither are required to cooperate in providing such data to litigants. Consequently, a claim against the manufacturer, in reported cases, is usually based on an alleged defect in labeling.

Suits brought against the health care providers based on medical malpractice claims require proof that acceptable medical care was not provided. Such proof usually involves the existence of a contraindication, or a condition in the patient where administration of the vaccine would be precluded by prudent medical care standards. Three parties bear responsibility for informing physicians when not to vaccinate: the manufacturers of vaccine; the American Academy of Pediatrics (AAP); and the United States Public Health Service (PHS). The most important standard is the AAP's Committee on Infectious Diseases report called the "Red Book". It is the standard used by private physicians. The PHS's Advisory Committee on Immunization Practices (ACIP) makes recommendations for physicians in public health clinics. These are published by CDC in the Morbidity and Mortality Weekly Report.

127 See supra notes 109–10; 116 and accompanying text.
129 Id.
130 See infra notes 134–43 and accompanying text.
131 97th Cong., 2d Sess., May 7, 1982 (testimony of Marge Grant).
132 See supra notes 134–38 and accompanying text.
There are some inconsistencies among the guidelines, but all groups agree further pertussis vaccination is contraindicated if previous reactions to the vaccine included: high fever, convulsions, encephalitis, collapse, shock, or focal neurological signs. High-pitched screaming or somnolence is a probable contraindication in the "Red Book," but is an absolute bar according to both the ACIP and the manufacturers. A history of convulsions in the child or the immediate family is a contraindication in West Germany, East Germany, Japan, and England, but is not usually listed in the American guidelines. It is against this medical background that law suits should be evaluated.

In Holcomb v. United States, the plaintiff received a series of DPT shots in army clinics and then suffered encephalopathy. The parents brought suit against the United States under the Federal Tort Claims Act and against Richard-Merrell, the vaccine manufacturer. The government settled for $390,000, Richard-Merrell contributed $210,000.

In Wilson v. United States, Air Force physicians gave a DPT shot to a child who had severe reactions to previous DPT inoculations. The adverse reaction left the child permanently, severely retarded. The suit was brought under the FTCA and the plaintiff agreed to a structured settlement with a present value of $2,299,948.

In Piefer v. Devitt, a pediatrician gave a third DPT shot to a child who had adverse reactions to the first and second shots. The plaintiff suffered febrile reactions and convulsions that left the child mentally retarded, requiring 24 hour care. A jury awarded the plaintiff $3.05 million.

In Toner v. Lederle Laboratories, a jury in Boise, Idaho awarded nearly $1.2 million to the parents of a child who developed transverse myelitis, allegedly as a result of a DPT shot. According to the plaintiff’s lawyer, the case turned on whether Lederle's vaccine was

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133 See COULTER & FISHER, supra note 112, at 190.
135 Encephalopathy is any dysfunction of the brain.
136 Holcomb, supra note 134.
139 Tarr, DPT Vaccine Injuries: Who Should Pay?, NAT’L. LAW JOURNAL 1 (April 1, 1985) [hereinafter cited as Tarr].
140 Transverse myelitis is an inflammation of the spinal cord. Death may result in a few days from upward extension and involvement of respiratory muscles.
as safe as another vaccine, Tri-Solgen, which was manufactured by Eli Lilly. That case is now on appeal before the Ninth Circuit.\textsuperscript{141}

In \textit{Tom v. Wyeth Laboratories},\textsuperscript{142} a brain-damaged girl received a settlement of $7.5 million from a private doctor and Wyeth Laboratories. In \textit{Morris v. Parke, Davis & Co.},\textsuperscript{143} the plaintiff suffered irreversible brain damage as a result of a DPT shot. Since the plaintiff was unable to identify the specific manufacturer of the vaccine, the suit was brought against five pharmaceutical companies which produced a substantial share of the DPT vaccine marketed in 1965 on a market share theory of liability. Ruling on a pretrial motion, the court held that, if the plaintiffs proved causation and could show that one or more of the defendants marketed the drug with conscious disregard for the health of consumers, then the plaintiffs will be entitled to recover punitive damages from each defendant.

It has been reported that there have been an estimated 150 lawsuits involving pertussis vaccine.\textsuperscript{144} Plaintiffs are seeking $1.5 billion in damages. Industry is settling most of these cases as a large corporation is unlikely to win before a jury when a very sick child is the plaintiff. The industry claims the financial impact is substantial,\textsuperscript{145} and vaccine manufacturers are leaving the field. In 1963, eight drug companies made the DPT vaccine. In 1984, there were only two U.S. companies left. In 1986, Lederle Laboratories is the only manufacturer left because Wyeth Laboratories stopped production, citing rising liability problems. Two state health departments, Michigan and Massachusetts, make their own vaccine.\textsuperscript{146} In addition, a Canadian company, Connaught Laboratories, distributes a more expensive vaccine through E.R. Squibb & Co. Connaught stated it might stop distribution too, but seems to have stayed in the market.\textsuperscript{147} The mix of who within the industry is producing each type of

\textsuperscript{141} Tarr, \textit{supra} note 139.
\textsuperscript{142} Id.
\textsuperscript{143} 573 F. Supp. 1324 (C.D. Cal. 1983).
\textsuperscript{144} \textit{Damage Lawsuits Settled For Millions}, The Fresno Bee, reprinted in DPT (Dec. 1984).
\textsuperscript{145} It is not easy to obtain a truly accurate picture of the fate of plaintiffs who sue for alleged DPT Vaccination injuries. Both industry (which seeks to avoid liability through federal legislation) and plaintiffs' lawyers, have a vested interest in publicizing large damage awards. There is, however, no overall source of information on the disposition of DPT cases filed. This is different from the swine flu example where the government is always the defendant. Claims against individual medical health providers are even more difficult to identify than the claims involving manufacturers.
\textsuperscript{147} Connaught removed DPT from its price list and limited its distribution to existing large
vaccine is rather volatile, but overall the industry is in a state of decline. Because of the costs of litigation, it is claimed, the price of the vaccine jumped from 12 cents to $2.80 per dose.

Whether the manufacturers of vaccine are permanently leaving the field, or are orchestrating a program to encourage Congress to relieve them of liability is difficult to determine. The president of Lederle Laboratories has testified before Congress that the total dollar demand of DPT lawsuits against them is 200 times greater than the total sales of DPT vaccine in 1983. Wyeth Laboratories which left the market because of "extreme liability exposure, cost of litigation and the difficulty of continuing to obtain adequate insurance" is continuing to produce vaccine, but it is distributed under the Lederle label. Wyeth sells the vaccine to Lederle at 20 cents a dose and Lederle charges $2.80 a dose to its customers but assumes litigation costs. Since these private corporations are not required to provide financial records for review, it is difficult to determine whether this sharp price increase is for political, legal, or business reasons (or a mix of all of them).

The litigation concerning DPT vaccination would diminish if a safer vaccine was developed. Unfortunately, for many reasons, the chance of this happening is small. The most important reason is that the medical establishment does not consider DPT vaccination reactions to be a serious problem. Physicians refer to the studies discussed earlier in this article, and conclude that the benefits of vaccination far outweigh the risks. The epidemics of whooping cough that have developed in Japan and in the United Kingdom are frequently cited to support this position. The American Academy of Pediatrics estimates a serious permanent neurological disorder will follow one out of every 310,000 DPT vaccinations. Including multiple inoculations, about 15 million doses are given in the United States each

contracts with public health departments and hospitals. However, by May 1985, Connaught seemed to be actively back in the market. Sun, The Vexing Problems of Vaccine Compensations, 227 SCIENCE 1012 (March 1, 1985) [hereinafter cited as Sun].


149 Id.

150 Id. at 295.


152 See Sun, supra note 147.

153 See 1984 Hearings supra note 148, at 73.
year. Still, the AAP supports vaccination, on the grounds that pertussis, the disease, produces ten times the rate of brain damage as the DPT vaccine, and other complications are more common for the disease as well. The National Academy of Science (NAS) estimates the risk from DPT to be 1–2 fatalities in 10 million injections and serious neurological dysfunction one year later to be 1 in 310,000 injections. These estimates, however, are projected on the basis of the flawed studies discussed above. Perhaps for this reason the NAS recommends an improved vaccine.

What vaccine is available to American consumers is not determined by health considerations alone, but is dependent as well upon business decisions made by companies whose profit incentive may sometimes conflict with their health protection goals. To put it another way, the nation may be unwilling to pay the costs necessary to produce a safer vaccine. Thus, manufacturers may have the technology to produce better vaccine, but the market will not support a price high enough to allow them to do it.

For example, one DPT vaccine, Tri-Solgen, existed on the United States’ market more than twenty years ago, but in 1975, Eli Lilly & Company, its manufacturer, stopped producing it. Tri-Solgen sold well, but was dropped because it was not profitable enough. Merck & Company developed two promising experimental partial-cell vaccines but never marketed them. They later patented another process for making partial-cell DPT vaccine, but never marketed it either.

The issue of profit is a complex one too. The vaccine market is an international one; vaccine is bought and sold at a fraction of the United States’ price. Furthermore there is excess industrial capacity in the international production of biologicals which limits their profitability. International buyers are price sensitive, so they negotiate contracts through organizations, such as the Pan American Health Organization, to get the lowest price possible. Thus, a substantial

156 Id.
158 Id.
159 Id.
160 Id.
156 See 1982 Hearings, supra note 151, at 33 (testimony of Mr. Umstead).
162 Id. at 9 (testimony of Dr. Cooney).
American investment in development of a new vaccine would be risky if the vaccine’s cost would not be acceptable to foreign purchasers.

To produce an improved DPT vaccine would take five years; the cost of development would be about $20 million and there would be an estimated 90 percent probability of success.\(^{163}\) Some time and about half the cost could be saved if the Japanese acellular vaccine, used in Japan since 1980 and now being reviewed, could be approved for use in the United States.\(^{164}\) A major problem for any new vaccine will stem from clinical trials. It will be difficult to find a meaningful control group because the incidence of the disease in the United States is so low. However, it would be unethical to use a placebo on a control group, because an effective and generally safe vaccine already exists. In order to have a new vaccine licensed, alternative testing methods that would be legally acceptable to NIAID may have to be developed.\(^{165}\)

Whether a new vaccine is developed will most likely depend on the political pressures that build in the coming years. Both the manufacturers and the medical establishment argue that the existing vaccine is effective, inexpensive, and has few adverse effects. The National Academy of Science study,\(^{166}\) outlining priorities for new vaccine development, offered recommendations based on a series of assumptions concerning available development funds. Under no assumption was pertussis ranked among the five diseases that would be best targets for new vaccine development. At the same time, however, the report recognized that the side effects of DPT vaccination may cause a widespread misconception about the risks and benefits of other vaccination programs. Therefore, a small reduction in morbidity and mortality might be justified in this case when public health priorities are set.\(^{167}\) As will be made clear in the material below, even the National Academy of Science understands the need to grease a squeaking wheel.

The problems associated with the DPT vaccine have led to extensive lobbying efforts to enact new legislation. The major citizen group involved in this issue is DPT (Dissatisfied Parents Together),\(^{168}\) located in the Washington, D.C. area. This organization is run primarily by parents whose children were adversely affected by DPT

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\(^{163}\) See Nat’l. Academy of Science, supra note 110, at 178.

\(^{164}\) Id.

\(^{165}\) Id.

\(^{166}\) Morgenstern & White, supra note 72, at 129.

\(^{167}\) See Nat’l. Academy of Science, supra note 110, at 124.

\(^{168}\) The address for Dissatisfied Parents Together is: 128 Branch Road, Vienna, Va., 22180.
shots. They argue that physicians, scientists, drug manufacturers, and federal health agencies have known for years that DPT vaccine causes severe neurological damage, and that death occurs in an unknown number of children. They have challenged much of the data used to support HHS's position favoring DPT inoculation.

Dissatisfied Parents Together does not advise parents to refuse DPT shots for their children. It does advise parents to ensure that the person giving the shots gets a complete medical history including information about neurological diseases and siblings' experience with the disease. The group warns that the child should be healthy when the shot is given, and that administration of the vaccine should be delayed for premature babies or babies with neurological problems. Following the shot, parents should watch their children carefully for three days. Their advice is not very different from that of the American Academy of Pediatrics. What the DPT organization stresses, which the American Academy of Pediatrics does not, is that the parents have a right to refuse the vaccination. The DPT organization has been active in encouraging parents to understand their rights before submitting their children to DPT vaccination.

169 1 DISSATISFIED PARENTS TOGETHER NEWS 17 (Fall, 1983).
172 See Sun, supra note 147. See also supra note 112 and accompanying text.
173 The questions posed in Pertussis Vaccine: Information for Parents, DISSATISFIED PARENTS TOGETHER, (1983) included: A. Is vaccine for pertussis legally required before my child may enter school? If so, how many shots are required? What flexibility does the law provide if a parent wants to defer the pertussis shots until the child is two years or older? What is the legal consequence if my child does not get the required number of shots before he or she enters school?; B. Does the law say that a child does not have to be vaccinated if his parents have a “personal conviction” or “philosophic objection”, i.e., if parents believe vaccination is not in the child's best interest? Does the law provide an exemption on the grounds of religious conviction?; C. What is the legal definition in your state or county of a “medical exemption” to the pertussis vaccine? What latitude is given to the physician's judgment as to whether or not the pertussis vaccine is medically contraindicated for a particular child?

The DPT organization stresses that, using government data, as of December, 1983, nine states did not have laws requiring DPT vaccination as a precondition for school entry: Arizona, Kentucky, Missouri, Montana, New York, Oregon, Pennsylvania, Rhode Island, and Washington. Twenty-two states permit parents to object to a mandated DPT 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, in these states a child may 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 will exempt a child from the vaccine requirement if the parent objects on the grounds of religious conviction. Vaccine laws vary from state to state, and even from county to county. A few states do not require DPT vaccine at all, and some areas require only three or four shots. Different school districts have different rules.
Dissatisfied Parents Together thus encourages parents who object to vaccination to use legally available means to avoid it. They have had one legislative success at the state level. On May 29, 1984, Maryland became the first state to adopt the vaccine reform legislation supported by the DPT organization. The law requires health care providers to give the parents written information regarding the risks and benefits of all required vaccines. Health care providers must record the name of the manufacturer and the lot number of all DPT vaccinations administered. The law requires health care providers to record any severe DPT vaccine reactions and to report them to the state health authorities. The State Health Department is required to identify contraindications to the vaccine and categories of high risk children. Individual doctors are authorized to exempt any child from mandatory DPT vaccination if the doctor finds that the risks of the vaccine outweigh the benefits to both the potential recipient and the public.

The new statute may limit the effect of Syska v. Montgomery County Board of Education. In Syska, decided in 1980, the court held that the exclusion of pupils who had not been immunized against rubella did not violate the constitutional rights of mothers who had personal, philosophical objections to the immunization program, even though the statute provided an exemption for people who have religious objections to immunizations. The new statutory exemption for individual children, if limited to contraindications along the lines of those listed in the “Red Book,” does little more than demand that physicians not engage in malpractice. If, on the other hand, the statute enables parents to opt out of the state’s vaccination program and the parents use it to do so, then the public health value of vaccination programs could suffer. Despite this worrisome issue, the information and record keeping requirements imposed by the statute will be useful.

Since the United States Supreme Court decided Jacobson v. Massachusetts in 1905, it has been clear that a state’s police power regarding pre-entry vaccination requirements. See Pertussis Vaccine: Information for Parents, Dissatisfied Parents Together (1983). See also U.S. DEPT. OF HHS, CENTERS FOR DISEASE CONTROL, DIVISION OF IMMUNIZATION, STATE IMMUNIZATION REQUIREMENTS APPLICABLE TO ANY OR ALL GRADES K-12 (December, 1983).
permitted the enactment of compulsory vaccination legislation. In that case, the statute provided an exception for "children who present a certificate, signed by a registered physician that they are unfit subjects for vaccination." The plaintiff, however, was an adult who sought to avoid smallpox vaccination based on the fear of an adverse reaction which he experienced as a child. The Court, after reviewing the development of the English and American laws of compulsory vaccination, upheld the statute but left open the possibility that the plaintiff Jacobson had a right to avoid vaccination if it could be shown with reasonable certainty that he was not a fit subject for vaccination, or that vaccination would seriously impair his health or probably cause his death. Thus, the current DPT controversy echoes the history of smallpox vaccination. Regulations requiring all school children to be vaccinated or to face exclusion from public schools have been upheld. However, exceptions when the health of the child makes the vaccination unsafe have also been upheld.

Most states have exceptions for those with religious objections to vaccinations. Unfortunately, those children whose parents' religion forbids immunizations may still develop communicable diseases, and those children can infect others in the population whose immunity is not complete. A recent example of this danger occurred at Principia College in Illinois where 100 students developed measles, and three students died. The college is a Christian Scientist institution; since Christian Scientists do not believe in medical intervention the student body lacked the usual immunizations. The college did, however, permit 415 of the approximately 750 students and staff to be immunized after the measles outbreak.

Concern over religious freedom must be balanced against society's need to be protected from disease. This was the position taken by the Mississippi Supreme Court when, in 1979, the statutory religious exemption from immunization was held to be a violation of the Fourteenth Amendment. The court concluded it would be unfair to

180 Id. at 12.
181 Id. at 39.
185 Id.
require the bulk of the school children to be vaccinated, and at the same time expose them to the hazard of associating with children who were exempted from compulsory vaccination. In a similar case, the State Supreme Court of Arkansas held that parents have no legal right to prevent vaccination of their children, even based on their good faith religious beliefs.\footnote{Cude v. State, 377 S.W.2d 816 (Ark. 1964).} The court quoted the Supreme Court of the United States: “the right to practice religion freely does not include liberty to expose the community or the child to communicable disease or the latter to ill health or death . . . .”\footnote{Id. at 819 (quoting Prince v. Comm. of Mass., 321 U.S. 158 (1943)).} This court ruled that the Arkansas probate court should appoint a guardian to take custody of the children with directions to have them vaccinated despite the father's testimony that if the children were taken from him and vaccinated he would not accept them back.

It may be understandable that parents who have seen their children suffer and even die from DPT vaccination complications should lobby for laws that limit required vaccinations, even though the potential effect might be to end effective immunization programs. Nevertheless, the effect of such legislation is adverse to public health interests. Unfortunately, the DPT immunization issue is complicated by its history of an insensitive health bureaucracy, and a manufacturing system that only provides the public with vaccine when it is profitable to the industry. Consequently, if safer vaccines are to be developed, federal subsidies must be provided whenever development costs are substantial and benefits are modest. This puts citizens seeking an improved DPT vaccine into a large group of disease lobbyists, each of whom seeks a larger slice of the federal public health budget. Since a new DPT vaccine is unlikely to be produced in the near future, citizen efforts today seem to be directed at allowing citizens the right to opt out of the system.

The host of exceptions to the need for obtaining vaccinations found in state law is unwise. The exceptions so far have existed without much ill result because few people have utilized them. If we are to have organized resistance to health programs, the societal tolerance of individual idiosyncrasies must end if public health is to be protected. The only exception from required vaccination should be in situations where the shot is contraindicated for medical reasons specific to the individual, keeping in mind that for DPT the list of contraindication may need to be expanded.
More governmental attention must be paid to the supervision of public health programs. Vaccines are not as safe as they could be, and the surveillance system is not designed to collect valid data upon which rational public policy can be made. Adverse DPT reactions could be reduced, however, by more careful decisions concerning when and who to vaccinate. Perhaps one way to encourage such improvements would be to force the public to absorb the costs of compensating vaccine-induced injuries. This is the focus of DPT bills that recently have been introduced in Congress.

V. PROPOSED NATIONAL LEGISLATION

On September 23, 1982, Senator Hawkins introduced a bill\(^1\) that called for a study of the DPT vaccine. Secretary of Health and Human Services Schweiker agreed to carry out the study under existing administrative authority, making the proposed legislation unnecessary. During 1983, Congressional hearings were held on the DPT issue, and on November 17, 1983, Senators Hawkins and Hatch introduced the National Childhood Vaccine Injury Compensation Act.\(^2\) More hearings were held in the spring of 1984, and on June 7, 1984, Representative Waxman introduced a similar bill in the House of Representatives.\(^3\) Although the House held hearings in the fall, the year ended without action on either of the bills. Senator Hawkins introduced a revised bill,\(^4\) on April 2, 1985, cosponsored by Senators Hatch, Bumpers, and Matsunaga. This bill is supported by the Academy of Pediatrics, Dissatisfied Parents Together, the Association of State and Territorial Health Officers, the American Nurses Association, and numerous other health-oriented organizations.

Another bill\(^5\) was introduced by Congressmen Madigan and Brynhill on March 27, 1985. Their bill is far less comprehensive than the Hawkins bill. It would give the drug companies, not the plaintiffs, the right to choose a compensation system. Compensation for vaccine-induced injuries would be discretionary, with a cap of $1 million on all compensation or tort recovery.\(^6\) There would be no compen-

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\(^2\) *Id.*
\(^3\) *Id.*
\(^6\) *Id.* at § 2107(b).
sation for death caused by vaccine.\textsuperscript{195} The Department of Health and Human Services would have control over the compensation and the program could apply to any vaccine listed by HHS.\textsuperscript{196}

On the other hand,\textsuperscript{197} the Hawkins bill is a far more comprehensive bill because it provides for compensation as well as vaccine reinsurance. In addition, it has a number of provisions designed to assure a safer childhood vaccination program in the future. It creates an affirmative and enforceable duty for HHS to promote the development of safer vaccines.\textsuperscript{198} Citizen suits are provided to force HHS to carry out the bill’s requirements.\textsuperscript{199} Recording and reporting of major reaction to vaccine is mandatory and other requirements are imposed that are aimed at improving surveillance and recall.\textsuperscript{200} Record keeping and reporting requirements for manufacturers are also made more stringent.\textsuperscript{201} The Secretary of HHS would have discretionary authority to provide for pooling arrangements, reinsurance or direct insurance to assure the availability of mandated vaccines at reasonable prices.\textsuperscript{202}

The bill’s most important, and most controversial, aspect involves its compensation provisions. Plaintiffs could elect to sue a manufacturer in tort, or could utilize the administrative and judicial system provided in the bill.\textsuperscript{203} Plaintiffs would bring an \textit{ex parte} civil action in the U.S. District Court for the District of Columbia and that court would designate special masters or magistrates to take evidence and develop a record.\textsuperscript{204} The magistrates would develop proposed findings of fact and conclusions of law subject to \textit{de novo} determination by the court.\textsuperscript{205} Appeals would be to the Court of Appeals for the District of Columbia Circuit and would be heard on an expedited schedule.\textsuperscript{206} If a plaintiff selects the tort approach, state law would be applied except that liability cannot be based solely on the manu-

\textsuperscript{195} Death resulting from vaccination is not listed as a compensable injury. \textit{Id.} at \S 2107(b).
\textsuperscript{196} The Act would add a new title XI to the Public Health Service Act. The Act’s proposed coverage is set forth in \S 2114(3) of the Act.
\textsuperscript{198} \textit{Id.} at \S 2144.
\textsuperscript{199} \textit{Id.} at \S 2161.
\textsuperscript{200} \textit{Id.} at \S 2141–43.
\textsuperscript{201} \textit{Id.} at \S 2145.
\textsuperscript{202} \textit{Id.} at \S 2121–2126.
\textsuperscript{203} \textit{Id.} at \S 2104.
\textsuperscript{204} \textit{Id.}
\textsuperscript{205} \textit{Id.}
\textsuperscript{206} \textit{Id.}
manufacturer's failure to directly warn the parent or the person vaccinated. 207

If a claimant is found to be eligible for compensation, then payment of damages is mandatory. 208 Pain and suffering damages are limited to a maximum of $100,000, plus the amounts necessary for medical care, education, rehabilitation, and custodial care necessary for the child to achieve maximum feasible potential and enjoyment of life. 209 Since a severely injured child may consume care and education that exceeds $10,000 a month, the amount recoverable can thus be very large. Damages can also include the anticipated loss of earnings when the child becomes an adult. 210 If death occurs, recovery will not be less than $300,000 or more than $700,000 plus expenses incurred. 211 Attorneys' fees are added to the award so as not to diminish the amount given to claimants. 212 After the federal government pays the award, it can then sue the physician, or other health care providers, based on negligence or the manufacturer for providing a defective or unreasonably dangerous vaccine. 213

The most unusual feature of this bill is that injuries that occur within the time period set forth in a vaccine injury table are deemed to be vaccine-related, and compensation is made mandatory. 214 It includes as compensable events those occurrences in which there is no scientific consensus as to whether or not the occurrences were caused by, or related to, the vaccine. 215 To avoid paying, the government would have to prove through incontrovertible evidence that other causation was responsible. Measles, rubella, polio, and related vaccines are also covered. The bill sets forth the evidence requirements to ensure that claimants have every possible opportunity to collect. If all the evidentiary aids still do not provide a basis for recovery, the petitioner can use any credible evidence that the injury was caused by a vaccine listed on the vaccine table. 216

For DPT vaccine, in addition to the diseases recognized as being related to these shots, the Secretary is required to review all relevant medical and scientific information and to determine the rela-

207 Id. at § 2102 (c) (2) (A).
208 Id. at § 2107.
209 Id. at § 2107(a)(1)(3), (b)(1), and (b)(2).
210 Id. at § 2107(a)(4).
211 Id. at § 2107(a)(2).
212 Id. at § 2107(f).
213 Id. at § 2108.
214 Id. at § 2105.
215 Id.
216 Id. at § 2105(a)(2).
tionship of the vaccine to a host of maladies including autism, learning disabilities, and hyperactivity. If such a relationship is found, the DPT vaccine table will be modified appropriately.217

This bill does not solve the liability problems of manufacturers or health care providers who face law suits based on strict product liability. The bill does, however, abolish liability based solely on the failure to provide a direct warning to the injured parties or the parties' parents.218 The manufacturers and health care providers can still be sued at the claimants' option, or by the government in a subrogation action. In the bill, the government is encouraged to provide subsidized insurance to manufacturers.219 The government may find itself paying for both the compensation system and the insurance so that it can sue in a subrogation action. The bill provides that compensation would be paid from a National Vaccine Injury Compensation Trust Fund, which may in turn be derived from charges on vaccines. Such a fund is designed to encourage the production of safer vaccines. However, sufficient discretion is given to HHS so that the Secretary has the latitude to attempt other methods of shifting costs to manufacturers.221

The large number of children vaccinated each year in the United States, the bill's liberalized evidence rules, and the broad scope of compensable injuries, make the potential cost of this bill enormous. The largest cost component of the Hawkins bill will be compensation for lost earnings. This is expected to compromise 63 percent of the average cost per case. Attorneys' fees, at 17 percent of the average cost per case, are the second largest component. Medical costs and rehabilitation costs combined are expected to amount to about 10 percent of the cost per case.222 Since most victims are children, the major cost will be to cover wages children might eventually have earned.

The potential expense was one reason the Reagan Administration opposed the bill as originally drafted. The Congressional Budget Office estimated that the program could cost $4.9 billion for the first three years.223 If the number of diseases covered by the bill expands, the costs of compensation could become astronomical. With an open-

217 Id. at § 2105(c).
218 Id. at § 2102(c)(2)(A).
219 Id. at § 2126.
220 Id. at § 2110.
221 Id.
222 See 1984 Hearings, supra note 148, at 75.
223 See Sun, supra note 147.
ended right to any and all medical services necessary to achieve "maximum feasible potential," the injured person or his parents have a federal, medical blank check. In an era of great concern for soaring medical costs, another law with major inflationary potential may be unwise.

This bill provides a useful subject for debate and its provisions for improvement of the vaccine programs deserve serious consideration. The concept of a compensation trust fund, through which the cost of vaccine can reflect at least some of the social costs, is a commendable one. However, the bill seems to be drafted with the assumption that public funds are infinite and that sick people have a right to unlimited federal resources. Unfortunately, both concepts are at variance with current economic and political reality.

What is needed is a compensation system modeled along the lines of workers’ compensation. Basic costs of medical care and rehabilitation costs would be covered, as well as actual lost wages. Perhaps a stipend could be paid to those who could not work because of vaccine-caused injuries. There would be no payment for pain and suffering.

A person developing a disease who did not receive a vaccination should not be eligible for compensation because immunizations are required for public benefit, so it is important that those injured by vaccination are better treated than those not vaccinated even if a vaccination was not given because of contraindication. Such individuals would be in no worse a position than they would be without the vaccination compensation program, in which case they would have to rely on traditional methods of financing for their health care.

The standards for recovery should be relatively generous in order to assure coverage for all actual victims, even if some injuries of questionable medical causation are covered. Compensation would be modest. The federal compensation payments would exist as a lien against any tort settlement or tort judgment. This would tend to reduce tort claims of questionable legal validity as well as those involving minor injuries. Litigation could be further controlled by allowing only recoveries in excess of the lien to be the basis for attorney fees. Tort actions against health delivery personnel would be unchanged, though it might be useful to define informed consent in the statute.\footnote{There seems to be no reason to shelter health care providers from malpractice claims in}

\footnote{224 Id.}
\footnote{225 See generally, Larson, Workers’ Compensation Law (1984).}
Manufacturers would be liable in tort if they provided defective vaccine. Vaccine that was produced to federal standards should benefit from at least a rebuttable presumption of soundness. In addition, manufacturers should not be liable for failure to warn the ultimate consumer when adequate warnings were given to health care professionals administering the vaccine program. Traditional tort liability would, however, still subject manufacturers to the cost of administering claims and litigation, which was a major concern in their demand for the protection provided in the Swine Flu Act. However, such claims would be reduced by requiring fault as a condition of liability and limiting the basis for attorneys' fees.

The Hawkins bill provides that plaintiffs may elect to sue in tort, or to apply for federal compensation. This approach maximizes the cost, while failing to address the needs of manufacturers who are exposed to major liability. The costs are maximized because of legal theories that make fault irrelevant, and that require manufacturers to be insurers, even though their business may be uninsurable.

The cost of a compensation approach is difficult to compare to a tort system approach. A compensation system could benefit a group that, depending on the statute's language, covered some, all, or a group larger than those injured from vaccines. The tort system usually provides a much larger recovery to a smaller portion of those injured. When a bill such as the Hawkins bill allows plaintiffs to choose, costs are maximized because those with strong tort cases will pursue that remedy and those with weaker claims will seek federal compensation.

VI. CONCLUSION

The pressure is on the public health profession to improve the public's perception of their performance. The swine flu program is perceived by the public as a governmental failure, even though the major problem was that the disease did not appear. DPT is still an issue that, at this writing, is surrounded by controversy. A reservoir of public frustration exists, and its depth is dependent upon the vaccine area. One cannot read the case law concerning vaccination injuries without being aware of the number of cases of obvious failure to provide acceptable medical care. There may be reasons to reexamine the entire medical malpractice field in light of soaring costs, but vaccine-related injuries are an insignificant part of the problem. See Dentzer & Tsuruoka, Malpractice Insurers Are Ill, NEWSWEEK (April 29, 1985) at 58.
number of Americans who perceive their children's health problems to be vaccine-related.

Since the French chemist Louis Pasteur (1822–1895) developed the technique of immunization and produced vaccines, the world has depended on them to control disease. His vaccine replaced such rabies treatments as filling the wound with gunpowder and then setting it afire or suffocating the victim between two mattresses. With a disease as deadly as rabies, the side effects of the vaccine are accepted, and today, with a much safer vaccine, 15 to 30 thousand Americans are treated for possible exposure to rabies. Unlike the rabies vaccine, most vaccinations are given before a person is exposed to the disease and thus few recipients of vaccines are choosing as clearly between probable death from the disease and the considerably smaller risk of dying from the preventive treatment.

Vaccination programs aimed at providing protection before exposure to the disease depend upon the population developing a high percentage of immune individuals to limit or prevent transmission of the disease. This is called “herd” immunity. For example, when the level of measles immunity in the population exceeds 53 percent, one study found epidemics were unlikely to develop. This concept of trying to use vaccination as a control measure applies primarily to disease where human-to-human transmission occurs. Since receiving a vaccination always carries some risk, the truly rational person would seek to avoid vaccination but would require everyone else to get one. This type of thinking could cause vaccination programs to become ineffective. If everyone could choose whether or not to be immunized, the necessary level of immunity in the population might not be maintained. This is an example of classical Hobbesian theory; there must be submission to the sovereign to maintain public order — the society must require immunization. The public health requirement of population-wide vaccination is accompanied by a compelling moral responsibility to compensate those who are injured by cooperating for the benefit of the “herd”. Moreover, today those who are inoculated may receive little personal benefit if the disease is largely absent. For example, in 1984 only 7 polio cases were reported in the United States. Since 1969 most polio cases were caused by vac-

228 See MEDICAL DICTIONARY supra note 6, at 1239.
229 Williams, A Disease Most Awful, AUDUBON, July 1984 at 16.
cine. Sometimes inoculations are given to one group to protect a different group such as injections given to prevent rubella (German Measles). Children receive the shots, but the target population to be protected is pregnant women and their unborn children. Vaccines are the only consumer goods required to be consumed by law. Since consumption often benefits the public far more than the recipient, justice requires that those receiving the benefits of having their fellow citizens vaccinated must share in the cost of caring for those whom fate or malpractice has decreed will be victims.

The obligation to pay compensation should be a federal one. Now that product liability law has removed fault and, perhaps, even the need to know that a danger might exist, the tort system's capacity to modify conduct has all but disappeared. Moreover, the manufacturers' unknown and long term continuing exposure to liability denies private insurers the ability to properly evaluate risk and determine the premiums. Although it is in the national interest to have an assured supply of vaccines available for public health protection, few manufacturers will sell products for a price of $3 thereby assuming a potential risk of legal damages in excess of $1 million. The vaccine industry exists in a tenuous state in which tort liability could drive the few remaining manufacturers out of the business. If the case law continues to develop as it has, and punitive damages are allowed against manufacturers in inadequate warning cases, we may find ourselves with no vaccine. While there is a declining number of DPT vaccine manufacturers, there is only one manufacturer each for polio, measles, German measles, and mumps vaccines. If any of these producers leave the marketplace, children

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233 As the American vaccination programs have become heavily federalized, decisions made by the federal government have largely come to determine what vaccines will be developed and when they will be licensed. The testing required by the federal government can delay or prevent a vaccine from being marketed. After licensing, the federal government has a major role in ensuring the safety of the manufacturing process. It can require testing of all lots produced, or statistical sampling of production, or merely rely on detailed descriptions by the manufacturer of its production steps (called protocols). For a discussion of the federal government's tort liability, see Griffin v. United States, 500 F.2d 1059 (3d Cir. 1974); Loge v. United States, 662 F.2d 1268 (8th Cir. 1981).

Since the Poliomyelitis Vaccination Assistance Act of 1955, the federal government has played a major role in the distribution of vaccine. More recently the federal government became involved in compensating victims as well. See Technical Information For Congress: Report to the Subcomm. on Science, Research, and Development of the Comm. on Science and Astronautics, 92d Cong., 1st Sess. (1969), revised April 15, 1971.

could go without immunization. There is a wealth of literature addressing the question of who should bear the risk of an activity causing harm. Under tests such as who can best avoid the harm, and who can best absorb the costs there is little reason to hold vaccine manufacturers liable in the absence of traditional fault concepts.

If Congress develops a national program to compensate vaccine-induced injuries, they must address several issues: which types of vaccinations will be covered; whether such a program continues to force those supplying vaccine to be at least as careful as they would be under a tort system; and whether there are compensable diseases causally related to the vaccination within acceptable limits of error.

A policy is needed that will encompass new advances in medicine. For instance, in the near future there may be a herpes vaccine developed. The other major subject of vaccine research is Acquired Immune Deficiency Syndrome (AIDS). CDC estimates that up to 1 million Americans have been exposed to or infected by the AIDS virus. The disease is spreading throughout the world, and is assuming the characteristics of a pandemic. Work goes forward on a vaccine. However, the complications discussed earlier concerning influenza could recur with AIDS because the antigen that stimulates production of specific antibodies varies considerably from strain to strain of the disease. Thus a single vaccine, even if it works, will

235 Judge Learned Hand analyzed these problems in the context of duty in United States v. Carroll Towing, 159 F.2d 169, 173 (2d Cir. 1947). He held that the duty of a plaintiff depended on the probability of injury, the gravity of the injury, and the burden of taking adequate precautions. This kind of analysis would not support the present trend toward strict liability for vaccine producers. More modern writers have produced much material on economic approaches to tort liability, but this literature does not supply much justification for holding manufacturers liable either. See generally RABIN, PERSPECTIVES ON TORT LAW (2d ed. 1983); POLINSKY, AN INTRODUCTION TO LAW AND ECONOMICS (1983).
236 Tetanus toxoid vaccine, for example, has few neurological complications. Tetanus toxoid vaccine may not be necessary to include in a compensation program. But pertussis and diphtheria vaccinations are usually given as a series of inoculations that include tetanus toxoid protection (DPT). Diphtheria shots do have complications and pertussis has become very controversial. From a policy point of view, it would make sense to include all the vaccines that are widely required for children by state law. This would include vaccination for tetanus, pertussis, mumps, diphtheria, measles, rubella, and polio (though, only the last four are required by all states).

Other diseases that are the subject of vaccination include typhoid, rabies, pneumonia, dysentery, and cholera. In the United States, however, these diseases are not the subject of widespread immunization programs, and therefore do not seem to require political or legal attention.

not wipe out the disease. The head of CDC’s task force on AIDS warns that if a practical vaccine is developed it will probably have to be administered to every citizen in the country.239

Other diseases for which vaccine research is ongoing include cancer, toxic shock syndrome, rheumatoid arthritis, diarrhea, malaria, infant meningitis, croup, pneumonia, and strep throat. Furthermore, the advances in recombinant DNA methods promise to produce new vaccines that may protect against more than one disease.240 It seems clear that there must be some reform of the legal system to address the issues involved in vaccination programs. The legal problems will only intensify as we move towards implementing programs which entail far more uncertainty than was the situation in the swine flu program.

In the swine flu program, the legal system worked reasonably well to compensate those injured. The legal system also has had an unquantifiable beneficial restraining effect on the federal health bureaucracy. However, on balance, the tort system of compensation without fault is inadequate because in order to function properly, it requires scientific judgment beyond the ability of most judges and juries. The inefficiencies of the tort system result in an expensive system which compensates a far larger group than the group that is actually injured by vaccine.241

If the incidence of medical side effects to the vaccine had been high, the costs of running the swine flu compensation program could have been extraordinary. In passing the swine flu legislation, Congress was lucky. Congress did not have such good luck with the black lung program242 which has turned into a foray on the national treasury.243 The black lung program began in 1969 and was intended to give temporary compensation to an estimated 100,000 retired miners.244 Two days before the passage of the 1969 legislation, a

240 Id.
241 Raeburn, Multipurpose Vaccines, High Tech., April 1985, at 70.
242 For example, in the swine flu program, the best scientific evidence indicates that less than 300 people were injured. If we compensate those who had a greater than 50 percent probability of injury from swine flu vaccine, the compensated group should have numbered approximately 600. To date there has been almost double that number of people compensated and 167 cases were pending as of April 1985. It can be expected that a compensation system will lead to recovery for those who can present a credible potential claim (a group much larger than the group actually injured).
Congressional committee expanded the proposed legislation to provide compensation for simple pneumoconiosis, as well as for complicated pneumoconiosis. In 1972, the Act was amended to make it easier for claimants to collect. The U.S. Supreme Court upheld the statute in 1976. In 1978, the program was amended again to make it still easier for miners to collect, and a Black Lung Disability Trust Fund was created to finance some of the liability through an excise tax on underground and surface-mined coal. By


246 Conf. Rep. 761, 91st Cong., 1st Sess., reprinted in 1969 U.S. Code Cong. & Ad. News 2578, 2603-06. Pneumoconiosis can be complicated or simple, neither of which is defined in the statute. Simple pneumoconiosis is diagnosed when fibrotic clusters in the lung produce x-ray opacities of 1 cm. or less or fibrotic masses on autopsy smaller than “massive lesions”. Simple pneumoconiosis may have some effect on the blood/gas exchange capacity of the lungs; it is not considered disabling and is seldom productive of significant respiratory impairment. Lopatto, The Federal Black Lung Program: A 1983 Primer, 85 W. VA. L. REV. 677, 679 (1983).


250 The 1969 Act contained three presumptions: (1) a coal miner with 10 or more years of underground coal mine employment who had coal worker's pneumoconiosis was rebuttably presumed to have contracted pneumoconiosis as a result of his coal mine employment; (2) a coal miner with 10 or more years of underground mine employment who died of any respirable disease was rebuttably presumed to have died due to coal worker's pneumoconiosis (this presumption was eliminated by the 1981 amendments); and (3) a coal miner with a chronic dust disease of the lung which was diagnosed by chest x-ray to meet certain criteria or was diagnosed by biopsy or autopsy to yield massive lesions created an irrebuttable presumption that the miner was totally disabled due to pneumoconiosis or that his death was due to pneumoconiosis. Pub. L. No. 91-173, § 411(c), 83 Stat. 742, 783 (1969).

The first presumption allows the claimant to establish that his disease arose out of his employment. The last two presumptions equate different lung diseases with coal worker's pneumoconiosis and thereby extend benefits to a much larger class of persons than those who are totally disabled due to pneumoconiosis.

The 1972 amendments added a fourth presumption. This presumption provided that: (1) if a miner was employed for 15 or more years in an underground coal mine; (2) his chest x-ray was negative for complicated pneumoconiosis (the third and most serious stage of the disease); and (3) other evidence established the existence of a totally disabling respiratory or pulmonary impairment, then the miner was presumed to be totally disabled by pneumoconiosis or his death was presumed to have been caused by it. Pub. L. No. 92-303, § 4(c), 86 Stat. 150, 154 (1972). This presumption ignored the cause of the respiratory or pulmonary impairment; it could be due to many factors not related to exposure to coal dust. The 1981 amendments repealed this presumption in regard to all claims filed after the effective date of the 1981 amendments.

With the 1978 amendments, Congress added another presumption: the “widows’ presumption.” If a miner who died before March 1, 1978 and had been employed for 25 or more years in a coal mine before June 30, 1971, the eligible survivors shall be entitled to benefits unless it can be established that the miner was not totally or partially disabled from pneumoconiosis
the end of 1981, 542,000 miners, dependents, and survivors of deceased miners had collected over $10 billion in benefits paid from general appropriations. In addition, by 1981, the Trust Fund had a deficit of 1.4 billion dollars and a projected deficit of 19.2 billion dollars by 1995.

The black lung program is the one federal program aimed at compensating members of the public who have a specific disease. Compared to the problems involved in determining causation for vaccination-related injuries, the black lung diagnosis is simple. Yet the black lung program has demonstrated the tenacity with which potential claimants, their lawyers, and their elected representatives attempt to change statutes and regulations to allow recovery from the federal treasury. Proposed programs to compensate those exposed to agent orange, ionizing radiation, or toxic dumps all suffer from the problem that accurate identification of the persons and injuries caused by the offensive substances is impossible with our current level of scientific and medical knowledge. The government's experience with the black lung program should emphasize to the drafters of any new compensation program the importance of dealing meaningfully and convincingly with the need for accurate cost projections and cost containment.

The Hawkins bill is a thoughtful legislative proposal. Its chance for eventual passage would be enhanced if the overall costs were lowered through less generous payments and tighter causation requirements. When, and if, a federal compensation program is en-

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at the time of his death. Pub. L. No. 95-239, § 3(a), 92 Stat. 95, 96 (1978). If the miner met the requirements under this provision regarding length of employment and date of death, his beneficiaries were entitled to benefits even if the miner's death was totally unrelated to his coal mine employment. This presumption was repealed by the 1981 amendments as of their effective date. 30 U.S.C. § 921 (1982).


252 Lopatto, supra note 246, at 678.

253 A Government Accounting Office (GAO) random study of Social Security Approvals indicated that 88.5 percent were not based on adequate medical evidence establishing total disability or death from black lung disease. LEGISLATION ALLOWS BLACK LUNG BENEFITS TO BE AWARDED WITHOUT ADEQUATE EVIDENCE OF DISABILITY, H.R. Doc. No. 80-81, 96th Cong., 2d Sess. (1980). After the 1981 legislation a similar conclusion was made by GAO concerning the Department of Labor's implementation of the 1978 amendments. LEGISLATION AUTHORIZED BENEFITS WITHOUT ADEQUATE EVIDENCE OF BLACK LUNG OR DISABILITY, H.R. Doc. No. 82-26, 97th Cong., 2d Sess. (1982).

Even without a compensation program, the federal government still pays, because it sup-
acted, its scope of coverage and generosity of payments will undoubtedly be a function of what the projected costs will be. After the legal surprise generated by the swine flu program and the black lung program, legislators will be wary of amorphous and ambiguous federal compensation programs. The tort system, particularly when it was based on fault concepts, served society by making a person or corporation responsible for the effects of their wrongdoing. This system is threatened as concepts for redistribution of wealth have come to dominate the tort field. Perhaps in an era prior to the industrial revolution, the tort system could be a social insurance system. Today it is not working well. The legislative proposal made here is a conservative one. It is designed to preserve the virtue of a tort system designed to redress wrongs. At the same time society, as the beneficiary of vaccination programs, should pay the costs of a social insurance program to assure at least basic financial support for those who become casualties in the war on disease. The type of legislation recently passed in Maryland, discussed above, and the pending federal legislation are the result of the public's diminishing faith in vaccination programs. The ultimate results of both federal and state legislative efforts could reduce the efficacy of vaccination programs. The exemptions provided in state laws may make it easier for people to avoid vaccination; the federal legislation could make the compensation costs so high that the government would avoid immunization programs. Vaccination programs require concentrated, constructive improvement. There is every reason to believe that our society will have an increased need for such programs. We no longer live in a frontier society where each family can decide whether it wishes to participate in public health programs. What is needed is an affordable and administratively manageable federal compensation program combined with a substantial effort to reduce the medical risks associated with current vaccines.

ports health care programs such as Medicaid, Social Security Insurance, maternal and child health block grants, and the Education For All Handicapped Children Act. No figures exist, however, as to how much these programs pay to victims of immunization injuries. The government also buys about 30 per cent of the most commonly used immunization vaccines. These vaccines have increased in price over the past ten years by an average of 6.9 to 25 percent a year. What portion of the price increases represent increases due to tort law and whether prices would decline with a federal compensation program is unknown. See 1984 Hearings, supra note 148, at 189–90.