

**Report for Recommendation 91-4**

**Innovation and Challenge: The First Year of the  
National Vaccine Injury  
Compensation Program**

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## Executive Summary

The National Vaccine Injury Compensation Program (Program) is a federal "no-fault" system of providing compensation to persons with serious adverse reactions to vaccines to prevent seven diseases of childhood: diphtheria, tetanus, whooping cough, poliomyelitis, measles, mumps, and rubella. Enacted on November 14, 1986, as part of the National Childhood Vaccine Injury Act of 1986, it became effective October 1, 1988.

The Program is an experimental solution to the inadequacy of the tort system in compensating children who died or were permanently disabled after a state-required immunization. It is expected to attract prospective litigants away from litigation. By removing the threat of litigation against vaccine manufacturers, it is also expected to encourage continued domestic childhood vaccine production.

Congress recognized that the Program would offer a comparative advantage over litigation only if it could award compensation quickly, fairly, and efficiently. Thus, programmatic efficiency is of paramount importance to the Program's success. This report presents a preliminary descriptive analysis of the Program's first year and a half of operation. It is intended to provide background information, raise questions, and generate hypotheses that warrant testing to evaluate the Program's long-term effectiveness.

## Program Summary

Decisionmaking authority is vested in the United States Claims Court. A new office of special masters hears petitions for compensation and determines both eligibility and amounts of compensation. A Claims Court judge reviews the special master's recommendation and makes the final judgment in cases filed before January 19, 1990. Pursuant to a December 1989 amendment the special masters issue the final judgment in cases filed thereafter, subject to limited review by a Claims Court judge. Persons with covered vaccine-related injuries submit a petition for compensation to the Claims Court. The Secretary of Health and Human Services (HHS) is named as respondent to the petition. The vaccine manufacturer and whoever administered the vaccine are not involved as a party to the proceedings. Decisions on cases filed under the original rules must be made within 1 year. For cases filed under the new rules, the time is 240 days, with some extensions possible.

Compensation may be sought for anyone who has a vaccine-related injury or death, regardless of when it occurred. However, petitions for injuries or

deaths that resulted from an immunization given before October 1, 1988 (retrospective cases), must be filed by October 1, 1990. This deadline was extended until January 31, 1991, by a November 1990 amendment to the statute. Moreover, to be eligible, such retrospective cases may not have received damages as a result of a judgment or settlement of a civil action for the same injury. Petitions for injuries or deaths from immunizations given on or after October 1, 1988 (prospective cases), must be filed within 2 to 4 years after the injury is manifested. No civil action for damages may be filed in prospective cases unless and until the petitioner has received a determination and elected to reject it in favor of proceeding with litigation. The Program is an alternative to litigation because petitioners may not obtain compensation from both the Program and litigation.

Compensation is awarded only if the petitioner died or was permanently injured as a result of one of the seven covered vaccines. Causation is presumed for conditions listed in the Vaccine Injury Table. Prospective cases are entitled to compensation for nonreimbursable medical and related expenses, lost earnings, pain and suffering, and, in the case of death, a fixed sum of \$250,000. Awards are paid from a Trust funded by a surtax on covered vaccine sales. Retrospective cases are limited to expenses incurred after the final judgment and not more than a total of \$30,000 for lost future earnings, pain and suffering, and attorneys' fees and costs. Awards in retrospective cases are paid out of funds specially authorized by Congress.

### **Experience from October 1, 1988 to February 28, 1990**

By the end of February 1990, 236 petitions for compensation had been filed, substantially less than predicted. More than 82 percent of these petitions cited pertussis (whooping cough) vaccine, alone or in combination with diphtheria and tetanus toxoid (DTP), as the cause of injury or death. By February 28, 1990, 87 cases had been finally disposed of. Final judgments were issued in 70 cases; 17 cases were voluntarily dismissed by the petitioner. Compensation totalling \$32,495,151.17 was awarded in 62 (88.5 percent) of the 70 final judgments. The vast majority of these awards (51 out of 62 or 82 percent) were in cases involving pertussis or DTP vaccine. The amount of compensation awarded in all 22 individual cases of permanent injury ranged from \$27,081 to \$2,772,855. Virtually all of the awards were for future medical, rehabilitative, and custodial expenses for the care of children immunized before October 1, 1988. Compensation in the statutory amount of \$250,000 was awarded in each of 41 cases of death.

As the deadline for filing retrospective petitions was about to expire, and after this study was completed, the Program received a disproportionately large

number of petitions in retrospective cases. Congress extended the deadline for filing to January 31, 1991, and by that date, 4,034 petitions had been filed in retrospective cases, and 98 petitions had been filed in prospective cases.

## Programmatic Innovations

The Program provides "no-fault," cause-based compensation. Unlike general benefit programs, compensation is limited to injuries from a single source--seven vaccines generally required for children before they enter day care or school. Yet compensation is available regardless of whether anyone is at fault or might be legally liable for the injury or death. The major decisions affecting entitlement involve the cause of injury, the nature of the resulting disability, and the amount of compensation needed to provide care for a permanently disabled person.

To simplify making decisions about the cause of injury, the Act includes a list of compensable injuries in the Vaccine Injury Table. Although the Table was intended to eliminate most disputes over the cause of injury, the majority of cases claiming Table injuries have been contested. Part of this is the inevitable result of applying statutory definitions to individual medical conditions and events. It suggests the need for more detailed interpretations of conditions that qualify as Table injuries and the proof required to demonstrate their occurrence.

The Act created a hybrid programmatic structure for deciding petitions, akin to an administrative tribunal. While Congress may have envisioned a simple administrative benefit determination, the statutory decisionmaking process is more similar to litigation. This hybrid structure requires participants to play new roles that are not well-defined in the statute. Considerable dissonance between the roles that may have been expected of the special masters and the Program's office within HHS and their statutory duties nearly brought the Program to a halt in mid-1989 and clarification is warranted. In particular, the role of the Secretary of HHS and the HHS Program office to which his functions are delegated merits further delineation. The Secretary is designated as respondent in proceedings to determine eligibility, administers the trust fund and makes payment of compensation awarded by the Claims Court. Although the Secretary is not granted general rulemaking authority for the Program, he may amend or modify the compensable injuries listed in the Vaccine Injury Table. These functions sometimes make it difficult for the Program office to review petitions both as an independent medical review body and as guardian of federal funds.

The Program's most innovative structural contribution is the creation of a unit of special masters empowered to make final determinations and develop

less-adversarial decisionmaking procedures. These include relaxed rules of practice, informal status conferences, conducting conferences and hearings by telephone conference call or in locations convenient for petitioners in order to save time and money. Such procedures are adaptable to other benefit programs and dispute resolution systems. Procedures alone, however, cannot be expected to eliminate difficult questions of fact. An example is the difficulty experienced in calculating the amounts of compensation to be awarded.

## Conclusion

This report describes the Program in its infancy. Aside from having undergone both statutory and administrative changes, the Program has dealt almost exclusively with retrospective cases. Its decisionmaking procedures should apply equally well to prospective cases. But, the Program's future acceptability, and consequently, its effectiveness, depends more on reducing the areas of potential dispute and clarifying the roles of participants. The fundamental question is whether this new, hybrid decisionmaking process can settle controversies over vaccine-related injuries that have stubborn roots. This report suggests that it has the potential to do so.

The Program's experience after the period covered by this report tends to confirm its conclusions. Almost everyone involved with the Program is satisfied with its current operation. However, the large influx of retrospective petitions in late 1990 and early 1991 poses two real, if temporary, problems. One is concern that the time required to decide these claims will exceed the limits established by the Act. The second is the possibility that the funds appropriated by Congress will be insufficient to pay awards permitted by the Act. In November 1990, Congress responded to the first concern by granting the special master the discretion to extend the time for deciding claims for up to 180 days. However, an additional extension is likely to be needed. The second problem is more fundamental. If funding adequate to finance approvable awards is not provided, the Program may cease to function for the excess claims. Petitioners seeking compensation would be relegated to tort litigation as though the Program had not existed. This would mark a return to the circumstances that gave rise to the Program in the first place.

The burden of this bunching of retrospective claims will dissipate over time, assuming adequate sources of compensation are identified. It need not affect the Program's effectiveness in prospective cases. However, if the Program is not able to provide compensation in appropriate retrospective cases, its appeal to those with prospective cases could be significantly diminished. Every effort should be made to ensure the continued operation of the Program. Its benefits appear clearer with the passage of time.

## Introduction

This report presents a preliminary descriptive analysis of the National Vaccine Injury Compensation Program ("Program") through the middle of 1990. Because the Program's success depends heavily on the effectiveness of the administrative process in carrying out congressional intent, this report focuses on the ways in which the programmatic structure laid out in the statute has been translated into administrative decisionmaking procedures. Chapter I presents some of the background leading to enactment of the Program and the goals it may achieve. The Program's statutory design and operation is summarized in Chapter II. Chapter III describes the special function played by the Vaccine Injury Table, which lists compensable injuries, and some of the difficulties experienced in its application. The decisionmaking process developed to suit the Program's hybrid programmatic structure is described in Chapter IV. Chapter V describes the special functions Program participants perform and the new roles they are assuming to do so. Chapter VI presents the results of decisionmaking during the Program's first 17 months. Chapter VII summarizes the Program's achievements as well as the difficulties it has faced and offers suggestions for evaluating the Program over the next few years. Recommendations follow Chapter VII.

Because the Program is new and the enabling legislation has been amended several times, the findings reported herein must be viewed with caution and as preliminary only. Any new program requires a break-in period to achieve workable procedures. This is particularly true in the case of this Program. Therefore, the conclusions reached with respect to experience during its first year and a half need not apply to its future operation. This report is intended to provide basic background information, raise questions, and generate hypotheses that warrant testing to evaluate the Program's future effectiveness.

After this report was submitted to the Administrative Conference, a large number of claims was filed with the Program. An epilogue is appended to the report, which summarizes the implications of this development for the Program.

## Chapter I. The National Vaccine Injury Compensation Program: Background and Goal

### Background

The National Vaccine Injury Compensation Program (Program) is a federal "no-fault" system of providing compensation to persons who have had serious adverse reactions to vaccines to prevent seven diseases of childhood: diphtheria, tetanus, whooping cough, poliomyelitis, measles, mumps, and rubella. The Program was enacted on November 14, 1986, as part of the National Childhood Vaccine Injury Act of 1986.<sup>1</sup>

The Program is experimental in the sense that it creates a new and almost unique system of benefits for injuries resulting from one source. It was believed to be a solution to the inadequacy of the existing tort system in compensating children who were severely disabled or who died after a required immunization against a childhood disease.<sup>2</sup>

The National Vaccine Injury Compensation Program is the result of almost 2 decades of debate over whether and how adverse reactions to childhood vaccinations should be compensated. The most fundamental controversy was and is over whether certain injuries suffered by children following an immunization were in fact caused by the vaccine that was administered. Many vaccines, like most pharmaceuticals, may cause side effects even when properly manufactured and administered. These may range from self-limiting soreness or fever to more severe reactions like anaphylaxis or even death.<sup>3</sup> The more serious side effects or adverse reactions are fortunately rare. Immunization has protected tens of thousands of children against serious infectious diseases that once claimed too many lives. Thus, in general, the risk of severe illness or death from an infectious disease in unimmunized children is far greater than the risk of an adverse reaction to immunization. It is for this reason that all states require children to be immunized against childhood diseases before they enter day care or school and come in regular contact with

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<sup>1</sup> 100 Stat. 3756, codified as Title XXI of the Public Health Service Act at 42 U.S.C. 300aa-1 et seq. (Supp. V 1987). The Compensation Program is codified as Subtitle 2 of Title XXI, 42 U.S.C. 300aa-10 to 300aa-34.

<sup>2</sup> House Rep. No. 99-908, House Comm. on Energy & Commerce, 99th Cong. 2d Sess., 1986 U.S. Code Cong. & Admin. News 6344, 6348 (Sept. 26, 1986) (hereafter "House Rep. 99-908").

<sup>3</sup> Institute of Medicine, VACCINE AND INNOVATION 69-80 (1985).



other children. If a sufficiently large proportion of the population is immunized, the disease will not spread significantly, and the entire population benefits.

Nonetheless, serious adverse reactions are a tragedy for the individual children and families who suffer them. Unfortunately, they are often unpredictable, occurring in children for whom there is no known medical contraindication, such as immunosuppression, for immunization. Identifying an adverse reaction to a vaccine is sometimes difficult since some medical conditions, especially neurological abnormalities, tend to first appear about the same time that infants receive immunizations. In individual cases, there may be no way to determine whether the condition was an adverse reaction to a vaccine or happened coincidentally as the result of an unrelated cause.<sup>4</sup> The salient example of this difficulty is the pertussis vaccine, usually given in combination with diphtheria and tetanus toxoids (DTP). The pertussis vaccine has been the subject of longstanding controversy over whether or how often the vaccine causes encephalopathy, infantile spasms, or residual seizure disorder, which may lead to permanent physical disability and mental retardation.<sup>5</sup> Many parents of children who suffered such injuries after vaccination and some physicians and scientists believe strongly that pertussis was the cause of injury and that such adverse reactions occur more frequently than has been reported. Other physicians and epidemiologists believe equally strongly that injuries are more often than not merely temporally associated with vaccination and that some injuries cannot be attributed to pertussis vaccine at all.

This controversy over whether and when a vaccine caused a particular injury to an individual child has been played out in civil tort actions against manufacturers. Since the critical issue in such cases is whether the vaccine caused the injury, the dispute over causation extended from the scientific arena to the courtroom. Vaccine manufacturers felt besieged by claims for disabilities that they believed were not vaccine-related. Parents felt abandoned

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<sup>4</sup> The cause of some adverse reactions, such as paralysis following immunization with oral poliovirus vaccine, may sometimes be determined by laboratory tests that distinguish a wild (disease) virus from that used in the vaccine.

<sup>5</sup> See Institute of Medicine, *VACCINE AND INNOVATION* 67-72 (1985).

at the time they most needed help.<sup>6</sup> By the 1980s, litigation was proving to be an unsatisfactory means of resolving this kind of dispute.<sup>7</sup>

At the same time, pediatricians and public health officials, particularly those in agencies of the Department of Health and Human Services, were becoming concerned about more than a decade of decline in the number of United States companies that produced childhood vaccines. They feared that if a manufacturer experienced any trouble in vaccine production or, worse yet, decided to stop producing vaccines, the country could be without enough vaccines to prevent a serious epidemic. They also worried that liability concerns might discourage manufacturers from continuing to supply vaccines.<sup>8</sup> Manufacturers raised their vaccine prices in the mid 1980s at least in part to cover anticipated liability expenses. But the price rise threatened both public immunization programs funded by the federal and state governments and private efforts to encourage immunization.

From the mid 1970s to the mid 1980s, several national groups studied this constellation of problems seeking a way to ensure a stable vaccine supply and affordable vaccine prices, and to provide assistance to persons with vaccine-

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<sup>6</sup> The cost of caring for severely disabled children was rarely covered by private or public insurance, such that the only source of financial assistance for many was compensation in damages from whomever might be legally liable for the injury. Although many states, like California, have programs to assist disabled children, it is not known how many parents were aware of the program or whether their benefits were adequate in these cases.

<sup>7</sup> "Much of the controversy in the United States over liability for vaccine-related injuries reflects a belief that the class of injuries deserving compensation is broader than the class of injuries for which manufacturers of vaccines should be held responsible." Mariner, *Compensation Programs for Vaccine-Related Injury Abroad: A Comparative Analysis*, 31 ST. LOUIS U.L.J. 599, 601-2 (1987). A civil action for damages against the vaccine manufacturer sometimes offered a source of compensation. However, a successful cause of action depended upon proving either negligence or a defect in the vaccine or inadequate warnings of vaccine risks. Most injuries caused by vaccines were the unpredictable result of inherent risks in a properly manufactured nondefective vaccine, for which no one would be liable in tort law. Even if a cause of action might seem plausible, the uncertainty and expense, coupled with the lack of success in the majority of reported cases, made litigation an unreliable source of compensation. Because all states required childhood immunizations for day care or school entry, with few exceptions, the option of refusing immunization was rarely available.

<sup>8</sup> See generally Institute of Medicine, *VACCINE AND INNOVATION* 85-122 (1985); *MEDICINE IN THE PUBLIC INTEREST, IMPEDIMENTS TO VACCINE RESEARCH* (1984); U.S. Dept. of Health Education and Welfare, *Reports and Recommendations of the National Immunization Work Groups* (1977); Mariner and Clark, *Confronting the Immunization Problem: Proposals for Compensation Reform*, 76 *AMERICAN JOURNAL OF PUBLIC HEALTH* 703 (1986); Kitch, *Vaccines and Product Liability: A Case of Contagious Litigation*, 1985, *REGULATION* II (May/June 1985).

related injuries.<sup>9</sup> While none recommended a definitive solution to all aspects of the problem, all proposed consideration of a system to compensate vaccine-related injuries. In 1984, the American Academy of Pediatrics took the initiative by seeking federal legislation to create such a compensation program. Several bills were introduced by members of Congress and debated vigorously in congressional hearings. Ultimately, the National Childhood Vaccine Injury Act of 1986 emerged under the sponsorship of Representative Waxman and Senator Hatch.

Like all legislation, the Act was the product of compromise. As Representative Waxman has pointed out, no one was entirely happy with it. Some vaccine manufacturers were unhappy with the fact that the compensation system was not an exclusive remedy. They preferred greater, if not complete, protection against civil product liability actions. The largest organization of parents of children with vaccine-related injuries, Dissatisfied Parents Together (DPT), lent its support largely because the Act included provisions to develop better information about adverse reactions to vaccines and to further research to improve existing vaccines to reduce their inherent risks. While DPT had initially joined with the American Academy of Pediatrics in preparing legislation, it was concerned that the final Act's focus on compensation would deflect attention from the problem of improving vaccines themselves. Other parents' groups opposed the Act for that reason.

The Reagan administration opposed much of the Act for fear of setting a precedent for no-fault compensation for injuries from other causes. Senator (now, Vice President) Quayle conveyed the gist of the Administration's objections to the bill when it was in the Senate in October 1986:<sup>10</sup>

There are some aspects of the bill about which the White House is very upset, in particular the National Childhood Vaccine Injury Act of 1986. They are concerned that this particular part of the legislation will be costly...that it may

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<sup>9</sup> U.S. Department of Health, Education, and Welfare. *Liability Arising Out of Immunization Programs: Final Report to Congress* (DHEW, 1978); U.S. Congress, Office of Technology Assessment. *Compensation for Vaccine-Related Injuries* (technical memorandum) (OTA, 1980); American Academy of Pediatrics. *Need for Legislation to Establish a Federal Compensation Program for Vaccine-Related Injuries in Childhood Immunization Programs* (March 11, 1983); American Medical Association. *Final Report of the ad hoc Commission on Vaccine Injury Compensation* (April 1984); American College of Physicians. *Compensation for Vaccine-Related Injuries* (July 26, 1984); American College of Physicians and American Academy of Pediatrics. *Joint Resolution on Compensation for Vaccine-Related Injuries* (November 4, 1985) (Approved by Council of Medical Specialty Societies, November 26, 1985.); Institute of Medicine. *VACCINE AND INNOVATION* (1985).

<sup>10</sup> 132 Cong. Rec. S 17344-45 (daily ed. Oct. 18, 1986).

open the floodgates to similar other coverage of types of injuries under a no-fault system.

The Department of Justice also opposed creation of a no-fault compensation system. In testimony on a predecessor bill, S. 827, the DOJ noted that creation of an entitlement program was a major step and argued that it should not be undertaken "in the absence of compelling evidence that the existing method of compensating victims through the tort system is inadequate."<sup>11</sup> The DOJ also predicted that "a no-fault approach will not significantly simplify the process of determining which claimants should receive compensation."<sup>12</sup> Moreover, it argued that because there appear to be "only a handful of childhood vaccine-related injury cases every year, it may be far more cost effective to leave such cases in the tort system...."<sup>13</sup>

Many in the Department of Health and Human Services were concerned that a federal compensation system would undermine immunization programs by focusing public attention on adverse reactions to vaccines instead of the benefits of immunization. In 1984, the Assistant Secretary for Health and the Directors of the Division of Immunization of the Centers for Disease Control testified in opposition to an earlier bill (H.R. 5810) that would have created an almost identical compensation program. Dr. Brandt noted that although the bill had a "laudable goal," it was impossible to support because of "major weaknesses."<sup>14</sup> These included the amount of compensation, which the department believed to be too high, the inclusion of retrospective cases, and, most importantly for today's Program, the list of compensable vaccine injuries. They believed that causation was too tenuous in many cases to allow the "nearly automatic" compensation afforded by the bill.<sup>15</sup>

Nonetheless, the Act did offer something for almost everyone and passed Congress in late 1986. Despite the compromises, it was the first change in policy that attempted to address the problems of fairness to injured persons and protection of the federal immunization program.

Given its history, it is not surprising that the Act did not get underway immediately. The provisions pertaining to increased vaccine research (the National Vaccine Program) were not funded by appropriations until 1989, and these activities are not yet fully staffed. The compensation Program had no

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<sup>11</sup> National Childhood Vaccine Injury Compensation Act of 1985: Hearing on S.827 Before the Senate Comm. on Labor & Human Resources, 99th Cong., 1st Sess. 228 (1985).

<sup>12</sup> *Id.* at 231.

<sup>13</sup> *Id.*

<sup>14</sup> Testimony of Edward Brandt, Assistant Secretary for Health, DHHS, before the House Subcomm. on Health and Environment on H.R. 5810, Sept. 10, 1984, at p. 60.

<sup>15</sup> *Id.* at 63-65.

source of funding for more than a year after its enactment. Congress specified that the compensation Program be funded from revenues derived from a surtax on vaccine sales, and that the Program would not become effective until the tax was enacted. But the tax was not enacted until 1987. Tax revenues would not be available for awards payable in retrospective cases during the first year or two of the Program. Accordingly, provisions for funding compensation awards in retrospective cases, authorizing the appropriation of \$80,000,000 for each of the first 4 years of the Program, were added in December 1987.<sup>16</sup> The Program was then set to become effective on October 1, 1988, almost 2 years after it was signed into law. Funding to create a separate unit of special masters to the United States Claims Court to hear claims was not made available until the end of September 1988, so the Program did not actually begin to consider petitions until February 1, 1989.

## Goals

Members of Congress and diverse constituencies who supported the National Childhood Vaccine Injury Act envisioned it as a means to achieve one or more of at least seven possibly conflicting goals:

- To provide reasonable compensation;
- To persons who were severely injured as a result of a childhood immunization;
- To stabilize, and ideally reduce, the price of childhood vaccines;
- To ensure the continued production of childhood vaccines to supply the country's immunization programs;
- To maintain or restore public confidence in immunizations and to improve national childhood immunization rates;
- To provide the public with adequate accurate information on the benefits and risks of immunization;

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<sup>16</sup> National Vaccine Injury Amendments, Pub. L. No. 100-203, Title IV, Subtitle D, 101 Stat. 1330-221, December 22, 1987, codified at 42 U.S.C. 300aa-15(i), (j). An additional \$80,000,000 for fiscal 1993 was added by later amendment.

—To encourage research to develop safer vaccines, both to replace existing vaccines and to prevent other diseases.

The compensation program was not necessarily expected to accomplish all these goals. A separate National Vaccine Program, which requires the Secretary of Health and Human Services (HHS) to coordinate federal vaccine research and immunization programs, was included in the Act to encourage more vaccine research.<sup>17</sup> Additional provisions in the Act are intended to collect and disseminate more and better information about vaccine use and adverse reactions to vaccines,<sup>18</sup> and to promote the development of vaccines that result in fewer and less serious adverse reactions.<sup>19</sup> An Advisory Commission on Childhood Vaccines appointed by the Secretary is to advise the Secretary on accomplishing these goals, as well as Program implementation.<sup>20</sup>

The compensation system created by the Program was most specifically intended to achieve the goal of fair compensation.<sup>21</sup> At the same time, most members of Congress hoped that it would also contribute to stabilizing vaccine supplies and prices and to improving immunization rates.<sup>22</sup> The basis for this

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<sup>17</sup> Public Health Service Act, Title XXI, subtitle 1, 42 U.S.C. 300aa-1 to 300aa-6 (Supp. 1987). The National Vaccine Program was established "to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines." 42 U.S.C. 300aa-1. The National Vaccine Program did not receive funding until 1989. The Director of the Program is Assistant Secretary for Health, James O. Mason, M.D.

<sup>18</sup> Requirements for recording and reporting vaccinations with childhood vaccines and adverse reactions to vaccines are included at 42 U.S.C. 300aa-25. Vaccine manufacturers are required to maintain detailed records on each batch or lot of vaccine produced. 42 U.S.C. 300aa-27. The Secretary of HHS is also required to develop and disseminate vaccine information materials for use by parents of children being vaccinated against covered diseases. 42 U.S.C. 300aa-26. Although the materials were to have been distributed by December 22, 1988, they had not been completed as of June 1990.

<sup>19</sup> 42 U.S.C. 300aa-27.

<sup>20</sup> 42 U.S.C. 300aa-19.

<sup>21</sup> In introducing the legislation, the House Committee on Energy and Commerce explained its desire to help those few children who suffered adverse reactions in an immunization program that provided a valuable public benefit: "The Committee recognizes that because of many States' standards of proof of liability, many vaccine-injured persons are presently without legal remedy under current tort law. The Committee anticipates that many of these persons will be compensated for their injuries under the compensation system." House Rep. 99-908 at 6354 (Sept. 25, 1986).

<sup>22</sup> In the Report accompanying technical amendments to the Act in late 1989, House conferees restated the original goals of the Program as follows: "The system will provide compensation, eliminate the need for litigation and assure the continued availability of and public confidence in immunizations in the United States." Conference Report No. 101-386 to accompany H.R. 3299, Omnibus Budget Reconciliation Act (OBRA) of 1989, Title VI, Subt. D.,

hope was the assumption that potential liability was a disincentive to manufacturers to enter or stay in the vaccine business.<sup>23</sup> The Program was intended to remove that disincentive by serving as a substitute for litigation against vaccine manufacturers.<sup>24</sup>

To do so, the Program must meet the more specific objectives of assuring prompt awards of fair compensation that will attract potential claimants away from civil tort actions.<sup>25</sup> This, in turn, is expected ultimately to reduce the cost or unpredictability of litigation against manufacturers and thereby remove a disincentive to vaccine research, development, and production. This is a lot to ask of one benefit program. The viability of the commercial vaccine industry cannot hinge on the success or failure of the Program.<sup>26</sup> But, to the

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A. Vaccine Injury Compensation Technicals, 101st Cong. 1st Sess., at 513 (Nov. 21, 1989). The amendments were enacted as section 6601 of the OBRA of 1989, Pub. L. No. 101-239, December 19, 1989, effective January 19, 1989.

<sup>23</sup> Representatives of some vaccine manufacturers testified before Congress that liability threatened the availability of vaccines. Both Congress and vaccine manufacturers remembered the difficulties surrounding swine flu production in 1976, when Congress enacted the Swine Flu Program in the face of manufacturer's unwillingness to produce swine flu vaccine after their insurers refused to provide insurance. No one welcomed a repeat of that episode. See R. Neustadt & H. Fineberg, *THE SWINE FLU AFFAIR: DECISIONMAKING ON A SLIPPERY DISEASE* (U.S.D.H.E.W. 1978). Although no data were presented to Congress to substantiate the assumption that liability costs represented an onerous proportion of revenues, it was widely accepted that the difficulties both in predicting liability costs and in obtaining liability insurance might discourage manufacturers from pursuing vaccines, especially when vaccines did not generate substantial profits. See *VACCINE AND INNOVATION* 45-64.

<sup>24</sup> The Act also limits the causes of action available under state tort law for damages resulting from a covered vaccination, 42 U.S.C. 300aa-22, prohibits most awards of punitive damages in such cases, and divides the action into separate stages for determining liability, general damages, and, if applicable, punitive damages. 42 U.S.C. 300aa-23. These provisions reinforce the attractiveness of pursuing compensation through the Program by eliminating or narrowing manufacturer liability in tort. However, they prohibit states from imposing stricter limits on the remaining causes of action. Mariner, *The National Vaccine Injury Compensation Program in the United States: A Preliminary Overview*, in S.R. Shulman & L. Lasagna, *TRENDS IN PRODUCT LIABILITY LAW AND NO-FAULT COMPENSATION FOR DRUG-INDUCED INJURIES* 41,44 (Tufts Univ. 1990).

<sup>25</sup> The House Committee on Energy and Commerce noted its expectations in its Report: "The Committee anticipates that the speed of the compensation program, the low transaction costs of the system, the no-fault nature of the required findings, and the relative certainty and generosity of the system's awards will divert a significant number of potential plaintiffs from litigation." House Rep. 99-908 at 6354.

<sup>26</sup> The decisions of manufacturers to pursue vaccine research, development, and sales are influenced by many factors, including the potential market for vaccines, the price of vaccines obtainable in the market, the costs of research and production, the degree to which the technology used is transferrable to or from other products, the public relations value of vaccines, and the

extent that vaccine related litigation deters manufacturers from pursuing vaccines, the Program may eliminate a negative influence on the decision.

Congress recognized that the Program could offer a comparative advantage over litigation only if it could assure speedy compensation. Moreover, a prompt award was the major justification for limiting the compensation payable to recipients.<sup>27</sup> The House Committee on Energy and Commerce 1986 Report on the original bill before Congress described the Program as "a 'no-fault' compensation program under which awards can be made to vaccine-injured persons quickly, easily, and with certainty and generosity."<sup>28</sup> It believed that the Program was "fair, simple, and easy to administer."<sup>29</sup> Programmatic efficiency is of paramount importance to the Program's success.

Congress made two key innovations to achieve this simple, streamlined system. The first was a policy decision to define the injuries eligible for compensation in the Act--the Vaccine Injury Table. This was intended both to avoid the controversy over what disabilities were in fact caused by vaccines, and to expedite decisions on claims by eliminating difficult, time-consuming disputes over causation in individual cases. A critical structural element of the Program, therefore, incorporates a policy decision. It is complicated by exceptions to the general rule; petitioners are entitled to compensation if they can prove their injuries were actually caused by a covered vaccine, even if not listed in the Table; and compensation can be denied where the injury is shown to result from an independent cause. As a result, perceptions of the utility of the Vaccine Injury Table are often colored by one's agreement or disagreement

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availability and cost of liability insurance. See Institute of Medicine, VACCINE SUPPLY AND INNOVATION 45-64 (1985).

<sup>27</sup> "The Committee notes that much of the equity in limiting compensation and limiting other remedies arises from the speed and reliability with which the petitioner can expect judgment; without such quick and certain conclusion of proceedings, the compensation system would work an injustice upon the petitioner." House Rep. 99-908 at 6358.

<sup>28</sup> *Id.* at 6344.

<sup>29</sup> *Id.* at 6348. The Committee Report is replete with references to the speed and fairness of the system: "The system is intended to be expeditious and fair." *Id.* at 6353. "The Committee has endeavored to create a swift, uncomplicated compensation system..." *Id.* at 6357. "In order to expedite the proceedings, the power of the Special Master is intended to replace the usual rules of discovery in civil actions in Federal courts." *Id.* at 6357. "The entire proceeding...is to take place as expeditiously as possible and, in no case, should take more than one year." *Id.* at 6358. When the Act was amended in 1989, Congress reiterated its original intent. The Conference Report noted that "Congress intended a quick, flexible, and streamlined system." Conference Report No. 101-386 to accompany H.R. 3299, Omnibus Budget Reconciliation Act of 1989, Subt. D.A. Vaccine Injury Compensation Technicals, 101st Cong. 1st Sess., p. 512 (Nov. 21, 1989). It intended that the "system be informal, flexible, and expeditious." *Id.* at 513.



with the policy choices embodied in the Table. The Program's experience with the Vaccine Injury Table is discussed in Chapter III.

The second innovation made by the Program was lodging decisionmaking authority with a self-contained unit of special masters within the U.S. Claims Court. This created a special hybrid programmatic structure that contains elements of administrative benefit determination systems and traditional litigation. The Program's experience with this new format for awarding federal benefits is discussed in Chapters IV and V.

The Vaccine Injury Compensation Program may be a creative solution to a complex problem. Its operation to date suggests that it has the potential to be one. But the issues of immunization policy, vaccine supply, and compensation for adverse reactions are multifaceted. There is a danger that the Program might founder in the face of expectations that it cannot reasonably be expected to meet. The most immediate objective of implementing a simple, streamlined system is itself a lofty goal, given the absence of ready precedents.

## Chapter II. The National Vaccine Injury Compensation Program: The Resulting Legislation

The National Vaccine Injury Compensation Program (Program) has been operating for more than a year and a half. It represents a creative policy measure intended to resolve some of the complex problems affecting immunization policy in the United States. Yet the program has faced an unusual array of difficulties in its short existence. It did not become effective until October 1, 1988, almost 2 years after it was signed into law. It did not begin to consider petitions for compensation for another 4 months. Then, in mid-1989, the Program was threatened with collapse when the Departments of Health and Human Services and Justice felt themselves unable to participate.

In response, in December 1989, Congress amended the statute in several procedural respects.<sup>30</sup> Thus, while the Program has operated continuously since February 1989, it has had two slightly different decisionmaking procedures. The major difference between the two is the degree of authority granted to the special masters. Under the original Program, the special masters made recommendations to the United States Claims Court and a Claims Court judge made the final decision. This original procedure is being applied to all petitions filed before January 19, 1990 when the Technical Amendments took effect. The New Rules apply the changes made by the

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<sup>30</sup> Vaccine Injury Compensation Technicals, Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-329, section 6601, December 19, 1989. For a discussion of the impetus for the Technical Amendments, see text accompanying note 172.

Technical Amendments to petitions filed on or after January 19, 1990, and permit the special master to make the final decision. When all pre-January 19, 1990 petitions have been decided, only the New Rules will apply.

## Eligibility

The Program provides compensation for persons who have died or received specified injuries following immunization with any of the covered vaccines against seven infectious diseases of childhood. The vaccines, whether given individually or in combination with other vaccines, are: diphtheria toxoid, tetanus toxoid, pertussis vaccine (usually combined as DTP), measles, mumps, and rubella vaccines (often combined as MMR), oral poliovirus vaccine (OPV), and inactivated poliovirus vaccine (IPV).

Persons who received vaccines before the Program went into effect, as well as those receiving vaccines on or after the effective date, may be eligible. The Program has two categories of petitioners. Persons who received a vaccine before the effective date of October 1, 1988, bring "retrospective cases." Persons who were immunized on or after October 1, 1988, bring "prospective cases." The classification of cases into prospective and retrospective categories serves to distinguish petitioners entitled to different treatment under the Program.

Eligibility for compensation is based on the type of vaccine, the specific disease or medical condition suffered, and U.S. citizenship or residence at the time of vaccination. Eligibility requirements are summarized in Table II-1 below. Although the Program was inspired out of concern for children who suffered injury as a result of immunizations that are required for school entry, it covers injuries to adults as well, and specifically mentions those who suffered paralysis after contact with a person (ordinarily an infant) who was vaccinated with oral polio vaccine.<sup>31</sup>

The Program offers an alternative source of compensation for persons with adverse reactions to vaccines who might institute a civil action in tort for damages for personal injury. All persons who were immunized with a covered vaccine on or after October 1, 1988, are prohibited by the Act from commencing a civil action for a vaccine-related injury unless and until they

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<sup>31</sup> The Act does not limit recipient cases to children, although adults do not ordinarily receive the covered vaccines. The so-called "contact cases" of polio resulting from contact with an infant who was immunized with oral polio vaccine are the only nonrecipient cases covered by the Program. 42 U.S.C. 300aa-11(c)(1)(A), (c)(1)(B)(ii). Live virus from the vaccine may be excreted by a vaccinated infant and, in rare cases, infect a person, such as a parent or caretaker, who handles the infant or contaminated diapers or clothing.

have entered the Program and received a determination thereunder.<sup>32</sup> For these "prospective cases," the Program is a first-resort but not exclusive source of possible compensation.<sup>33</sup>

Persons who were vaccinated before October 1, 1988, may either enter the Program<sup>34</sup> or commence a civil action for damages for a vaccine-related death or injury, subject to several limitations. Many such persons with "retrospective cases" may have already commenced a civil action for their injuries. If the action has been completed and they did not recover any damages, they may enter the Program.<sup>35</sup> If the action is still pending, they have the option of either proceeding with their civil action or dismissing it and seeking compensation from the Program; they may not do both.<sup>36</sup> However, a person who has already recovered compensation as a result of a judgment or settlement of a civil action for the same injury is not eligible for the Program, regardless of the amount of compensation recovered.<sup>37</sup> These rules allow persons who were injured before the Act took effect to obtain its benefits as long as they have not received (and are not pursuing) damages in tort litigation. A person who files a civil action after November 15, 1988, with respect to a vaccination given before October 1, 1988, is not eligible for the Program.

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<sup>32</sup> 42 U.S.C. 300aa-11(a)(2)(A).

<sup>33</sup> Prospective cases must be filed within 36 months after the first symptom or onset of injury occurs. 42 U.S.C. 300aa-16(a)(2). In the case of death, prospective cases must be filed within 24 months after the date of death and no later than 48 months after the first symptom or onset of the injury from which death resulted. 42 U.S.C. 300aa-16(a)(3).

<sup>34</sup> Retrospective cases must be filed within 24 months after the October 1, 1988 effective date. 42 U.S.C. 300aa-16(a)(1). The last day for filing will be October 1, 1990, since September 30, 1990 is a holiday.

<sup>35</sup> 42 U.S.C. 300aa-11(a)(4).

<sup>36</sup> 42 U.S.C. 300aa-11(a)(5).

<sup>37</sup> 42 U.S.C. 300aa-11(a)(7).

## Table II-1

### *Vaccine Injury Compensation Program Eligibility Requirements*

1. Received one of the following vaccines, alone or in combination:
  - diphtheria, tetanus, pertussis
  - poliomyelitis (OPV or IPV),
  - measles, mumps, rubella;

Or contracted poliomyelitis from a person who received an oral polio vaccine.
  
2. Received the vaccine:
  - in the United States (or its trust territories); or
  - outside the United States while a U.S. citizen who was:
    - serving in U.S. armed forces or
    - employee of U.S. government, or
    - dependent of such a citizen

OR

  - outside the United States and returned to the United States within 6 months if vaccine was manufactured by U.S. manufacturer;

OR

Contracted polio while a U.S. citizen (or a dependent of U.S. citizen) from a person who received oral polio vaccine
  
3. Suffered:
  - death listed in Vaccine Injury within time specified in Vaccine Injury Table, or
  - injury listed in Vaccine Injury Table within time specified in Vaccine Injury Table that lasted more than 6 months, and resulted

- in more than \$1,000 in unreimbursable expenses, or
- injury or death caused by covered vaccine.

4. Has not previously collected an award or settlement of a civil action for damages for the injury or death.

Source: 42 U.S.C. 300aa-11(c).

## Review of Claims

Eligibility for compensation is determined by the United States Claims Court.<sup>38</sup> As originally enacted, the Act provided for designated special masters in the Claims Court to make recommendations to the Court on eligibility and amounts of compensation in all cases.<sup>39</sup> The Claims Court was the final decisionmaker, with broad powers to review and accept or modify the special master's findings or to make a *de novo* determination.<sup>40</sup> Under recent amendments to the Act, which became effective January 19, 1990 (the Technical Amendments),<sup>41</sup> the special master is authorized to make the final determination on eligibility and the amount of compensation.<sup>42</sup> This new format, sometimes called the "New Rules", creates a specialized group of decisionmakers within the Claims Court whose sole function is to make benefit determinations under the Program.

Claims for compensation are made by submitting a petition claiming eligibility to the Claims Court, and serving a copy on the Secretary of Health

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<sup>38</sup> The Act grants the Claims Court and its special masters "jurisdiction over proceedings to determine if a petitioner ... is entitled to compensation under the Program and the amount of such compensation...." 42 U.S.C. 300aa-12(a).

<sup>39</sup> 42 U.S.C. 300aa-12(c)(2) (1987) originally described the special master as an adjunct to the Court and required the special master to "prepare and submit to the court proposed findings of fact and conclusions of law." The Program began with eight special masters to work full time on Program petitions, although all eight special masters were not in place until the end of March 1989. As of July 1990, only six special masters will be assigned to the Program.

<sup>40</sup> 42 U.S.C. 300aa-12(d) (1987).

<sup>41</sup> See note 30.

<sup>42</sup> 42 U.S.C. 300aa-12(d)(3)(A) (1990). The Claims Court now acts as an appellate body with limited power to review a special master's determination upon objection by either party. 42 U.S.C. 300aa-12(e) (1990).

and Human Services.<sup>43</sup> The Secretary is the sole named respondent in the proceedings. No manufacturer or other person who might be responsible for any injury may intervene or participate as a party to the proceedings. The National Vaccine Injury Compensation Program Office (Program Office) has been created within the Department of Health and Human Services, Public Health Service, Health Resources and Services Administration, Bureau of Health Professions, to review petitions and act on behalf of the Secretary with respect to the Program. The Program Office reviews each petition to determine whether a petitioner has met the eligibility requirements. In particular, at least one physician reviews the information concerning the injury or death to determine whether it qualifies as a compensable event defined in the Act. Although the Act does not specify the Secretary or Program Office's responsibilities, its designation as respondent obliges it to respond to petitions. Thus, its opinion is submitted to the presiding special master as an answer to the petition.<sup>44</sup>

One special master is randomly assigned to an individual case and makes a determination as to eligibility on the basis of the evidence submitted by the petitioner and the Program Office. The critical issue in determining eligibility is whether the injury or death qualifies as a compensable injury as defined in the Act.<sup>45</sup> Although the Program is a compensation system limited to injuries presumed to result from one source--childhood vaccines--and not a general disability benefit program, it does not condition eligibility on causation in the traditional sense. Rather, it lists in the statute itself the medical conditions that are compensable.<sup>46</sup> This list is the Vaccine Injury Table shown in Table II-2.

The Vaccine Injury Table lists the types of compensable medical conditions and the time within which they must occur to qualify for compensation. The medical conditions listed in the Table were derived from existing epidemiologic studies of adverse reactions to the covered vaccines and reports of the American Medical Association and the American Academy of

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<sup>43</sup> 42 U.S.C. 300aa-11(a)(1). Under the Vaccine Rules adopted by the Claims Court January 18, 1990, the original plus two copies of the petition should be filed with the Clerk of the Court. Vaccine Rule 2(a), U.S. Claims Court General Order No. 26 (Jan. 28, 1990) (hereafter Vaccine Rules). Both the Act and the Vaccine Rules specify service upon the Secretary, 42 U.S.C. 300aa-11(a)(1), Vaccine Rule 2(c); the Secretary's authority to participate in the Program has been delegated to the Director of the Program within the Bureau of Health Professions. The Vaccine Rules helpfully include the mailing addresses of the Clerk and the Secretary.

<sup>44</sup> The Program office is now represented by attorneys from the Department of Justice, Civil Division. They incorporate the medical review into an answer accepting or objecting to each petition.

<sup>45</sup> 42 U.S.C. 300aa-11(c)(1)(C).

<sup>46</sup> 42 U.S.C. 300aa-14(a). Compensable medical conditions include acute complications and sequela.

Pediatrics. While they represent an effort to approximate a list of conditions that are thought to be caused by the vaccines, they are not intended to precisely reproduce actual causation. Congress recognized that the Table favored compensating some persons whose injuries were not in fact caused by a vaccine. Nonetheless, it was expected that the savings in time and expense over a system based on causation-in-fact would more than offset the small number of such cases. The statute also includes "qualifications and aids to interpretation," that define medical conditions like encephalopathy and describe symptoms that should and should not be considered indications of a Table injury.<sup>47</sup> In addition, the Secretary is authorized to revise the Table by adding or deleting compensable conditions or the time of onset.<sup>48</sup>

Injuries that are found by the special master to result from a cause other than a covered vaccine are not eligible for compensation,<sup>49</sup> so there is a check on the reach of the Vaccine Injury Table. At the same time, petitioners are entitled to prove that an injury was in fact caused by a covered vaccine even if it is not listed in the Vaccine Injury Table or, if listed, even if it did not occur within the specified time period.<sup>50</sup> However, causation-in-fact must be proved by a petitioner without the benefit of the Table.

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<sup>47</sup> 42 U.S.C. 300aa-14(b).

<sup>48</sup> 42 U.S.C. 300aa-14(c). Revisions are to be made by regulation after notice and opportunity for public comment. Anyone may petition the Secretary for a revision, but all revisions must be reviewed by the Advisory Commission on Childhood Vaccines.

<sup>49</sup> 42 U.S.C. 300aa-13(a)(1)(B).

<sup>50</sup> 42 U.S.C. 300aa-13(c)(1)(C)(ii).

**Table II-2**  
**Vaccine Injury Table**  
 42 U.S.C. 300aa-14(a)

- I. DTP; P; DTP/Polio Combination; or Any other Vaccine Containing Whole Cell Pertussis Bacteria, Extracted or Partial Cell Bacteria, or Specific Pertussis Antigen(s). Illness, disability, injury, or condition covered: Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration:
- A. Anaphylaxis or anaphylactic shock ..... 24 hours
  - B. Encephalopathy (or encephalitis) ..... 3 days
  - C. Shock-collapse or hypotonic-hyporesponsive collapse ..... 3 days
  - D. Residual seizure disorder in accordance with subsection (b)(2) ..... 3 days
  - E. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed ..... not applicable
- II. Measles, mumps, rubella, or any vaccine containing any of the foregoing as a component; DT; Td; or Tetanus Toxoid.
- A. Anaphylaxis or anaphylactic shock ..... 24 hours
  - B. Encephalopathy (or encephalitis) ..... 15 days  
 (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). ..... 3 days  
 (for DT, Td, or tetanus toxoid).
  - C. Residual seizure disorder in accordance with subsection (b)(2) ..... 15 days  
 (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). ..... 3 days  
 (for DT, Td, or tetanus toxoid).
  - D. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed ..... not applicable
- III. Polio Vaccines (other than Inactivated Polio Vaccine).
- A. Paralytic polio
    - in a nonimmunodeficient recipient ..... 30 days
    - in an immunodeficient recipient ..... 6 months
    - in a vaccine-associated community case ..... not applicable



- B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed ..... *not applicable*

IV. Inactivated Polio Vaccine.

- A. Anaphylaxis or anaphylactic shock ..... *24 hours*
- B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed ..... *not applicable*

## Compensation

The compensation available under the Program varies with the date of vaccination. Petitioners with retrospective cases are entitled to the same types of compensation as those with prospective cases, but the amounts are more limited.

The categories of compensation available in prospective cases are: actual past and estimated future medical expenses, including rehabilitation and home care, that are not reimbursable by private insurance;<sup>51</sup> actual and future losses of earnings;<sup>52</sup> actual and projected pain and suffering and emotional distress not to exceed \$250,000;<sup>53</sup> and reasonable attorneys' fees and costs.<sup>54</sup> Attorneys' fees may be awarded if the petition is determined to have been brought in good faith, regardless of whether the petitioner is ultimately determined to be eligible for compensation.<sup>55</sup> In the case of a person who died, the estate may receive a fixed death benefit in the amount of \$250,000.<sup>56</sup>

Petitioners with retrospective cases are entitled to the same general categories of compensation, but special restrictions apply. A death benefit of \$250,000 is payable in the event of death, as in prospective cases.<sup>57</sup> But only future unreimbursable medical and rehabilitation expenses are available; expenses incurred prior to the date of the Claims Court judgment are not allowed.<sup>58</sup> The remaining three categories of compensation--loss of earnings, pain and suffering, and attorneys' fees and costs--are limited to an aggregate amount of \$30,000 for all three.<sup>59</sup>

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<sup>51</sup> Eligible expenses include the cost of reasonably necessary diagnostic, medical or other remedial care, and "rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses [to enable the person to live at home], special equipment, related travel expenses, and facilities determined to be reasonably necessary." 42 U.S.C. 30011-15(a)(1)(A)(iii) and (B)(iii).

<sup>52</sup> For persons injured as adults (age 18 and over), actual and anticipated lost earnings are payable, as in litigation, computed in accordance with actuarial principles for expected future losses. 42 U.S.C. 300aa-15(a)(3)(A). Children who have a disability that can be demonstrated to reduce their future earning capacity may receive lost earnings calculated at the rate of average private, nonfarm wages, but these are payable only after the child reaches 18 years of age.

<sup>53</sup> 42 U.S.C. 300aa-15(a)(4).

<sup>54</sup> 42 U.S.C. 300aa-15(e).

<sup>55</sup> *Id.*

<sup>56</sup> 42 U.S.C. 300aa-15(a)(2). The statute does not expressly limit compensation to \$250,000 in cases of death, so prospective cases may be entitled to other losses incurred before death.

<sup>57</sup> 42 U.S.C. 300aa-15(b).

<sup>58</sup> *Id.*

<sup>59</sup> *Id.* See text accompanying notes 137-140.

## Time for Review

Determinations on eligibility and the amount of compensation, if any, to be awarded are to be made within a relatively short time period compared with tort litigation. As originally enacted, the Act required a final judgment by the Claims Court within 365 days after the petition was filed. Under the New Rules, effective with respect to petitions filed on or after January 19, 1990, the decision is to be made within 240 days after filing.<sup>60</sup> However, this period may be extended up to an additional 180 days in certain circumstances.<sup>61</sup>

Under the New Rules, the special master's decision will ordinarily be the final determination under the Program.<sup>62</sup> However, either party--the petitioner or the Secretary--may request the Claims Court to review the decision of the special master by motion made within 30 days after the decision is issued.<sup>63</sup> The Claims Court is to review the decision in the manner of an appellate court with limited powers of review. The Court may set aside any finding of fact or conclusion of law only if it is found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."<sup>64</sup> Alternatively, the Court may remand the case to the special master for further proceedings.<sup>65</sup> This review procedure is to be completed within 120 days after the motion for review has been responded to by the other party.<sup>66</sup> One final level of appeal is available. Either party, if aggrieved by the decision, may appeal to the United States Court of Appeals for the Federal Circuit.<sup>67</sup>

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<sup>60</sup> 42 U.S.C. 300aa-12(d)(3)(A)(ii).

<sup>61</sup> The special master may grant a one-time suspension of the proceedings upon motion by either the petitioner or the Secretary/Program Office. Thereafter, suspensions may be granted only if reasonable and necessary, and may not exceed 150 days in the aggregate. 42 U.S.C. 300aa-12(d)(3)(C). Thus, while the new time period is 4 months shorter than the year originally provided for, if all possible suspensions were granted, it could extend for 14 months. It is unclear whether this limit is jurisdictional, or merely a goal.

<sup>62</sup> As originally enacted, the special master merely submitted proposed findings of fact and conclusions of law to the Claims Court. The Claims Court had sole power to issue a final judgment and could hear a case de novo, as well as modify or reject specific findings and remand for additional proceedings.

<sup>63</sup> 42 U.S.C. 300aa-12(e)(1).

<sup>64</sup> 42 U.S.C. 300aa-12(e)(2)(B). If the Court does set aside any element of the special master's decision, it may issue its own findings of fact and conclusions of law. *Id.*

<sup>65</sup> 42 U.S.C. 300aa-12(e)(2). The Court must limit remand proceedings to not more than 90 days.

<sup>66</sup> 42 U.S.C. 300aa-12(e)(2). The responding party has 30 days in which to file a response to the request for review. 42 U.S.C. 300aa-12(e)(1).

<sup>67</sup> The appeal must be filed within 60 days after the Claims Court's final judgment is filed. 42 U.S.C. 300aa-12(f). There may be a question about whether the judgment is final enough to

Since the Program is an alternative, not an exclusive, source of compensation, each petitioner has the option to accept or reject the decision made on his petition. A petitioner must elect to accept or reject the decision within 90 days after the final judgment, or the judgment on appeal.<sup>68</sup> If the decision awarded the petitioner compensation, the award becomes payable. If a petitioner does not accept the judgment, he may file a civil action for damages for the vaccine-related injury or death.<sup>69</sup>

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merit appeal, since the petitioner may elect to reject it. However, it is the Program's final decision.

<sup>68</sup> 42 U.S.C. 300aa-21(a). Failure to file an election with the Clerk of the Claims Court is deemed an election to accept the decision. *Id.*

<sup>69</sup> Petitioners in retrospective cases who had dismissed pending civil actions without prejudice before entry into the Program may reject the Program's judgment and reactivate their civil actions. Petitioners with prospective cases may not commence a civil action prior to going through the Program. If they reject the Program's judgment, they may institute a civil action. State and federal statutes of limitation applicable to the civil action are tolled until the final judgment is issued under the Program, but not until the date of an election.

## Payment of Awards

Compensation awarded under the Program becomes payable only after a petitioner has filed an election to accept the judgment.<sup>70</sup> The Act originally required awards to be paid in a lump sum, with payments in retrospective cases being made in four equal annual installments. The Technical Amendments added some flexibility to the payment options by allowing the special master to use all or part of the award to purchase an annuity or other payment mechanism that would best serve the petitioner's interests.<sup>71</sup>

Awards in the prospective cases are to be paid out of a new Vaccine Injury Compensation Trust Fund that is intended to become self-sustaining in the long run. The Trust Fund is to be funded by taxes on vaccine manufacturers based on covered vaccine sales.<sup>72</sup> Congress separately appropriated \$80,000,000 out of general revenues for each of the fiscal years 1989 through 1993 to fund awards in retrospective cases.<sup>73</sup> In addition, Congress limited the number of retrospective cases in which the Program could award compensation to 3,500.<sup>74</sup> If appropriations are insufficient to permit payment of any award, the petitioner who is entitled to the payment is exempted from the prohibition against bringing a civil action for damages.<sup>75</sup>

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<sup>70</sup> 42 U.S.C. 300aa-15(f)(1).

<sup>71</sup> Payments that are in neither lump sum nor annuity form require the petitioner's consent. It is not clear from the statutory language whether purchasing an annuity also requires the petitioner's consent. Compensation is to be paid in a lump sum or installments "of which all or a portion of the proceeds may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner." 42 U.S.C. 300aa-15(f)(4)(A), (B). In practice, special masters seek the petitioner's agreement to all payment methods.

<sup>72</sup> Internal Revenue Code, sec 9510. The taxes specified currently per dose of vaccine are: DTP—\$4.56; MMR—\$4.44; Polio—\$0.29; DT—\$0.06. The Trust Fund now contains approximately \$290,000,000.

<sup>73</sup> 42 U.S.C. 300aa-15(j).

<sup>74</sup> 42 U.S.C. 300aa-11(b)(2).

<sup>75</sup> 42 U.S.C. 300aa-15(4)(B).

## Summary

The Program creates a "no-fault" alternative system for providing compensation for vaccine-related deaths and injuries. Its programmatic structure represents an innovation in federal benefit systems. It is not a general benefit or entitlement program based on injury alone because compensation is limited to injuries from a single source. It does, however, provide compensation to injured persons regardless of the presence or absence of any product defect or negligence. It is "no-fault" in the sense that compensation is not predicated on establishing that the injury was the fault or legal responsibility of any person or entity. Those who produced or distributed the vaccine or administered the immunization play no role in the Program. However, manufacturers contribute to the Trust Fund by means of the vaccine surtax. In this sense, it is similar to worker compensation programs. However, it is not the exclusive remedy or source of compensation for such injuries. The option of pursuing a civil action is preserved, subject to compliance with certain prerequisites. The Program is an optional alternative, though not additional, source of compensation for uncompensated injuries occurring before the Program took effect. For prospective cases, it is a first-resort alternative to civil actions for damages, conceptually akin to an administrative remedy that must be pursued before resort to the court is permitted. Again, however, the Program is an alternative to civil actions because claimants may not obtain compensation from both the Program and litigation.

The Program is cause-based in the sense that compensation is available only for injuries that are presumed to result from one source--required childhood vaccines. However, the concept of causation is given a new twist in order to expedite the process of determining claims for compensation. Proof of causation-in-fact--that a vaccine actually caused the injury in question--is presumed for certain medical conditions listed in the Vaccine Injury Table. The Act thus creates a Program based on causation-in-law, whereby the statute defines the nature of injuries that will qualify for compensation. Causation-in-fact is preserved, however, to permit compensation in cases in which injuries are actually caused by a covered vaccine, even though not included in the Vaccine Injury Table, and to preclude compensation in cases in which something other than a vaccine actually caused the injury.

The Program offers the promise of an expeditious award of compensation for anyone who has suffered a vaccine-related death or injury. The time required for deciding cases--ordinarily 1 year or less--is quite short. Although in some cases awards may be less than might be recoverable in civil actions for damages, they are swifter and more certain than litigation can promise. If the

Program functions smoothly, potential petitioners may be attracted to the Program as an alternative to litigation.

The differential treatment of retrospective and prospective cases found in the Program underscores an unusual feature: the extension of benefits to persons with injuries that occurred before the Act took effect. Such persons were influential in convincing Congress of the need for the Act. A compensation system with the normal prospective application would have been a victory for the principle of assisting persons with adverse reactions to vaccines, but it would have left them unaided. Congress attempted to fashion a system that would extend the benefits of the Program to those who exemplified its intended beneficiaries without depleting scarce revenues. Ultimately, it did so by limiting both the number and amount of awards payable in retrospective cases.

As in any new benefit program, there remain many questions about its ability to function smoothly and achieve its objectives. The Program's requirements are spelled out in considerable detail in the Act creating it. Yet there remain ambiguities in the statute that will require some interpretation. The Act requires all concerned to function in new roles. Ultimately, the attitudes of all those who come into contact with the Program and their ability and willingness to work within its framework will determine whether it can help to solve or exacerbate the problems it was designed to address. The remaining chapters offer some preliminary information to begin to answer such questions.

### Chapter III. The Vaccine Injury Table: Questions of Policy and Proof

The Program's use of the Vaccine Injury Table represents a departure from the structure of most federal compensation or disability benefit programs in this country. Eligibility for these programs generally is defined as a stated level of functional physical or mental disability or inability to perform gainful work, rather than a specific disease or medical condition. In addition, such programs ordinarily specify only the severity of injury by statute, leaving it to the administrative agency to develop rules or informal guidelines for determining what qualifies as an eligible disability.<sup>76</sup> The Program also differs

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<sup>76</sup> For example, the general definition of disability in the Social Security Old Age, Survivors and Disability Insurance Program, 42 U.S.C. 416(I), 423(D)(1)(A), is "inability to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last...not less than 12 months." See also, Railroad Retirement Act, 42 U.S.C. 321a(a)(1)(iv) and

from vaccine injury compensation programs in other countries for the same reasons.<sup>77</sup>

The Black Lung Benefits Act<sup>78</sup> is the closest precedent for the Program in that it compensates coal miners who are totally disabled due to pneumoconiosis or black lung disease. Moreover, there was some uncertainty, if not controversy, over the causal relationship between black lung disease and coal mining, at least in individual cases. Congress responded to the plight of the miners by creating presumptions, such as those that broadly define pneumoconiosis to include a wider range of respiratory problems than black lung disease strictly defined, that favor compensating claimants.<sup>79</sup> The Vaccine Injury Compensation Program emerged from a somewhat similar history and embodies a somewhat similar presumption that gives claimants the benefit of the doubt to permit compensation in a large proportion of cases.

The Vaccine Injury Table was adopted to eliminate disputes over whether an individual's death or injury was actually caused by a particular immunization.<sup>80</sup> Proving causation-in-fact is perhaps the most time-consuming and expensive element of civil actions for personal injury. This is especially true in civil tort actions claiming injury from adverse reactions to vaccines. By substituting the Vaccine Injury Table's list of compensable events for a requirement that causation be proved, Congress intended to remove the problematic issue of causation and create a prompt decisionmaking process.

There is no doubt that Congress recognized that the Table it drafted was merely a best estimate presumption of causation and that it would permit compensating some cases that may not actually have been caused by a vaccine. In its Report on the bill as originally adopted, the House Committee on Energy and Commerce said:<sup>81</sup>

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(v); Federal Employees Retirement System 5 U.S.C. 8451(a)(1)(B) (Supp. IV 1986); Veterans Disability Program, 5 U.S.C. 8337(a).

<sup>77</sup> Compensation systems created by statute in Denmark, the Federal Republic of Germany, France, Japan, Switzerland, and the United Kingdom also base eligibility on the severity of injury rather than a list of compensable medical conditions and require a determination that the vaccine caused the injury. See Mariner, *Compensation Programs for Vaccine-Related Injury Abroad: A Comparative Analysis*, 31 ST. LOUIS U. L. J. 599 (1987).

<sup>78</sup> 30 U.S.C. 901-945.

<sup>79</sup> Bloch, *The Use of Medical Personnel in Social Security Disability Determinations* 20 (Administrative Conference of the United States 1989).

<sup>80</sup> The House Committee on Energy and Commerce said the Program was intended "to compensate persons with recognized vaccine injuries without requiring the difficult individual determinations of causation of injury." House Rep. 99-908 at 6353.

<sup>81</sup> H.R. Report No. 99-908, 99th Cong., 2d Sess., pt. 1, at 18 (1986), U.S. Code Cong. & Admin. News 1986, at 6287, 6359.



The Committee recognizes that there is public debate over the incidence of illnesses that coincidentally occur within a short time of vaccination. The Committee further recognizes that the deeming of vaccine-relatedness adopted here may provide compensation to some children whose illness is not, in fact, vaccine-related.

The Committee Report went on to explain that ongoing research could provide better information on the incidence of vaccine injury, and that the Secretary or the Advisory Commission on Childhood Vaccines could propose appropriate revisions in the Table based on new information.<sup>82</sup> "Until that time, however," continued the Committee, "the Committee has chosen to provide compensation to all persons whose injuries meet the requirements of the petition and the Table and whose injuries cannot be demonstrated to be caused by other factors."<sup>83</sup>

All of the reported Claims Court decisions that have considered the issue have concluded that a petitioner who demonstrates that an injury listed in the Table occurred within the specified time period has satisfied his burden of proof as to a Table injury. As one decision put it, "Temporal association alone establishes legal causation for a Table injury."<sup>84</sup>

In practice, this has proved easier said than done. In the opinion of the Program Office, fewer than a quarter of the petitions it reviewed by March 1990 demonstrated a condition that qualified as a Table injury or death. It thus recommended against awarding compensation in almost three quarters of the cases it reviewed. Table III-1 shows the recommendations of the Program Office, together with the decisions of the Claims Court, in cases decided as of March 27, 1990. Table III-2 contains the recommendations and decisions that involved DTP vaccine, together with Claims Court decisions, by the injuries set forth in the petition. It can be seen that petitioners and the Claims Court often disagree with the Program Office on what medical conditions constitute a Table injury.

It appears that most petitioners believe that their injuries are listed in the Table. They considered the Program Office's opposing opinion to evidence disagreement with the Table itself. In other words, the Program Office was seen as disputing the accuracy of the conditions listed in the Vaccine Injury

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<sup>82</sup> *Id.* The part of the Act that was intended to encourage research was not funded until 1989.

<sup>83</sup> *Id.*

<sup>84</sup> *Shaw v. Secretary*, 18 Cl. Ct. 646, 650 (1989). This and other decisions have distinguished "legal causation":—the presumption used in the Act—from "causation in fact" as used in civil tort actions.

Table, presumably because it did not consider some conditions to be likely to be caused by the vaccine at all. This attitude, some believed, led the Program Office to search at length for what it considered to be the real cause of injury, even in cases in which the petitioner's injury was described in the Table. They felt this ignored the Table as a substitute for actual causation and was inconsistent with the Program's purpose and structure.

Even the Program Office concedes that it was conflicted initially in its ability to apply the Table to specific petitions. Because medical reviewers were familiar with the medical literature on adverse reactions to vaccines and the frequent difficulty of identifying individual cases, they could not help reacting skeptically to a statutory listing of conditions that seemed to them to ascribe actual causation. Perhaps inevitably, their awareness of the range of possible causes of neurological injury and death inspired them to consider all potential sources of injury, even in cases in which no other cause was apparent. This search for nonvaccine causes antagonized several petitioners and their attorneys, who felt that they had clear evidence of an injury defined in the Table and no indication of any other possible cause.

**Table II-1**  
*Comparison of Program Office Recommendations and Judgments  
as of March 27, 1990 (All Vaccines)*

Vaccine	<u>Program Office Recommendation</u>				<u>Claims Court Judgment</u>	
	<u>Table Injury</u>		<u>Award Compensation</u>		<u>Award Compensation</u>	
	<u>Yes</u>	<u>No</u>	<u>Yes</u>	<u>No</u>	<u>Yes</u>	<u>No</u>
DTP or P %	11 22.4	38 77.6	11 22.4	38 77.6	44 89.9	5 10.2
DT %	1 100	0 0	1 100	0 0	1 100	0 0
Polio %	1 100	0 0	1 100	0 0	1 100	0 0
MMR %	2 33.3	4 66.7	2 33.3	4 66.7	5 83.3	1 16.7
Total % of Total	15 26.3	42 73.7	15 26.3	42 73.7	51 89.5	6 10.5

**Table III-2**  
*Program Office Recommendations and Final Judgments in DTP  
 Cases as of 3/27/90*

<u>Injury Stated in Petition</u>	<u>Program Office Recommendation</u>				<u>Claims Court Judgment</u>	
	<u>Table Injury Yes</u>	<u>No</u>	<u>Award Yes</u>	<u>Compensation No</u>	<u>Award Yes</u>	<u>Compensation No</u>
Hypotonic- Hyporesponsive State or Col- lapse (HH)	0	2	0	2	2	0
Residual Seizure Disorder (RSD)	2	1	2	1	3	0
Encephalopathy or Enceph- litis (E)	0	1	0	1	1	0
Death (D)	0	0	0	0	0	0
Shock Col- lapse (SC)	0	0	0	0	0	0
RSD&E	3	8	3	8	9	2
RSD & D	2	0	2	0	2	0
RSD,E&D	0	1	0	1	1	0
HH & D	0	3	0	3	3	0
HH,E & D	1	8	1	8	9	0
E & D	2	5	2	5	7	0
SC & D	0	1	0	1	1	0
E, HH, RSD & D	0	1	0	1	1	0
E, SC, RSD & D	0	1	0	1	1	0

<u>Injury Stated in Petition</u>	<u>Program Office Recommendation</u>				<u>Claims Court Judgment</u>	
	<u>Table Injury</u>		<u>Award Compensation</u>		<u>Award Compensation</u>	
	<u>Yes</u>	<u>No</u>	<u>Yes</u>	<u>No</u>	<u>Yes</u>	<u>No</u>
Anaphylaxis (A), HH & D	0	1	0	1	1	0
A & E	0	1	0	1	1	0
A, HH, E & D	0	2	0	2	1	1
Allergic Reaction & D	0	1	0	1	0	1
Learning Disabilities	0	1	0	1	0	1
Unspecified	1	0	1	0	1	0
TOTAL	11	38	11	38	44	5
Percent	22.4	77.6	22.4	77.6	89.9	10.2

## The Function of the Vaccine Injury Table

The controversy over Table injuries raises both practical and conceptual problems. The practical problem is that causation-in-fact has become a disputed issue in a substantial number of cases, undermining the Program's intended efficiency. This is discussed in greater detail below.

The conceptual problem is the function of the Vaccine Injury Table; that is, whether the Table represents Congress' best estimate of causation in fact or merely definitions of compensable injuries. If, as the Program Office appeared to believe in the early months of operation, the Table is supposed to present a reasonably accurate list of adverse reactions actually caused by vaccines, one might believe that only those cases that are proved to be the specific result of a vaccine are eligible for compensation. That belief might be reinforced by the Act's provision for denying compensation in cases in which an unrelated factor was determined to cause the injury. However, Congress made clear that the Table was to serve as a substitute for proving causation-in-fact. Although it was compiled from the best estimates of causation available, its application was not intended to depend upon its accuracy in any individual case.<sup>85</sup> Once compiled and enacted, the Table was a list of compensable injuries. Recourse for those who disagree with the conditions listed in the Table lies in amending the Table.

To date, there has been no formal effort to amend the Table. However, renewed controversy over whether specific permanent injuries, such as encephalopathy and death, have resulted from the DTP vaccine raises the possibility. Although Congress contemplated revisions if new scientific information proved the Table to be in error, changes in the conditions listed for DTP vaccine could threaten the Program's future.

In February 1990, an article in the British medical journal *The Lancet* reevaluated the 1981 British National Childhood Encephalopathy Study, on which much opinion about adverse reactions is based, in light of a more recent assessment of its results and the decision in the British *Loveday* case.<sup>86</sup> It concluded that pertussis vaccine probably poses no risk of permanent neurological damage and that the British vaccine injury compensation system should be repealed. A study published in a March 1990 issue of the *Journal of the American Medical Association* reported that there was no increased risk of febrile, afebrile or acute symptomatic seizures in the days after immunization

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<sup>85</sup> See text accompanying notes 81-84.

<sup>86</sup> Bowie, *Lessons from the Pertussis Vaccine Court Trial*, 335 LANCET 397 (1990). See, also, Griffith, *Permanent Brain Damage and Pertussis Vaccination: Is the End of the Saga in Sight?* 7 VACCINE 199 (1989).

with DTP as compared with 30 or more days after immunization.<sup>87</sup> The study results contrast with earlier studies that found an increased risk of febrile seizures in the immediate post-immunization period (3.7 times that of the period 30 days or more after immunization).<sup>88</sup> However, the authors warned that their findings with respect to febrile seizures must be viewed with caution, in part because the study design may have caused them to miss cases that were not seen in a hospital or recorded in the medical record.

An editorial accompanying the JAMA study argued that these studies demonstrated that DTP vaccine could not cause encephalopathy.<sup>89</sup> The editorial called the Program a "new national tragedy"<sup>90</sup> because the Vaccine Injury Table lists encephalopathy as a compensable injury resulting from pertussis or DTP vaccine.<sup>91</sup>

Such articles have revived a controversy that the Program was intended, in part, to avoid: whether pertussis causes encephalopathy, seizures or death. The Institute of Medicine has convened a committee to review estimates of adverse reactions to pertussis vaccine and generally to take a fresh look at the evidence linking pertussis with adverse reactions.<sup>92</sup> Its report, not due until May 1991, is not likely to settle the issue, although it could shed some light on the quality of the scientific data available.

Whatever the merits of pertussis vaccine encephalopathy, the controversy lies at the heart of Program--both its *raison d'etre* and its administrative

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<sup>87</sup> Griffin, Ray, Mortimer, Fenichel & Schaffner, *Risk of Seizures and Encephalopathy after Immunization with the Diphtheria-Tetanus-Pertussis Vaccine*, 263 J. AM. MED. ASSN. 1641 (March 23/30, 1990). The study followed 38,171 children who received at least one DTP immunization in the Tennessee Medicaid program for about 3 years after birth. Less than 1 percent (0.9 percent or 356) of the children had a hospital medical record of having a seizure or encephalopathy within 14 days after DTP immunization. Only 2 children had encephalopathy, both more than two weeks after immunization, and neither had any permanent injury.

<sup>88</sup> Walker, Jick, Perera, Knauss, & Thompson, *Neurological Events Following Diphtheria-Tetanus-Pertussis Immunization*, 81 PEDIATRICS 345 (1988).

<sup>89</sup> Cherry, "Pertussis Vaccine Encephalopathy": *It Is Time To Recognize It As The Myth That It Is*, 263 J. AM. MED. ASSN. 1679 (1990).

<sup>90</sup> *Id.* at 1680.

<sup>91</sup> It blamed "the sensationalistic media," the organization of parents, and "the unique destructive force of personal-injury lawyers" for creating the Program and allowing it to perpetuate "the myth of pertussis vaccine encephalopathy." The editorial's author came under scrutiny by ABC News. He was accused of bias for failing to disclose in the editorial or to JAMA consulting fees and grants he and his university had received from Lederle Laboratories, which manufactures pertussis vaccine. Most recently, attorneys for some petitioners under the Program have claimed that the editorial was an attempt to mislead physicians and the public by discounting the real risks of pertussis vaccine.

<sup>92</sup> The committee has also felt the heat of controversy; at least one member resigned after a public challenge was raised as to his objectivity.

functioning. Adverse reactions to the diphtheria-tetanus-pertussis (DTP) vaccine were the primary concern of organized parents who supported the adoption of the Act. They also constitute the overwhelming preponderance of claims in petitions filed and decided (81.6percent) under the Program.

The majority of Program Office objections to petitions filed under the Program have been made in cases involving pertussis vaccine (77.6 percent). However, most awards of compensation (82.2 percent) have been granted in cases involving pertussis vaccine. If the Vaccine Injury Table were amended to exclude encephalopathy following pertussis vaccination, the Program might collapse. Such a change in the Table would undoubtedly provoke the strong opposition of many parents. That opposition might be sufficient to block any change in the Table. If so, one might expect Program Office physicians and many pediatricians associated with HHS to object and obstruct the Program's operation in pertussis cases.

The Program could become quite small if pertussis vaccine encephalopathy (or any adverse reaction to pertussis listed in the Table) were excluded as a compensable injury; many of the pertussis petitions would be excluded. On the other hand, the Program might get bogged down with efforts by petitioners to prove that their children's encephalopathy was caused by the vaccine, regardless of its omission from the Table. Parents and their attorneys might withdraw their support of the Program as a whole, and press their claims more vigorously in independent tort litigation. It is doubtful that the vaccine manufacturing industry would welcome a resurgence of litigation, unless it found the surtax attributable to pertussis cases under the Program especially onerous and it believed that it could defend lawsuits more cheaply. Thus, the controversy that in large part gave birth to the Program may resurface as the Program's greatest challenge.

In the absence of conclusive new evidence that a condition listed in the Table is not an adverse reaction to a covered vaccine, it would be difficult to remove a Table injury without jeopardizing the efficient continuation of the Program itself. Existing scientific studies indicating the probability of specific adverse reactions to pertussis vaccine have not quelled disagreement on either the nature or incidence of particular reactions.<sup>93</sup> The Vaccine Injury Table serves a critical function because it was intended to keep unresolvable disputes from affecting eligibility for compensation. It represents a policy choice made by Congress. As long as disputes over causation remain unresolved, that policy choice retains its justification and utility.

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<sup>93</sup> Disagreements even manifest themselves in efforts by the Advisory Commission on Childhood Vaccine to prepare informational materials for parents whose children are offered vaccination. The definitions of benefits and risks of pertussis vaccine and the emphasis given each has been hotly debated by members and invited experts.



## Practical Difficulties in Applying the Table

The primary merit of the Vaccine Injury Table lies in its elimination of disputes over the cause of injuries. However, applying the Table in individual cases has been more difficult than might have been expected. One reason was the apparent misunderstanding of the Table's function, discussed above. This kind of problem is not inherent in either the use of the Table or the Program itself and can be erased as Program participants better appreciate that the Table lists compensable injuries, not suggested examples of causation-in-fact.

A second, more difficult problem lies in interpreting the Table in individual cases. An example is the characterization of death following vaccination with a covered vaccine. The Act clearly contemplates death as a compensable injury and petitioners generally assume that it is a Table injury. However, the Vaccine Injury Table lists death only as an acute complication of other specifically listed conditions, such as anaphylaxis or shock-collapse. Thus, in cases in which a child died following vaccination, but there is no evidence of symptoms of another listed medical condition before death, the petitioner has assumed that the death qualifies as a Table injury, while the Program Office has frequently attributed the death to Sudden Infant Death Syndrome (SIDS), arguing that it does not qualify as a Table injury. Thus, the issue of causation-in-fact has intruded in a significant number of cases that Congress may have expected to be simple Table cases. While the Claims Court has awarded compensation in more than three times as many cases as the Program Office thought eligible, the necessity of resolving such disputes has slowed the decisionmaking process.

A third practical problem is that of proving that a Table injury occurred. The critical condition for establishing entitlement to compensation is that the injured person sustained, or had significantly aggravated, an injury or death listed in the Table within the time period specified in the Table. There is no doubt that the petitioner bears the burden of proof on this issue.<sup>94</sup> But the type of proof required to satisfy petitioner's burden remains problematic.

The most difficult cases often concern immunization with DTP. The Program Office has objected to more than 77 percent of petitions listing injury or death following vaccination with DTP vaccine, often on the ground that petitioner's evidence does not demonstrate that encephalopathy, hypotonic collapse, or other Table injury was the condition diagnosed shortly after vaccination. For example, in one case, the petitioner submitted an electroencephalogram (EEG) indicating neurologic abnormalities in support of a claim that a child had encephalopathy. The DOJ, on behalf of the Program Office, objected that "an abnormal EEG is not conclusive of an

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<sup>94</sup> 42 U.S.C. 300aa-13(a)(1)(A).

encephalopathy."<sup>95</sup> The Claims Court judge noted that the Act's aids to interpretation included a statement that "Encephalopathy can usually be documented by slow wave activity on an electroencephalogram."<sup>96</sup> Nonetheless, the Court required additional medical testimony on this issue because, in the absence of expert medical testimony, it did not consider itself able to decide whether the child in question suffered an encephalopathy as defined in the Act within the required time period.<sup>97</sup> Such decisions encourage presenting more extensive medical evidence to demonstrate a clear diagnosis.

The question remains whether the petitioner must present evidence of a physician's definitive diagnosis (of encephalopathy or other injury), or whether any kind of evidence of a condition described in the Table should satisfy the petitioner's burden of proof. The Program Office generally takes the former position, while petitioners, for the most part, take the latter. Most final judgments issued by the Court have adopted the latter position, although rarely explicitly. The Act specifies that the court may not find that the petitioner has satisfied his burden of proof "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion."<sup>98</sup> But it does not require that the medical opinion be contemporaneous with the injury. Some petitioners who are unable to produce medical records of a child's evaluation and treatment at the time of injury must themselves describe the child's behavior and condition. Then, to place the condition within the Table, they may offer medical testimony that the condition the parents describe indicates a Table injury. This approach would satisfy the requirements of the Act read literally, since the section calls for substantiation by "medical records or medical opinion" (emphasis added).<sup>99</sup> But medical opinion as to the meaning of symptoms or behavior that the physician has not personally verified is not always persuasive to the Program Office. Thus, proof (that a Table injury occurred) becomes a contested issue in a substantial number of cases.

Finally, there is the problem of determining whether an individual injury has been caused by something other than a vaccine, even if the injury clearly fits the Table. Section 13(a)(1) of the Act provides:<sup>100</sup>

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<sup>95</sup> Shaw v. Secretary, 18 Cl. Ct. 646, 650 (1989).

<sup>96</sup> *Id.*, citing 42 U.S.C. 300aa-14(b)(3)(A).

<sup>97</sup> *Id.*

<sup>98</sup> 42 U.S.C. 300aa-13(a)(1).

<sup>99</sup> It is also consistent with a related subsection that permits the special master or court to find that an injury occurred within the *time* prescribed in the Table, even if symptoms were not recorded or were inaccurately recorded, as long as there is a preponderance of the evidence that the injury did in fact occur within the Table's prescribed period. 42 U.S.C. 300aa-13(b)(2).

<sup>100</sup> 42 U.S.C. 300aa-13(a)(1).

(1) Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole--

(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 2111(c)(1) [300aa-11(c)(1)], and

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

Some difficulty has surrounded the question of who, if anyone, bears the burden of producing evidence that the injury is "due to factors unrelated to the administration of the vaccine." The Act does not assign any burden of proof of unrelated cause to anyone.<sup>101</sup> Instead, subsection 13(a)(1), quoted above, requires the special master or court to find "on the record as a whole" that it is not more likely than not that the injury was caused by an unrelated factor.

It is not entirely surprising that the Act does not specify responsibility for proving unrelated cause. Once it was decided to have two parties to a proceeding--the petitioner, and the Secretary as respondent--it may have been assumed that the respondent would function as a defendant-respondent in a civil action and produce evidence to rebut the petitioner's claim in doubtful cases. At the same time, it is unlikely that Congress expected the Program to receive many claims that were caused by factors unrelated to the vaccine. Congress wished to screen out of the Program cases that were patently caused by something other than a vaccine. But there is no reason to believe that Congress expected or desired an intensive investigation of causation akin to that conducted by civil defendants.<sup>102</sup> The Program's structure was crafted to avoid just such proceedings. Congress may have expected any evidence of a cause of injury unrelated to vaccination to appear in the petitioner's documentation of injury. If so, it may have assumed that the special master or judge could consider this evidence and identify ineligible injuries.

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<sup>101</sup> The Act refers to the court's finding "upon demonstration by a preponderance of the evidence" that an injury did not fit the Table, because of onset outside the time period, 42 U.S.C. 300aa-13(a)(2), but does not specify the source of the evidence.

<sup>102</sup> In the case of encephalopathy, the Act's aids to interpretation provide that if it is not possible to determine the cause of an encephalopathy by a preponderance of the evidence, it will be presumed to be a Table injury. 42 U.S.C. 300aa-14(b)(3)(B).

While the burden of proof of any unrelated cause is not specified in the Act, the burden of decision rests squarely with the special master, and, in early cases, with the Claims Court. The special masters have felt compelled by subsection 13(a)(1)(A) to make a finding of fact with respect to the presence or absence of an unrelated cause of injury. Some have been reluctant to do so in cases in which the Program Office has not taken a position.

In several cases, the Claims Court has stated that once a petitioner establishes a rebuttable presumption of causation, the burden shifts to respondent to show that the injury is due to unrelated factors.<sup>103</sup> Other cases have implicitly imposed the same burden by indicating that it is up to respondent to rebut a presumption of causation.<sup>104</sup>

The Program Office feels an obligation to present the special masters with any relevant arguments favoring an unrelated cause of injury. This falls somewhat short of formally assuming a burden of proving an unrelated cause, although the difference is not always apparent. This leads the Program Office to search the petitioner's evidence for indications of disease etiology independent of vaccination and to offer alternative explanations for the injury based on epidemiological studies.

The special master's role would be simplified if the Act placed on the respondent the burden of proving an unrelated cause of injury. In any case in which the respondent did not produce a preponderance of evidence (including evidence submitted by the petitioner) that an unrelated factor actually caused the injury, the special master could avoid weighing the evidence and award compensation on the ground that the respondent had failed to meet its burden of proof. Under existing circumstances, few special master feel that this option is open to them.<sup>105</sup> Instead, they must consider all the evidence and the often conflicting interpretations of the same evidence; they must find both a preponderance of evidence supporting petitioner's eligibility and no preponderance of evidence that the injury was caused by an unrelated factor.

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<sup>103</sup> *Bell v. Secretary*, 18 Cl. Ct. 751, 756 (1989); *Ciotoli v. Secretary*, 18 Cl. Ct. 576, 588 (1989).

<sup>104</sup> *Dunham v. Secretary*, 18 Cl. Ct. 633, 640 (1989).

<sup>105</sup> Several judges have found: "A successful showing of legal causation or causation in fact does not entitle petitioners to compensation. The court must still determine that the preponderance of evidence does not show an alternative cause for the injury." *Shaw v. Secretary*, 18 Cl. Ct. 646, 651 (1989).

## Conclusions

The most promising innovation made by the Program--the Vaccine Injury Table--has also proved to be one of the most controversial. Some of the controversy has historical roots in the debate over the kind and incidence of adverse reactions to covered vaccines. Some who believe that the Table includes conditions that are not caused by vaccines find it difficult to accept the Table's list as a substitute for causation-in-fact. But others, whether they agree or disagree with specific conditions listed in the Table, endorse the policy decision to eliminate causation as an issue for dispute in as many cases as possible. Thus, the utility of the Table has been widely accepted. To the extent that there are disagreements, they focus on the justifications for including one or more specific conditions in the Table. These kind of disagreements can be worked out within the Program's existing structure as long as it is accepted that the Table need not reflect indisputable proof of causation-in-fact but the desirability of settling a complicated problem.

As useful as the Table has been, it has not eliminated all problems of proving entitlement to compensation based upon a compensable injury. Although the Program permits petitioners to prove that a nonTable injury was in fact caused by a covered vaccine, most causation disputes have arisen in Table injury cases. Some of the disputes seem attributable to the inherent difficulties of proving that the injury was described in the Table and occurred within the requisite time period. Medical facts are not always obvious. Cases are not as easy as might have been expected. Different interpretations of some medical evidence seem inevitable, in retrospect. A list of compensable injuries will not avoid all disagreement over whether an individual's injury is described in the Table.

At the same time, the surprisingly high proportion of disputed cases suggests that some disagreement may have been unnecessary. In particular, the Program Office's objection to many Table injury cases, later found compensable by the Claims Court, on the theory that there might be an unrelated cause of injury appears to have been unfortunate. The time and energy required to locate and analyze nonobvious sources of information that might bear upon the actual cause of injury created an unnecessary burden on petitioners where there was no indication of any unrelated cause. The Table was made part of the Program to ensure speedy decisions. Protracted disputes over causation undermines the Program's efficiency and its ability to achieve its purposes.

## Chapter IV. Programmatic Structure and Administrative Innovation

Perhaps the most notable and innovative aspect of the Program is its programmatic structure. The nature and purpose of the Program might seem more readily suited to a simple benefit determination system administered by an agency within the federal executive branch. Since the Program sought to provide compensation for injuries on a no-fault basis, the major decisions affecting entitlement involve the cause of the injury, the nature of the resulting disability or death, and the amount of compensation needed to provide care for a permanently injured person. The first two factors turn on medical and scientific information; the third on medical and financial predictions. These are primarily questions of fact within the realm of expertise of administrative agencies like the Social Security Administration and the Health Care Financing Administration which administers Medicare and Medicaid.

The Program, however, uses the United States Claims Court and its special masters to make decisions respecting eligibility and compensation. While the Program Office reviews claims for compensation and presents its opinions to the Court, it does not act as decisionmaker for the Program. Although the Secretary of Health and Human Services may amend the Vaccine Injury Table by regulation, he is not authorized to issue regulations governing the decisionmaking process or interpreting the statute generally. The decisionmaking process is more similar to litigation or arbitration than to administration. Indeed, it operates most like an administrative tribunal.

### The Court or Special Master as Decisionmaker

The decision to vest jurisdiction for the resolution of claims with a court rather than a federal agency (or parallel state agencies) was primarily an effort to win the support of parents of children with vaccine-related injuries for the Act. Many parents placed little faith in the Department of Health and Human Services--the most obvious choice for a purely administrative program--because the agencies it oversaw, such as the Public Health Service and the Centers for Disease Control, were heavily involved in childhood immunization programs, and were seen as unsympathetic to compensating vaccine-related injuries.<sup>106</sup> Moreover, the Reagan administration opposed the adoption of the Program and made its opposition clear to the Department. The judicial system, on the other hand, was viewed by most parents as a more objective

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<sup>106</sup> See text accompanying notes 14-15.

arbitrator of vaccine injury claims, even though many courts had not permitted certain causes of action to be pursued on behalf of those with vaccine-related injuries.<sup>107</sup>

The Act as initially drafted and adopted in 1986 granted jurisdiction to the United States district courts to determine claims under the Program.<sup>108</sup> That court, however, was concerned with the possibility of having to handle a large number of new cases at a time when it had a full caseload. Some casting about for alternatives yielded the United States Claims Court, which was familiar with handling claims against the federal government. The Claims Court successfully sought additional resources to enable it to take on the anticipated cases and became the decisionmaker for claims under the Program. The Act was amended to reflect this change in 1987.<sup>109</sup>

The United States Claims Court was created by an Act of Congress in 1982 to succeed the Court of Claims.<sup>110</sup> Like its predecessor, the Claims Court has jurisdiction over monetary claims against the United States founded upon the Constitution, an act of Congress, an Executive Order, a regulation of an Executive Department, or a contract, express or implied-in-fact, with the United States.<sup>111</sup> Since an act of Congress authorizes the Secretary of Health and Human Services to make payments from the federal Trust Fund to eligible petitioners, the Claims Court is a comfortable choice for determining claims of entitlement to compensation. It also carried the advantage of national

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<sup>107</sup> See, e.g. *Brown v. Superior Court of San Francisco*, 44 Cal. 3d 1049, 245 Cal. Rptr. 412, 751 p. 2d 470 (1988).

<sup>108</sup> 42 U.S.C. 300aa-11(a)(1) (1987).

<sup>109</sup> Pub. L. No. 100-203, Title IV, Subtitle D, 101 Stat. 1330-221 (December 22, 1987).

<sup>110</sup> Federal Courts Improvement Act, Pub. L. No. 97-164, sec. 105(a), 96 Stat. 27, 28 (1982). For a brief description of the court, its history, and jurisdiction, see United States Claims Court Bar Association, *THE UNITED STATES CLAIMS COURT: A DESKBOOK FOR PRACTITIONERS* (1987).

<sup>111</sup> 28 U.S.C. 1502 (1982). The federal Statute specifying the major spheres of jurisdiction of the Claims Court is known as the "Tucker Act," 28 U.S.C. 1491 (1982). Claims against the United States commonly heard by the Claims Court under the Tucker Act include eminent domain cases claiming compensation for the taking of private property for a public purpose pursuant to the Fifth Amendment to the Constitution; suits for federal tax refunds pursuant to the Internal Revenue Code and IRS regulations; suits by federal government employees or military personnel for back pay for unlawful termination of employment; and suits to obtain compensation for the use by the federal government of patents or copyrights. The Claims Court is also granted specific jurisdiction to hear other types of claims under particular statutes. However, except where specifically authorized by statute, it may not grant declaratory judgments nor issue equitable relief. With few exceptions, the Claims Court may only hear claims for money against the United States. The Claims Court has 16 judges who are appointed by the President and confirmed by the Senate. A Chief Judge, currently Loren A. Smith, is designated by the President. 28 U.S.C. 171 (1982).

jurisdiction that permits one court to handle cases regardless of the residence of claimants.<sup>112</sup>

Within the court, a new group of special masters created expressly for the Program is responsible for handling petitions. This specialized unit was unusual when originally established because the special masters heard only Program cases. As a result of the Technical Amendments, it has become unique in possessing final decisionmaking authority on all Program petitions filed since January 19, 1990.

Siting the decisionmaking process in an existing court makes the Program's structure quite distinct. It has the advantage of placing decisionmaking in the hands of persons who are truly disinterested in the outcomes of the claims they decide. The judges and special masters have not been involved in any medical or scientific controversy surrounding the existence or frequency of adverse reactions to vaccines. At the same time, this impartiality can be seen as disadvantageous by those who believe that some expertise in immunizations is necessary to understand the issues to be resolved.

The use of a court to make Program determinations has also created some difficulties in implementing the informal, expedited process envisioned by Congress. The difficulties may be attributable in part to the statutory structure established by the Act, in part to the organization and structure of courts as an institution, and partly to the decisionmaking needs of the Program.

The Act essentially grafted an administrative benefit system onto a judicial institution. While the Program was to be, and now is, a largely self-contained unit housed within the Claims Court, it was also subject to the internal administrative control of the judiciary. This meant that the Program would function within what anthropologists might call the culture of the courthouse. While there are both advantages and disadvantages to such a culture, it generated some consternation both at the Program Office and in Congress in the Program's earliest days.

## The Vaccine Rules

A significant example of this controversy was the Vaccine Rules. One of the first administrative actions taken by the Court was the adoption of rules to govern Program determinations. While the Act specified requirements for eligibility for compensation in great detail, it did not prescribe the internal procedures for filing and reviewing petitions, proving eligibility, or determining amounts of compensation. This hardly made the Act different

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<sup>112</sup> The Claims Court is located in Washington, DC. Claims Court judges may travel to any location to hear cases for the convenience of the parties.



from other legislation creating new programs. There is necessarily a gap between the general programmatic structure that the legislature can draft and the day-to-day actions that the Program participants must perform to operate it. The rules were an attempt to fill this gap. After the Program became effective in late 1988, the Court began drafting rules. After modifying the draft in response to comments on the proposed rules, the first Vaccine Rules were adopted by the Claims Court on January 25, 1989.<sup>113</sup> Four special masters, including the chief special master, were then in a position to begin to consider petitions that had been filed since October 1, 1988.

What troubled critics of the Rules was their similarity to the detailed rules of practice before the Claims Court, which, like the rules of most courts, are familiar to practicing lawyers and incomprehensible to most laypersons.<sup>114</sup> The Claims Court rules of practice prescribed such things as the time for filing pleadings and other papers, how service is made on parties to an action, the form of motions, procedures for discovery, conducting hearings, presenting evidence, entering judgments, and writing briefs. Such rules are intended to help attorneys present their cases efficiently to the Court. The Vaccine Rules followed this format for the sake of consistency. They were intended to help attorneys, especially since no one could be very familiar with the new Program and it was expected that few attorneys for petitioners would have practiced before the Claims Court or be familiar with its particular rules practice. In large part, they reproduced the general Claims Court Rules for use in the Program.

The Vaccine Rules, however, dismayed some in Congress who thought their technical legal nature inconsistent with the Act's mandate for informality in the Program. In particular, specific rules for conducting discovery and hearings, including the presentation of testimony, seemed more appropriate for traditional adversary litigation than for a Program designed to decide claims expeditiously. There was also concern that petitioners would be unable to enter the Program without the assistance of an attorney, because only attorneys could understand and comply with the Rules. While the Act clearly contemplated that petitioners might be represented by counsel, many feared that such representation coupled with traditional court rules could delay proceedings and make them overly adversarial. Interestingly, however, complaints about the Rules' formality or technicality came primarily from Congress and the Program Office, not from petitioners or their attorneys. The Vaccine Rules were ultimately revised and reissued in simpler form<sup>115</sup> in

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<sup>113</sup> Vaccine Rules, General Order No. 23, United States Claims Court, January 25, 1989.

<sup>114</sup> The Claims Court is bound to follow the federal rules of evidence and procedure.

<sup>115</sup> Vaccine Rules, General Order No. 26, United States Claims Court, January 18, 1990, in Appendix J to the Rules of the United States Claims Court.

response to such concerns. The revision was undertaken by the Office of Special Masters after it had become the Program's decisionmaking unit as a result of the Technical Amendments. By then, experience with several vaccine petitions helped to clarify the kinds of rules that might serve the Program. Perhaps more importantly, as a separate unit, the special masters felt themselves free of any constraint experienced by the judges to adhere to the Federal Rules of Civil Procedure and Evidence. They considered themselves free to adopt informal measures to develop the record and hear evidence.

### Hearings and Informality in Decisionmaking

The most important decision to be made in the Program is, of course, whether a petitioner is eligible for compensation. The Act makes eligibility turn on six factors: the type of the vaccine; the nature of the injury, when it occurred, and whether it is listed in the Vaccine Injury Table or, if not, whether it was caused by a covered vaccine; the person's residence or citizenship; whether a person has received compensation for the same injury; whether the injury generated more than \$1,000 in unreimbursable expenses; and whether the injury or death resulted from another cause.<sup>116</sup> The Act also requires the special master to make a determination on eligibility. On what basis is the determination to be made?

Petitioners have the burden of proving the first five eligibility requirements by a preponderance of the evidence.<sup>117</sup> Thus, the special master must base a determination on a review of the evidence. It is possible that Congress originally intended the special master to do this acting alone like an administrative decisionmaker. Before the Act was drafted in final form, it envisioned an *ex parte* proceeding in which the petitioner merely submitted a claim to the Program for decision. No other parties--not the vaccine manufacturer, the person who administered the vaccine, or the government--were to become parties to the process. Ultimately, however, the Act created a two-party proceeding with the Secretary as respondent. Thus, the Program became a variant on a civil action. The petitioner is required to prove eligibility and damages. The respondent may object to any such proof or its weight. Although some may have expected the Program Office to submit expert opinion as the nominal respondent without being a real party in interest, its statutory designation makes it a real adversary in the Program's structure. The Act treats the special master like a judge, not like an administrative medical reviewer. The quasi-judicial role of the special master led to some

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<sup>116</sup> 42 U.S.C. 300aa-11(c)(1).

<sup>117</sup> 42 U.S.C. 300aa-13(a)(1)(A).

misunderstanding in the first few months of the Program's operation. The Act required the special master to base a decision on a preponderance of the evidence substantiated by medical records or by medical opinion.<sup>118</sup> Special masters could not decide cases based on their own knowledge. But they knew how to review evidence presented by parties to litigation. In an effort to ensure impartial decisionmaking, they relied primarily on trial-type procedures to elicit a fair and complete airing of the evidence. For most, this included a hearing on the evidence. The hearing entailed having the petitioner or the petitioner's attorney present the evidence supporting eligibility, including medical records and expert testimony on the date and nature of the injury. The physician who reviewed the petition on behalf of the Program Office was also expected to offer expert opinion on the cause of the injury. The actions of special masters in setting rules about what kind of documents could be introduced as authentic, and who should speak when, and encouraging cross-examination of experts looked to many like an effort to hold a mini-trial.<sup>119</sup>

As a practical matter, it is hard to fault the special masters for their reliance on hearings. If evidence is to be presented, there must be a place for the parties to do so. If the evidence is to be considered critically by the special master, it must be subject to some kind of testing for relevance and accuracy. The special masters had no factual basis for critiquing the evidence themselves, at least during the first months of the Program when they confronted vaccine-related issues for the first time. It should not be surprising, therefore, that they asked counsel for the parties, who were familiar with the issues, to pose questions to their own and opposing experts to elicit an adequate analysis of the evidence to permit a reasoned decision. This process, however, looked too much like cross-examination in a trial to fit within the informality mandate for the Program. Petitioners' counsel often viewed Program office physicians as expert witnesses for the respondent and cross-examined them vigorously both as to their expertise and their opinions. It disturbed Program Office physicians who had no experience with litigation and, not being adequately informed of its purpose, made them feel they were targets of an inquisition instead of the independent experts they thought they were. This tension apparently reinforced the feeling that the Program Office, as well as petitioners, needed representation by counsel. Attorneys from the Department of Justice were

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<sup>118</sup> 42 U.S.C. 300aa-13(a)(1).

<sup>119</sup> Special masters wore judicial robes when holding such hearings. The court believed that the parties were entitled to feel that the petition was being taken seriously by an impartial decisionmaker and that the robes were a sign of respect for the Program. Others viewed the use of robes as overly judicial and the special masters abandoned the practice in deference to the concern. Although a trivial issue, it illustrates the degree of sensitivity that existed over the formality appropriate to the Program.

expected both to protect Program Office staff and to communicate with the special masters in their own language.

Some members of Congress took particular exception to the litigation appearance of hearings.<sup>120</sup> When the Program began to get stymied in the summer of 1989, Congress agreed to consider amending the Act to get rid of formalistic procedures. The Technical Amendments of 1989 specifically required the adoption of new rules that would "provide for a less adversarial, expeditious, and informal proceeding for the resolution of petitions," "include flexible and informal standards of admissibility of evidence," limit discovery, and include opportunities to submit arguments and evidence without cross examination or hearings.<sup>121</sup>

The hearing problem has been largely settled by a modified hearing format with less reliance on formal rules of presentation. It qualifies as a hearing largely because it is an opportunity for all parties to hear each other, present evidence, and pose questions. That is the essence of a hearing. The formality has been diluted and the hearing made more congenial by the special masters' addition of one or more status conferences in which the parties or, ordinarily, their attorneys, meet with the special master to identify areas of agreement and dispute.<sup>122</sup> This is consistent with trial practice, but the actual conferences have a more casual feeling than most pretrial conferences.

The most interesting adaptation of the pretrial conference is the Rule 5 Conference, devised to expedite decisionmaking. Under Vaccine Rule 5, the special master may meet with the parties (usually just the parties' counsel, in person or by telephone) to clarify points of agreement and dispute. Because all of petitioner's documentation and respondent's reports must be submitted before the meeting, it is an excellent opportunity to test the merits of a case. Deficiencies can be identified and often remedied early enough to meet the statutory deadline for decisions. Each party can explain its position and question the other party to narrow the points actually in dispute. Not infrequently, the discussions lead to settlement. Most important, the special master may offer a tentative, nonbinding reaction to the arguments and how it

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<sup>120</sup> The Conference Report on the Technical Amendments noted,

"The Conferees have received reports that the current rules of the court are formal rules akin to those of the Federal courts for civil litigation. The Conferees once more reiterate their desire that the vaccine proceedings be made as swift and uncomplicated as possible." Omnibus Budget Reconciliation Act of 1989, Conference Report to accompany H.R. 3299, at 515 (Nov. 21, 1989). The Report also stated their concern that the authority given to the special master "not be used to re-create an adversarial process...." *Id.* at 516.

<sup>121</sup> 42 U.S.C. 300aa-12(d)(2).

<sup>122</sup> The parties are also allowed and encouraged to reach agreement themselves both on eligibility and amounts of compensation, that is, to "settle" the case.

appears the case should be decided. In some instances, a final decision emerges rapidly from a Rule 5 Conference. In others, additional proceedings can be arranged conveniently and expeditiously. The off-the-record atmosphere is valuable in producing an honest and critical appraisal of a case and moving it quickly to resolution.

Another interesting innovation, instituted early in the Program, is the conduct of hearings and conferences by telephone. All special masters now conduct some hearings by telephone conference call with attorneys for the parties and witnesses all on the line. This procedure enhances the Program's efficiency. Since experts who may testify may come from a different state than the petitioner, and some attorneys represent petitioners outside their own state of practice, it is often difficult and expensive to bring all the necessary people together in one place. Telephonic hearings eliminate the travel time and expense, as well as problems finding a date convenient for all. These hearings are growing in popularity and use. Most special masters began to use them after having met the parties--or at least the petitioner's attorney--and having heard the experts (usually in an earlier case)--in person. Having had an opportunity to assess a witness' credibility in person, they were comfortable receiving oral testimony over the telephone.

The national jurisdiction of the Claims Court made the use of telephone conferences both possible and popular. In addition, it enables the special masters to travel to other locations to conduct conferences and hearings in person. This saves petitioners considerable time and expense. Although the Claims Court pays for the travel of the special master and the government for a DOJ attorney and sometimes Program Office expert to travel, the total number of persons traveling is usually smaller than would be necessary to bring everyone to Washington, DC.<sup>123</sup> Thus, the net outlay is lower. The Program saves money because it ordinarily pays the travel fees incurred by and on behalf of petitioners as part of attorneys' fees and other costs. These and other procedures have been summarized recently in *Guidelines for Practice* issued by the Office of Special Masters in April 1990.<sup>124</sup> The *Guidelines* supplement the Vaccine Rules by explaining the general conduct of Program proceedings, emphasizing the flexibility of the procedures available in the spirit of a renewed commitment to the informality mandate.

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<sup>123</sup> Moreover, the program Office and/or DOJ attorneys sometimes appear by telephone in Washington, DC hearings.

<sup>124</sup> Office of the Special Masters, U.S. Claims Court, *GUIDELINES FOR PRACTICE UNDER THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM*, April 1990 (available from the U.S. Claims Court).

## Front-End Loading

Another innovation created by the Program is the requirement that all evidence supporting eligibility for compensation be submitted at the time the petition is filed. This is known as "front-end loading." The Act initially permitted a petition to be filed with "supporting documentation" of eligibility.<sup>125</sup> The Program Office was frequently of the opinion that many materials relevant to determining eligibility were omitted. Petitioners sometimes disagreed. Considerable time was spent in discovery trying to identify and obtain additional medical and other records before a petition would be reviewed, or in resolving disputes about just what documentation was necessary.

The Technical Amendments clarified the kinds of documentation that must be submitted with the petition.<sup>126</sup> This reduced the opportunities for dispute and simplified assessments of whether a petition was complete. Identifying and collecting the documentation before a petition is filed, however, may delay the commencement of review.<sup>127</sup> Thus, front-end loading may merely shift the document collection time period from after filing to before filing a petition. In cases in which a potential petitioner learns of possible eligibility to enter the Program shortly before the statute of limitations expires, it may be difficult or impossible to produce an acceptable petition by the filing deadline.

## Calculating Compensation

While the issue of eligibility for compensation has been the focus of the greatest conceptual dispute, determining the amount of compensation payable to eligible petitioners has been more time-consuming than might have been predicted. The Act says very little about how to calculate compensation.<sup>128</sup> It

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<sup>125</sup> 42 U.S.C. 300aa-11(c)(1987).

<sup>126</sup> Petitioners must attach to a petition "maternal prenatal and delivery records, newborn hospital records..., vaccination records..., pre and post-injury physician and clinic records..., all post-injury inpatient and outpatient records..., if applicable, a death certificate, and, if applicable, autopsy results..., and identify records that are not available and the reasons for their unavailability. 42 U.S.C. 300aa-11(c)(2),(3). These were the records that the Program Office stated they would "view as necessary" to conduct its review in an advice to the public, published in the Federal Register, 53 Fed. Reg. 49360, on December 7, 1988.

<sup>127</sup> Several petitioners attorneys estimated that, in ordinary circumstances, at least 2 months would be required to obtain medical records from physicians, clinics, and hospitals.

<sup>128</sup> See text accompanying note 51.

does specify that medical expenses be those that are actually incurred<sup>129</sup>--both before and after the final judgment in prospective cases, but only after judgment in retrospective cases. But since the award must be made before future expenses are incurred, an estimate is needed.

To estimate future expenses of caring for a disabled child, petitioners have used the testimony of economists, actuaries, and case managers. Special masters have held separate conferences or hearings to consider compensation awards. Settlement of compensation amounts has proved difficult in many cases. Petitioners and DOJ attorneys may have different expectations of appropriate amounts.<sup>130</sup> Thus, hearings must often be held on the kinds of therapy, rehabilitation, and other care that will be needed and for how long and at what cost, exclusive of possible insurance and other benefits. In the absence of statutory measures, such as inflation or discount rates to reduce future costs to present values, the parties may disagree not only as to the kind of expenses that are necessary, but also how to calculate their current value.

Many issues are quite narrow and technical. In one case, for example, the DOJ has challenged the inclusion of compensation to cover future taxes on interest earned on the invested compensation award as without basis in the statute. The Claims Court rejected the challenge. Noting that the Act calculates compensation "on the basis of the net present value of the compensation,"<sup>131</sup> the Court observed that net present value would reflect both future interest payments and drains on such interest, such as taxes.<sup>132</sup> Moreover, the Act requires that future earnings losses be reduced by expected income taxes as such earnings. Thus, it found it consistent to account for the tax effect as it reduces both future losses and future interest. Similarly, the Court rejected a DOJ contention that leisure equipment like swings did not qualify as equipment for therapy,<sup>133</sup> stating that the terms or labels used to describe otherwise appropriate rehabilitative equipment should not take precedence over substance. The Program Office also argued, unsuccessfully,

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<sup>129</sup> Expenses reimbursable to the petitioner are not incurred expenses. Compensation will not be awarded for benefits paid by any insurer, state compensation program, or federal or state health benefits program, except medicaid. 42 U.S.C. 300aa-15(g). The Technical Amendments added the medicaid exception to ensure that medicaid is not a primary payor.

<sup>130</sup> DOJ attorneys may also be hampered in some cases by limitations on the amounts they can authorize for payment to settle a petition. Settlements exceeding \$750,000 must be approved by the Deputy Attorney General.

<sup>131</sup> 42 U.S.C. 300aa-15(f)(4)(A).

<sup>132</sup> *Shaw v. Secretary*, 18 Cl. Ct. 646, 654 (1989).

<sup>133</sup> *Clark v. Secretary*, 19 Cl. Ct. 113, 126-7 (1989).

that compensation should be offset by future Medicaid benefits on the theory that the child could qualify for Medicaid in the future.<sup>134</sup>

Resolution of these kinds of issues is time consuming and, if financial and life care plan experts are used, expensive.<sup>135</sup> The time saved by the use of the Vaccine Injury Table may be lost in the determination of compensation awards. Of course, this problem is largely restricted to cases of injury and not death. But an increasing proportion of cases now being reviewed involve injury, partly because more death cases were decided earlier. Because injury cases generally involve severely disabled children who will require many years of care, the amounts at issue are high, often reaching above \$1 million. Thus, the Program faces the likelihood of a growing number of hearings to decide significant amounts of compensation. Since these occur at the end of the decisionmaking process, protracted proceedings can jeopardize the program's ability to reach a final decision within statutory time limits. While it might be desirable to begin to consider compensation amounts earlier in the decisionmaking process, it could prove a waste of time and money for those cases in which the petitioner was found ineligible for compensation. An alternative might be to develop compensation schedules that could be applied, with some flexibility, more efficiently.

### Attorneys' Fees

The structure of the Program tends to encourage petitioners to be represented by counsel and to discourage proceeding *pro se*. Thus, the willingness of competent counsel to represent petitioners will affect the number of petitions filed and decided and, presumably, petitioners' general satisfaction with the Program's existence. The availability of attorneys' fees influences an attorney's ability and willingness to represent petitioners.<sup>136</sup> The Act's provisions governing attorneys' fees<sup>137</sup> gave rise to some initial confusion and may pose additional difficulties in the future.

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<sup>134</sup> *Clark v. Secretary*, 19 Cl. Ct. 113 (1989); *Moorhead v. Secretary*, 18 Cl. Ct. 849 (1989). The argument was rejected largely because the government had no evidence that the child could become eligible for Medicaid, even though the Secretary, as nominal respondent, had superior knowledge respecting eligibility.

<sup>135</sup> An extreme example is a hearing on the amount of compensation in one case that lasted 30 hours.

<sup>136</sup> *Clark v. Secretary*, 19 Cl. Ct. 113, 131 (1989) ("It is in the public's interest to encourage attorneys to accept vaccine injury cases by assuring a reasonable attorney fee.").

<sup>137</sup> 42 U.S.C. 300aa-15(b) & (e).



## The \$30,000 Limit in Retrospective Cases

The initial controversy concerned the amount of attorneys' fees in retrospective cases. The Act limited the amount payable for attorneys' fees and costs, together with compensation for lost earnings and pain and suffering, to \$30,000.<sup>138</sup> Some petitioners' attorneys and two special masters interpreted the statute to mean that the \$30,000 limitation applied only to costs and attorneys' fees for services undertaken to establish lost earnings and pain and suffering,<sup>139</sup> so that fees and costs attributable to other services were not limited. This interpretation seems a bit strained, even considering the rather cumbersome wording of the statute, especially since there is little, if any, precedent for limiting attorneys' fees on the basis of the nature of damages for which services were performed. Those who drafted the legislation certainly meant to place the cap on the combined total of all four items.<sup>140</sup> Congress made its intent explicit in the Technical Amendments by rewriting section 15(b) to limit to \$30,000 the sum of all attorneys' fees and costs, pain and suffering, and lost earnings in retrospective cases.<sup>141</sup>

It is unfortunate that time and resources had to be used to clarify the section. But the process of clarification did not damage the structure or operation of the Program. Careful analysis of statutory language to settle conflicting interpretations of available compensation seems inevitable in any new benefit program.

Some participants, however, are concerned that the \$30,000 limit is still too low to permit representation in many cases. In cases in which the petitioner had instituted a civil court action for same injury before the Program began, substantial out-of-pocket costs and many attorney's hours may have

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<sup>138</sup> 42 U.S.C. 300aa-15(b).

<sup>139</sup> See *Hanagan v. Secretary*, Report of the Special Master, 1989 U.S. Cl. Ct. Lexis 277; *Clark v. Secretary*, Report of the Special Master, 1989 U.S. Cl. Ct. Lexis 113; *Shepherd v. Secretary*, Report of the Special Master, 1990 U.S. Cl. Ct. Lexis 292; *Shaw v. Secretary*, Report of the Special Master, 1990 U.S. Cl. Ct. Lexis 258.

<sup>140</sup> See H.R. Rep. No. 391(I), 100th Cong. 1st Sess., 1987 U.S. Code Cong. & Admin. News 2313-1, 2313-371 to 2313-372. The majority of special masters and judges accepted this interpretation. A detailed explanation is set forth in *Mikulich v. Secretary*, 18 Cl. Ct. 253 (1989). See, *Clark v. Secretary*, 19 Cl. Ct. 113 (1989); *Hanagan v. Secretary*, 19 Cl. Ct. 7 (1989); *Shepherd v. Secretary*, 18 Cl. Ct. 774 (1989); *Shaw v. Secretary*, 18 Cl. Ct. 646 (1989); *Matthews v. Secretary*, 18 Cl. Ct. 514 (1989); *Bazan v. Secretary*, 18 Cl. Ct. 309 (1989). But, see *Brown v. Secretary*, 18 Cl. Ct. 834, 845 (1989).

<sup>141</sup> That section now provides: "Compensation awarded under the Program to a petitioner [in retrospective cases] may also include an amount, not to exceed a combined total of \$30,000, for (1) lost earnings (as provided in paragraph (3) of subsection (a)), (2) pain and suffering (as provided in paragraph (4) of subsection (a)), and (3) reasonable attorneys' fees and costs (as provided in subsection (e))."

been spent.<sup>142</sup> If these out-of-pocket costs and some compensation for legal services is not recoverable under the Program, there may be little incentive for an attorney to encourage filing with the Program rather than pursuing the civil action.<sup>143</sup> The \$30,000 limit may have a more dramatic impact on cases that do not appear to fit the Table, because the evidence needed to prove that a covered vaccine caused the injury or death can be expensive. Even in Table injury cases, the Program Office significantly influences the documentation and expertise that should be presented and, with them, the time spent demonstrating eligibility for compensation.

Because these concerns apply only in retrospective cases, they will expire with the right to file retrospective petitions on October 1, 1990. Nevertheless, to the extent that attorneys' fee limits reduce access to the Program by potential petitioners, they may undermine public satisfaction with the Program. In addition, if Congress were to consider placing limits on attorneys' fees for prospective cases in the future, the same issues would resurface. Then it would be important to determine the actual reasonable costs of pursuing both Table and nonTable cases, and to compare those costs with the Trust Fund resources available.<sup>144</sup>

## Reasonable Attorneys' Fees

The question of what constitutes a reasonable attorney's fee will continue to confront prospective cases. While petitions concerning post-October 1, 1988 vaccinations will not have incurred prior litigation expenses, they will have no limitation on attorneys' fees and costs. Will the Program have developed acceptable rules of thumb for calculating reasonable attorneys' fees and costs? There is, of course, a substantial body of law governing the award of attorneys' fees in federal court actions and the Claims Court has drawn upon

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<sup>142</sup> In one case, for example, an attorney estimated that \$100,000 were spent in costs alone in prior litigation.

<sup>143</sup> The Act tries to encourage choosing the Program by permitting an award of past costs and expenses (including the reasonable value of time spent by attorney) in cases in which the petitioner dismissed a pre-October 1, 1988, civil action in order to enter the Program. 42 U.S.C. 300aa-15(e)(2). Eligible costs and time spent must have occurred before October 1, 1988. This subsection appears to permit such an award in addition to the award for attorneys' fees and costs under the Program because it does not specify that this award counts as part of the regular award authorized in subsection 300aa-15(e)(1). But the award does not appear to apply to civil actions that were lost by petitioner or settled without compensation before filing a petition with the Program. 42 U.S.C. 300aa-11(a)(4).

<sup>144</sup> One astute judge noted potential problems with the \$30,000 statutory limit and observed that if "experience teaches us that a problem exists, it will be up to the Congress to formulate a solution." *Clark v. Secretary*, 19 Cl. Ct. 113, 128 (1989).

it in determining awards in retrospective cases.<sup>145</sup> But each case must be decided upon its own facts.

An alternative method would be to establish a fee schedule based on the type of injury, with or without adjustments for expertise, geographic location or other cost factors. A schedule has the advantage of predictability and speed of application, but lacks the flexibility ordinarily thought necessary in varied circumstances. Attorneys' fees awards in retrospective cases have spanned a wide range. The variation cannot be explained by whether or not the petitioner claimed a Table injury. It remains to be seen whether future cases will exhibit enough regularity to permit consistent fee awards.

The limitation on attorneys' fees in retrospective cases may have contributed to streamlining the Program's operation. With fee limits, attorneys may have spent less time on a case than they ordinarily might or moved it along more efficiently. There may be less incentive for efficiency in prospective cases unless a fee schedule is created or reasonable fee awards become predictable as a result of consistent Program decisions. The Program's ability to award fees and costs in good faith cases even if the petitioner is not entitled to compensation should help encourage attorneys to represent petitioners even if fee awards are relatively modest.

## Conclusions

The Program's programmatic structure represents an innovation in federal benefit programs. It is a hybrid organization composed of elements of a traditional administrative agency review system and traditional civil litigation proceedings for the resolution of disputes. It may be most comparable to an administrative tribunal. In spite of Congressional wishes that the process be nonadversarial, however, it is more like litigation than administrative review. Part of this is the result of the different expectations for the Program harbored by different participants. But most is attributable to the very programmatic structure created in the Act. Establishing petitioners and a respondent and putting the decisionmaking authority in a court virtually guaranteed that the

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<sup>145</sup> The special masters and the Court have adopted the "lodestar" method described in *Lolley v. Secretary*, 88-33V, 99 W.L. 132196 (Cl. Ct. Oct. 18, 1989). See, e.g. *Gregson v. Secretary*, 17 Cl. Ct. 19 (1989); *Ciotoli v. Secretary*, 18 Cl. Ct. 576 (1989). This method calculates fees as the product of a reasonable number of hours multiplied by a reasonable hourly rate. Most cases have approved hourly rates of between \$100 and 200 per hour, depending upon the attorney's place of business and expertise. However, at least two judges have limited fees to \$75 per hour as in the Equal Access to Justice Act, largely for lack of reliable justification for a higher rate. *Moorhead v. U.S.*, 18 Cl. Ct. 849, 853-4 (1989); *Brown v. Secretary*, 18 Cl. Ct. 834, 844 (1989).

process would simulate court procedures. The use of special masters and judges whose experience is limited primarily to litigation encourages their reliance on judicial procedures to ensure impartial results in cases whose facts they knew little about prior to the enactment of the Program. Nonetheless, an impartial decisionmaker is especially valuable in a program intended to address issues with a history of controversy. Moreover, the procedures have been adapted to suit a process that must be completed in a relatively brief amount of time. The Program offers an exciting alternative both to litigation and to administrative review. While the alternative has taken some getting used to, it is settling into place and gaining increasing acceptance with each month of operation.

## Chapter V. New Roles for Program Participants and the Technical Amendments

The new hybrid structure of the Program has assigned special functions to the special masters, judges, Program Office physicians, Department of Justice attorneys, and petitioners' attorneys. Some of these functions are specified in the Act; others have developed as responses to the need to create the administrative procedures necessary to implement the Program. Because the decisionmaking process employs petitioners, respondents, and a court, and is intended to provide a simple and efficient compensation mechanism, the participants have assumed hybrid roles suitable to the programmatic structure. Defining these new roles has been an iterative process requiring some creativity and patience, and is still ongoing. This chapter describes this process of role definition because it appears to be especially important to the efficient functioning of the Program itself.

### A Special Role for Special Masters

The role of the special masters of the U.S. Claims Court was rather unusual as initially set forth in the original Act and has been made even more so as a result of the Technical Amendments that became effective January 19, 1990. Under the original Act, the Claims Court had jurisdiction over proceedings to determine eligibility for compensation and the amount of compensation,<sup>146</sup> and special masters appointed by the Court were charged with the duty of reviewing the petition, hearing evidence,<sup>147</sup> and submitting to the Court

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<sup>146</sup> 42 U.S.C. 300aa-12(a) (1987).

<sup>147</sup> 42 U.S.C. 300aa-12(b)(2) (1987).

proposed findings of fact and conclusions of law with respect to eligibility and compensation.<sup>148</sup> The special master was described in the original Act as an "adjunct to the court"<sup>149</sup> and functioned like most special masters in court proceedings. They were empowered to require the submission of evidence, including the production of documents and the testimony of witnesses, and to conduct hearings.<sup>150</sup> In theory, the special masters controlled the evidence to be submitted; the Act precluded discovery that was not "required" by the special master.<sup>151</sup> However, at the Program's start, it was difficult for the special masters to know what kind of information and evidence to "require." As a practical matter, discovery was proposed by the parties and authorized by the special master.

While the special masters supervised the factfinding and all procedures to make an initial determination both on eligibility for compensation and the amount of any award, their findings and conclusions had to be submitted to a Claims Court judge who was to issue the final judgment. The judge could accept or modify the special master's recommendation, hear the case *de novo* and issue a final judgment, or remand the case to the special master for additional factfinding or reconsideration of specific issues, with final review and judgment by the judge thereafter.<sup>152</sup>

In 1988, the Claims Court had estimated that with the Program budget allotted to it, it could hire eight special masters to handle Program claims. The Technical Amendments later limited the Program to eight special masters, to be appointed by the Claims Court judges for a term of 4 years, subject to removal either for cause or in the event that fewer special masters are needed.<sup>153</sup>

The most significant change made by the Technical Amendments was the grant of power to the special masters to make final judgments on eligibility and

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<sup>148</sup> 42 U.S.C. 300aa-12(c)(2) (1987).

<sup>149</sup> *Id.*

<sup>150</sup> *Id.*

<sup>151</sup> *Id.*

<sup>152</sup> 42 U.S.C. 300aa-12(d) (1987). This section permitted the court to accept the special master's recommendation without review if neither the petitioner nor the respondent objected to the recommendation. Still, the court had the power to review on its own initiative.

<sup>153</sup> 42 U.S.C. 300aa-12(c)(1). Because the Program received fewer petitions than originally expected during its first year, the Claims Court determined that it is not likely to continue to need the full complement of eight masters. One special master left in April 1990, another is planning to leave in July 1990, and a third may serve part-time for the immediate future. This will leave the Court with five and one half full-time special masters, including a Chief Special Master. Each is to serve a term of 4 years from the date of his or her original appointment in 1989.

amounts of compensation.<sup>154</sup> This was intended to avoid unnecessary duplication of effort before a judge to reach a final judgment. No cases had been decided under these new rules by the end of February 1990, but the general attitude toward the new rules among many of those involved with the Program is positive.

A second significant and positive change made by the Technical Amendments was to describe the powers of special masters more explicitly. Indeed, it appears that the fact that special masters are granted considerable freedom to devise administrative procedures and move cases along is the most important benefit of the Amendments. This freedom enables them to act quickly and decisively in response to administrative needs. Their authority with respect to procedures for reviewing petitions, however, actually changed very little. Originally, they could require the submission of "appropriate" evidence and hold "appropriate" hearing, whereas the Technical Amendments describe the power to require such evidence and conduct such hearings "as may be reasonable and necessary," suggesting that Congress wanted to narrow the evidentiary search and formal proceedings as much as possible. But the difference between "appropriate" and "reasonable and necessary" is subtle at best, indicating perhaps that certain basic powers are necessary to a decisionmaker and that an enabling statute can express little more than the general grant of authority.

The Technical Amendments also specified the federal salary level for special masters (up to level V of the Executive Schedule, with the chief special master at level IV).<sup>155</sup> This greatly simplified the determination of such issues as rates of travel expense reimbursement and per diems for cases in which hearings were held outside Washington, DC. In the absence of such a designation, it had been unclear what rates should apply, and time was wasted determining eligibility and making hearing arrangements.

The Technical Amendments also required the special masters to recommend new Vaccine Rules for adoption by the Claims Court. The Amendments specified that the rules should "provide for a less-adversarial, expeditious, and informal proceeding." Since most of the procedures later included in the new Vaccine Rules were already being used by mid-1989, incorporating the requirements into the Act was mostly symbolic.

Interestingly, one change contemplated by Congress did not appear in the Technical Amendments. The Committee Report suggested that it would be desirable to appoint persons--including nonattorneys--with expertise in

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<sup>154</sup> 42 U.S.C. 300aa-12(d).

<sup>155</sup> 42 U.S.C. 300aa-12(c)(5).

medicine and public health as special masters.<sup>156</sup> The Amendments do not state qualifications for serving as a special master, neither that one be an attorney nor that one have a medical background or not be an attorney. Although eligibility for compensation turns largely on medical evidence of a Table injury or one caused by a covered vaccine, the procedures used to identify relevant evidence are largely legal. In addition, the amounts necessary to compensate an injured petitioner within the terms of the Act turn on financial evidence. Decisions about whether such evidence meets the statutory requirements are basically legal decisions. Thus, it is not clear that a nonattorney would function more effectively than an attorney in the role of special master. The point may be moot for the time being. In view of the likelihood that no additional special masters will be hired during the next few years, it is not likely that nonattorneys will be appointed in the foreseeable future.

The special masters are unusual in that they serve only in Program proceedings and do not hear other types of cases. This enables them to develop some expertise in the subject matter and should contribute to a rising level of efficiency. Since special masters serve only a 4-year term, however, any turnover in individual special masters could dilute the advantage of expertise. It is possible that individuals may find 4 years concentrating on Program cases to be sufficient and opt to move to a different career path.

The special masters and judges have the most clearly defined roles to play in the Program. This is partly because their functions are specified in the statute, and partly because they serve as decisionmakers, a traditional role that has been altered only slightly to meet the informality mandate. Still, the special masters' role is not that of traditional special masters. Their powers have been called "inquisitorial," rather than judicial or administrative. But it is not clear what this means. The term suggests the power to examine witnesses and perhaps compel evidence. But the Act now specifies the evidence that petitioners must submit, so that the special masters can apply the Act without needing to call forth evidence of their own choosing. Thus, while the powers and duties of special masters have been clarified, they serve a hybrid function that continues to evolve.

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<sup>156</sup> "The Conferees would note their concern that special masters be well-advised on matters of health, medicine, and public health. No-fault vaccine compensation proceedings raise fewer legal issues than issues of medicine and masters need not be lawyers by training. Masters with health training and background should be considered for appointment and those without such training should be encouraged to seek independent experts to provide information." Conference Report No. 101-386, 101st Cong. 1st Sess. 509, 515.

## The Role of Counsel for Petitioners

Virtually all petitioners have been represented by counsel, if not by the time a petition is filed, then shortly thereafter. The Act clearly contemplates such representation by its explicit provision for the award of reasonable attorneys' fees and costs in good faith cases,<sup>157</sup> but does not require it. The structure of the Program, the proof required to establish eligibility, and the need to comply with the Vaccine Rules, however simplified, encourage petitioners to retain legal counsel to shepherd them through the proceedings.<sup>158</sup> In particular, the Act's requirement that the petitioner prove eligibility for compensation--rather than providing for a purely administrative determination--creates an incentive for petitioners to engage counsel who can collect and analyze evidence for presentation to a court.

The way in which attorneys should optimally function as representative of petitioners, however, remains unsettled. Extensive participation by litigators does raise questions about the fit between litigation skills and the Program's structure. The Program encourages attorneys to use their traditional litigation skills in presenting evidence to satisfy a petitioner's burden of proof. At the same time, it now requires amassing the petitioner's entire case and presenting it to the Court when the petition is filed. The "front-end loading" now specified in the Technical Amendments is not a traditional litigation technique.

In ordinary tort litigation, much of a plaintiff's attorney's time is spent trying to establish that a defendant acted wrongfully or that a product was defective and that this was the cause of the plaintiff's injury. These are the issues the Act intended to remove from dispute in the Program. In cases in which a petitioner claims eligibility for compensation by reason of an injury specified in the Table, there is no need to prove that a vaccine caused the injury. Rather, the proof relates to demonstrating that a particular injury or death described in the Table in fact occurred within the prescribed period of time. However, in cases in which the injury is not described in the Table, causation-in-fact must be proved, much as in traditional litigation. Since the existence of a Table injury has frequently been in dispute, litigation skills have been required more than might have been expected.

Still, the Program makes limited use of the skills in which litigators have comparative advantage over attorneys specializing in other areas. It requires litigators to adopt new modes of behavior and to adapt their skills to new uses. This has led a few participants to question whether litigation is the best

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<sup>157</sup> 42 U.S.C. 300aa-15(e).

<sup>158</sup> In the few cases in which petitioners filed with the Program *pro se*, the special master recommended that the petitioner retain independent counsel. This suggests that at least some special masters believe that petitioners may be unable to present their cases unaided by counsel.



specialty for an attorney representing a petitioner. They speculate that attorneys specializing in corporate representation or administrative law might be better prepared to present a full and complete petition and to engage in less formal discussions to reach a speedy decision. On the other hand, attorneys specializing in vaccine litigation are already familiar with the medical issues that may arise and how to present them,<sup>159</sup> and should be in a good position to counsel petitioners as to the risks and benefits of rejecting a Program decision in favor of pursuing litigation.

A clearer definition of the precise role of petitioners' attorneys is beginning to emerge under the Program. Congress may find it frustrating to have attorneys insist on certain rules of evidence or cross-examination of witnesses because it is too reminiscent of litigation.<sup>160</sup> On the other hand, they are usually in the best position to point out strengths and weaknesses in a case. In any event, attorneys who are litigators are already adapting their behavior to suit a more casual decisionmaking process. Their apparent general satisfaction with the Program suggests that such adaptation will continue. If so, it suggests that the Program could serve as an alternative to litigation not only for petitioners but also for attorneys.

## New Roles for the Program Office and the Department of Justice

### The Program Office

The first section of the Act establishes a Program "to be administered by the Secretary."<sup>161</sup> The Secretary, through the Program Office, does administer the Trust Fund and makes payments of compensation awarded by the Program. However, decisionmaking authority is vested in the Claims Court, not the Program Office. The Act does not specify a typical administrative role for the Program Office. There is no authorization to promulgate regulations implementing or interpreting the statute. Instead, in the few references to its participation in the Program, the Act tends to treat the Secretary as the defendant in an action claiming money damages against the federal

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<sup>159</sup> This may be seen in the relatively lesser number of hours vaccine litigators spend on cases compared with attorneys unfamiliar with vaccine issues.

<sup>160</sup> Such conduct can be displayed by any attorney, whether representing a petitioner or the respondent.

<sup>161</sup> 42 U.S.C. 300aa-10(a).

government.<sup>162</sup> To the extent that the Secretary is responsible for paying awards, this is, of course, entirely appropriate. However, the Act also reflects the ambiguous nature of the Program Office's role.

The Secretary was added to the Act as a respondent in a proceeding on a petition for compensation to provide an action in which opposing parties presented a case.<sup>163</sup> This was done to ensure that the proceeding would qualify as a "case or controversy" required for jurisdiction of the federal district courts under Article III of the Constitution. When the Act was amended to substitute the Claims Court, which is an Article I court, for the federal district courts, the original petitioner-respondent structure was not disturbed. Then, there was less concern over creating an image of a dispute suitable for judicial determination. Nonetheless, the mere designation of the Secretary as respondent in a claim for federal funds places the Program Office in the position of defending the government against the payment of awards that are not authorized by the Act.

At the same time, the Act does not require the Secretary to oppose petitions filed by persons seeking compensation. Indeed, the only explicit reference in the original Act to the Secretary's response to a petition allowed the Secretary, like the petitioner, to object to a special master's recommendation to the Claims Court, which triggered review of the decision by a Claims Court judge.<sup>164</sup>

The main task that the Program Office performs in practice--medical review of petitions--is not even mentioned expressly in the Act. It is certainly implied from receipt of the petition as respondent and from its power to object to a special master's decision on the petition. Nonetheless, the structure suggested by the Act is far from a purely administrative one. Rather, it mimics a civil action against the federal government.

The Program Office is organized along the lines of an administrative office for reviewing benefit claims. It is headed by a Director responsible for all its activities, and now has several administrative and secretarial staff.<sup>165</sup> The bulk

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<sup>162</sup> For example, a proceeding is commenced by "service upon the Secretary" as well as filing a petition with the Claims Court, in the same way that ordinary litigation is commenced by service of a complaint upon the defendant. 42 U.S.C. 300aa-11(a)(1). The Secretary must object to determinations and file appeals within specified time periods like any defendant in civil litigation.

<sup>163</sup> "The Secretary shall be named as the respondent in all proceedings brought by the filing of a petition...." 42 U.S.C. 300aa-12(b)(1).

<sup>164</sup> 42 U.S.C. 300aa-12(d)(1) (1987). As currently amended, this section, renumbered 300aa-12(e)(1), simply permits both "parties" to move for Claims Court limited review of a special master's decision.

<sup>165</sup> The program has had two Directors so far. The second accepted a new position elsewhere and is scheduled to leave in September 1990.

of the work is devoted to reviewing petitions. This is done by staff physicians who act as medical reviewers. Until very recently, the Program Office was able to hire, at most, two full-time physicians. One, a pediatric neurologist, has been with the Program since its inception.<sup>166</sup> However, a second physician has not always been available, except on a part-time basis.

The Program Office appears to view its role in the Program as having two primary components. The first is protecting the fiscal integrity of the Trust Fund as fiduciary to preserve enough funds to permit the payment of compensation to all those who receive awards. The second is to ensure that only those petitioners whose injuries are clearly demonstrated to be listed in the Vaccine Injury Table or actually are caused by a covered vaccine are awarded compensation. This latter purpose reinforces the adversarial nature of Program proceedings. It is based on the Act's requirement that the special master or Claims Court shall award compensation to an eligible petitioner if "there is not a preponderance of the evidence that the illness, disability, injury, condition, or death...is due to factors unrelated to the administration of the vaccine...."<sup>167</sup> Although the Act does not charge the Program Office with responsibility for finding an unrelated cause of the injury or death, it is in the best position to identify such a cause and bring it to the Court's attention by virtue of its review of petitions and supporting evidence. Moreover, the Program office is the only party likely to bring an unrelated cause to the Court's attention. The vigilance with which it performs this function has been the subject of some controversy.<sup>168</sup>

The Program Office has experienced the greatest conflict between the role that its physicians prefer and that Congress may have envisioned, on the one hand, and the role it is given in the Act, on the other. While it may be desirable to have petitions assessed by independent medical experts, the Act made the Program Office, through the Secretary, the respondent in a two-party court action on a claim against the United States for money. Even if Program Office physicians would understandably prefer to act as independent advisers to the court, they have been statutorily categorized as the defendant in an adversary proceeding. But their status need not preclude them from offering an impartial opinion in any case. They are not under any obligation to oppose every petition simply to provide the government with a defense. Indeed, the Program was expected to avoid unnecessary adversarial positions. Still, reconciling the Program Office status as an adversary with its function as an

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<sup>166</sup> Since neurological conditions in children form the bulk of adverse reactions listed in the Vaccine Injury Table and claimed by petitioners, the specialty of pediatric neurology is especially relevant.

<sup>167</sup> 42 U.S.C. 300aa-13(a)(1)(B).

<sup>168</sup> See text accompanying notes 84 and 85.

impartial reviewer of medical issues defined by the Act is an especially difficult task.

## The Department of Justice

The Department of Justice (DOJ) has acted as counsel for the Secretary of Health and Human Services and the Program Office before the Claims Court judges and special masters. The precise role of DOJ attorneys was somewhat unclear when the Program began. The DOJ was only peripherally involved in deliberations leading to the creation of the Program. While it had participated in an interagency task force that recommended some reforms in tort law in general, it had not been an active participant in the development of a vaccine injury compensation program. Thus, the department did not focus on preparing for an active role implementing the new Program.

Nonetheless, DOJ attorneys were assumed by many to be participants in the Program. The Attorney General is designated by statute to represent the Secretary in the federal courts.<sup>169</sup> Thus, there was no need to specify that the DOJ act as attorney for the Program Office. However, since the Program Office did not really expect to act as the petitioner's adversary, DOJ attorneys had a new but largely undefined role as its counsel.

The DOJ is fully familiar with representing federal agencies in federal courts. It is less active in representing the federal government in administrative proceedings. DOJ attorneys are primarily litigators. It should not be surprising, then, that DOJ attorneys acted like litigators when they first appeared in Claims Court proceedings. Physician reviewers appeared to appreciate having legal counsel to act on their behalf before the Court. They were unfamiliar with litigation and uncomfortable serving as expert witnesses. Moreover, there were at most two physician reviewers during the first year of the Program. If they had responded to each petition by means of a personal appearance before a special master, they feared they could not keep up with the timely basic review of petitions. The DOJ could present the reviewer's findings to the special masters and relieve the Program Office of this pressure.<sup>170</sup>

This working relationship was, at bottom, a traditional attorney-client relationship. Critics of DOJ representation have argued that DOJ attorneys were acting too much like traditional litigators, trying to defend the

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<sup>169</sup> 28 U.S.C. 518 (1982); *Hanagan v. Secretary*, 19 Cl. Ct. 7, 10 (1989)(appealed on other grounds).

<sup>170</sup> This procedure was adopted by the DOJ and the Program Office in most early cases. Program Office physicians did not appear as witnesses in hearings before the special masters. Instead, DOJ attorneys submitted their reports as evidence.

government against any claim against it, and opposing a petitioner's position as a matter of duty. While a few petitioners' attorneys expected this to be the role of DOJ, others found it too adversarial for their vision of the Program's purpose.

One alternative source of Program representation would be the Office of the General Counsel of the Department of Health and Human Services, or its division, the General Counsel's Office within the Public Health Service (PHS). The PHS General Counsel's Office is more familiar with PHS programs, and with immunization issues and the Program in particular. It also frequently represents the PHS in administrative hearings and other proceedings, although less frequently in litigation. It may have had a comparative advantage over the DOJ in representing the Program Office in the Claims Court. However, the PHS General Counsel's Office considered that it had too few attorneys to take on the additional task of representing the federal government in all cases in the Program. Unfortunately, the DOJ found itself similarly stressed.

When the Program began, the DOJ assigned two full-time attorneys and one half-time supervisor to work on Program cases in the Claims Court. It apparently did not reorganize its staff so as to allocate specific resources for Program cases. Thus, DOJ attorneys found themselves with a new Program to learn, a commitment to represent the Program Office, and no new funds to create a division or office with sufficient resources to get the job done. In this respect, the DOJ felt as overextended as the Program Office physician reviewers. Several petitioners' attorneys complained that they had difficulty meeting Court directed deadlines, for filing stipulations of agreed facts, for example, because they were unable to reach DOJ attorneys by telephone. They believed that the DOJ attorneys were too busy to be able to return calls in a timely manner.

## **A Request for Suspension and Problems with Participation**

Within 2 months after case review began under the Program, the DOJ and the Program Office felt they could not continue the pace and comply with the procedures that were developing for deciding petitions. Ultimately, in April 1989, the DOJ, on behalf of the Program Office and incidentally for its own respite, brought a motion before the Claims Court to suspend proceedings for 90 days in all cases filed in the Program. The Chief Judge of the Claims Court invited petitioners' counsel to respond and held a hearing on the motion on

May 5, 1989.<sup>171</sup> The Court denied the motion, evidencing little sympathy for the position of the federal government.<sup>172</sup>

Both the DOJ and the Program Office argued that they could not handle the caseload and meet the statutory 365-day time period with the small numbers of attorneys and physicians that were assigned to the Program. They also were concerned that trial-like procedures employed by the special masters exacerbated the workload.<sup>173</sup> They wanted the 90-day moratorium to allow time to reconsider the decisionmaking process before it became fixed.<sup>174</sup>

Petitioners agreed that the time for processing cases was very tight, but felt it necessary to meet the Act's 365-day period for making decisions. They also agreed that many discovery orders were unnecessary, but argued that it was the Program Office, not the special masters, that requested the discovery they thought unnecessary. The disagreement crystallized a growing difference of opinion on the role of the Program Office and the interpretation of eligibility for compensation under the Act.<sup>175</sup>

The Claims Court did not take a position on this hidden controversy. Instead, it focused on the ability of the Program Office and the DOJ to perform their functions under the Act. While acknowledging the pressures of the Program's timeframe, the Court could not excuse government agencies from their responsibilities even when they were not provided with sufficient resources to perform them.

[T]he court is convinced that it is respondent's (both the Department of Justice and the Department of Health and Human Services) lack of resources that has precipitated respondent's extraordinary request to suspend all vaccine cases. However, government's lack of resources cannot be allowed to penalize petitioners. When the United States undertakes a statutory program, this court must presume that

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<sup>171</sup> *Gregson v. Secretary*, 17 Cl. Ct. 19, 10 (1989). The Chief Judge chose to hear the motion because it presented an issue of immediate and general applicability to the Program as a whole and because he had not heard any individual petitioners' cases that might influence his judgment on the motion. He has maintained this division of labor, leaving the review of individual cases to other Claims Court judges.

<sup>172</sup> *Id.*

<sup>173</sup> In particular, they objected to frequent status conferences, with orders to complete discovery within especially short time periods, unnecessary and overly formal requirements for discovery, memoranda of law, lists of witnesses and exhibits, stipulations of agreed and disputed issues, and application of the rules of evidence at hearings. *Id.* at 21.

<sup>174</sup> Unfortunately, there was hardly any time for a leisurely analysis of programmatic efficiency. The clock was running and the time for final decisions on petitions filed early in 1988 was approaching rapidly.

it has the minimal resources required to carry out the statute.<sup>176</sup>

At the time of the hearing, one of the DOJ attorneys had left, at least partly out of frustration at the caseload, leaving only one attorney actively participating in proceedings before the Claims Court. The Program Office also had only one physician in its employ at that time. More than 122 petitions had been filed and were being handled by eight special masters. The Court made it clear that, while it appreciated the burden on the individuals in the DOJ and the Program Office, there was no basis in law for excusing the federal government from meeting its own statutory obligations. It found it would be acceptable to allow individual motions for suspending particular cases for good cause shown, but did not grant the general suspension request. The Program was to continue.

In its petition seeking the general suspension, the DOJ noted its intention to limit participation by DOJ attorneys in the Program to "such action as is contemplated by 42 U.S.C. 300aa-12(d)(1)."<sup>177</sup> The Court refused to speculate on the meaning of this statement.<sup>178</sup> But as the Court probably inferred, the DOJ apparently meant that its attorneys would no longer participate in proceedings before the special masters; rather, they would limit themselves to filing objections to a special master's recommended decision and perhaps to representing the Program Office in any proceedings before a judge of the Claims Court. Whatever the specific intention, this is what the DOJ did. After the decision was issued on May 16, 1989, the DOJ ceased participating in proceedings before the special masters. It did not send attorneys to represent the Program Office in status conferences or hearings before special masters. Although it did follow through with some nearly completed cases it was handling, it generally limited itself to filing objections to a special master's decision and arguing against specific awards reviewed by the Claims Court. The Program Office continued to review petitions in order to identify

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<sup>175</sup> See text accompanying notes 84 and 85.

<sup>176</sup> 17 Cl. Ct. at 23.

<sup>177</sup> Quoted in *id.* at 20. The section referred to at that time provided: "Upon objection by the petitioner or respondent to the proposed findings of fact or conclusions of law prepared by the special master or upon the court's own motion, the court shall undertake a review of the record of the proceedings and may thereafter make a de novo determination of any matter and issue its judgment accordingly...."

<sup>178</sup> The Court required the DOJ to respond to specific questions about its intentions, including whether it would appear before special masters, whether it would file a notice of withdrawal as counsel of record in any pending case or in general as counsel for the Program Office, and whether a new attorney would be designated for either the Program Office or individual cases. *Id.* at 29.

petitions that were not eligible for compensation and frame objections to recommended awards, but did not participate in proceedings before the special masters. These circumstances persisted until mid-January 1990.

The lack of participation by the Program Office and the DOJ threatened the continuation of the Program. While it did not stop the processing of cases by special masters, it did make visible the underlying tensions among Program participants. The number of petitions filed dropped off somewhat during the months of June through September 1989, although summer vacations may have contributed to the decline. About 75 percent as many petitions were filed in the 9 months after the Court's decision on the request for suspension as were filed in the preceding 9 months. Thus, while the special masters were not inundated with new petitions, they still had to process a substantial number of cases without the assistance of the Program Office or the DOJ. Some petitioners found this advantageous because there was no opposition to their petitions. However, others were disconcerted when the DOJ interposed objections to a special master's recommendation for compensation after not having participated in the deliberations leading to that decision.<sup>179</sup> This often resulted in relitigating the case in its entirety before a Claims Court judge, duplicating much of petitioners' effort.

## The Technical Amendments

The Program could not operate efficiently in this manner or comfortably without the participation of the DOJ and the Program Office. All concerned began to seek a way to enlist their support. The first step was to find financial support to hire adequate staff to participate in Program proceedings. The next was to try to simplify the procedures employed by the Claims Court even more. The result was a group of Technical Amendments to the Act that were presented to Congress and adopted December 19, 1989 as part of the Omnibus Budget Reconciliation Act of 1989.<sup>180</sup> The statute did not become effective for

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<sup>179</sup> Some petitioners' attorneys moved to exclude a Program Office report or to strike an objection to a special master's recommendation that compensation be awarded on the grounds that it was unfair for the Program Office to refuse to participate and then attempt to reverse decisions it disagreed with on the basis of evidence that the petitioner had not seen and could not cross-examine for accuracy.

<sup>180</sup> The DOJ objected to certain portions of the Technical Amendments when it became aware of their existence, but ultimately acquiesced in their spirit after passage.



30 days--January 19, 1990--to provide a grace period in which to restructure Program procedures as required by the amendments.<sup>181</sup>

Congress clearly sought to straighten out what it perceived to be unnecessary problems with the implementation of the Program. The Committee Report on the Technical Amendments had a bad word for almost everyone:

The Claims Court has issued rules...that force proceedings to be formal and that virtually foreclose any opportunity for petitioners or respondents to proceed without litigators at their side. Petitioners have failed to include adequate information in initial petitions and have pursued traditional rights of exclusion of evidence. Respondents have withheld sufficient personnel and administrative support and mounted defenses incompatible with a no-fault system of compensation.<sup>182</sup>

Members of Congress were particularly sensitive to the charge that the proceedings were adversarial. They recognized that statutory amendments could not overcome the more fundamental problems, which they characterized as "the nature of the adjudication of petitions." Instead, the Report said, "Correction of these problems will require revision of the vaccine compensation process of the Special Masters and U.S. Claims Court and a re-dedication of all parties to the creation of an expeditious, less adversarial, and fair system."<sup>183</sup> The Technical Amendments were intended to initiate a new era.

From the point of view of the Program Office and the DOJ, the merit of the Technical Amendments lay in their authorization of funds to hire new staff.<sup>184</sup> The Program Office, the DOJ, and the Claims Court each were allocated \$1.5 million for the coming fiscal year. The DOJ set about hiring eight new attorneys, who would join the department by the spring of 1990. In the interim, the DOJ concentrated its limited resources on those few cases in which it felt a generally applicable question of law or principle was in dispute, and did not appear in the rest.

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<sup>181</sup> Thirty days proved to be insufficient to hire new personnel under federal government hiring procedures and allow the Program to make a real new start.

<sup>182</sup> Conference Report No. 101-386 to accompany H.R. 3299, Omnibus Reconciliation Act of 1989, 101st Cong. 1st Sess. 509, 512.

<sup>183</sup> *Id.*

<sup>184</sup> The Technical Amendments also made other changes in processing petitions. See text accompanying notes 153-155.

The Program Office was able to hire a new physician as a medical reviewer and look for others. In addition, the Program Office compiled a list of nonemployee physicians who were willing to serve as medical reviewers on an ad hoc basis. This was intended to relieve the staff physicians of the burden of reviewing all petitions. However, the time-saving has not been fully realized. The staff physician has continued to review all incoming petitions to select those appropriate for outside review. This can create a bottleneck that delays decisions. Moreover, the Program Office has had difficulty recruiting and retaining physician employees, and by June 1990 was back to only one full-time physician in its office.

While the Technical Amendments called for "a less-adversarial, expeditious, and informal proceeding,"<sup>185</sup> they did not change the basic structure of the Program. Nor did they alter the adversary relationship between petitioners and the federal agencies. The Program Office is still a respondent. The DOJ continues to act as counsel for the respondent, consistent with Congress' intent that it participate actively in the Program. Perhaps the most important contributions of the Technical Amendments were Congress' renewed commitment to the Program, backed by funds to staff it, and the catalyst they provided to all participants to work together to resolve difficulties in getting a new program off the ground.

## Chapter VI. Early Program Experience

This chapter summarizes data on petitions filed and decided under the Program through February 28, 1990. Although the statutory effective date for the Program was October 1, 1988, the Program did not begin to operate fully until February 1, 1989. It was not until November 15, 1988, that a Chief Special Master was in place to administer the process. Four special masters arrived at the Claims Court in January 1989, and began reviewing petitions by the beginning of February 1989. The remaining three special masters joined them in March 1989.

### Petitions Filed

As of February 28, 1990, 236 petitions had been filed with the United States Claims Court. (Table VI-1.) Twenty-four or 10 percent of these petitions were filed before the effective date of the Program, October 1, 1988. Since then, an average of 12 petitions were filed each month until the end of

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<sup>185</sup> 42 U.S.C. 300aa-12(c)(2).

February 1990. However, the rate of filing did not follow any pattern, with as many as 26 petitions filed in the month of November 1988, and as few as 3 petitions filed in August and September 1989.

**TABLE VI-1**  
*PETITIONS FILED*

<u>Month</u> <u>Ending</u>	<u>Monthly</u>			<u>Cumulative</u>		
	<u>Total</u>	<u>Death</u>	<u>Injury</u>	<u>Total</u>	<u>Death</u>	<u>Injury</u>
3/1/88--						
9/30/88	24	10	14	24	10	14
10/31/88	18	6	12	42	16	26
11/30/88	26	14	12	68	30	38
12/31/88	11	6	5	79	36	43
1/31/89	10	5	5	89	41	48
2/28/89	6	2	4	95	43	52
3/31/89	16	5	11	111	48	63
4/30/89	11	6	5	122	54	68
5/31/89	22	7	15	144	61	83
6/30/89	8	4	4	152	65	87
7/31/89	14	3	11	166	68	98
8/31/89	3	2	1	169	70	99
9/30/89	3	0	3	172	70	102
10/31/89	14	3	11	186	73	113
11/30/89	12	4	8	198	77	121
12/31/89	6	0	6	204	77	127
1/31/90	23	4	19	227	81	146
2/28/90	9	2	7	236	83	153

A surge of petitions were filed just after several important events took place. The first was, not surprisingly, during October and November 1988 after the Act became effective and the Claims Court formally began accepting petitions. The second occurred in May 1989, with 22 petitions filed, when the Claims Court refused to grant a request by the HHS Program Office to place a moratorium on the Program's operation. The third was in January 1990, with 23 petitions filed in the month in which the Technical Amendments to the Act took effect. It is possible that these events triggered filings, but given the fairly random distribution, it would be unwise to draw conclusions from the date of filing alone.

The total number of petitions filed has fallen short of some early estimates. Only 125 petitions were filed during calendar year 1989. When the Act was under consideration in Congress, the Congressional Budget Office first estimated that approximately 1,500 people might have suffered qualifying injuries in the preceding 8 years.<sup>186</sup> It assumed that all those eligible would file with the Program, and doubled its estimate as a precaution. Congress limited the total number of retrospective cases for which compensation could be awarded to 3,500 in the Act itself.

There are several possible explanations for the relatively small number of petitions filed thus far. One is that there might have been fewer serious adverse reactions to covered vaccines than predicted. In the absence of a formal reporting mechanism, such estimates had to be extrapolated from voluntary reports. However, voluntary reporting can miss a significant number of cases. Perhaps this led Congress to increase the number of cases predicted from the estimate of adverse reactions. Another reason for the shortfall in petitions filed may be that people who have suffered an adverse reaction to a vaccine may not be aware that it is vaccine-related. Lack of awareness seems less widespread than it might have been a decade ago because of media publicity surrounding childhood vaccines. In addition, an organization of parents of children with vaccine injuries or deaths has disseminated considerable information about adverse reactions to the DTP vaccine in particular.

A more plausible explanation may be that a significant proportion of persons with vaccine reactions are not aware of the availability of compensation under the Program. Media coverage of the Program has been sparse and, with some exceptions, generally limited to descriptions of the passage of the Act and its subsequent amendments. The Act charges the Secretary to develop information materials, but the Program Office has not been able to put a large publicity campaign in place yet. It now has an toll-free telephone number for inquiries about the Program and sends a packet of materials describing the Program upon request. However, people must be alerted to the Program's existence in order to call.

The Program office has published notices of its receipt of petitions in the Federal Register, but that publication is rarely seen by the public at large. It has also published announcements in several journals. Legal journals occasionally have reported on the Program's availability. The Special Masters Office presented an educational conference directed primarily at attorneys in April 1990. Medical journals directed at pediatricians have published a few articles on the Program by independent authors, but it is unknown whether

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<sup>186</sup> Congressional Budget Office Estimate, Sept. 25, 1986, House Report No. 99-908, accompanying H.R. 5546, U.S. Code Cong. & Admin. News 6378, 6380 (1986).

pediatricians are informing their patients, since no one reported them as a source of information. The Program Office has reported receiving an increase in inquiries about the Program following one or two television programs that mentioned it or reported on an individual case.

Several petitioners' attorneys suggest that petitioners learned about the Program from newspaper or television reports or from a parents' organization. Many were already aware of the Program by virtue of having followed or worked for its enactment. A significant minority of petitioners had pending a civil action for the injury and their litigation counsel advised them of the Program. Interestingly, a few attorneys were unaware of the Program until a colleague or prospective client seeking representation mentioned it. So far, no one reported first learning about the Program from information or publicity disseminated by the Program Office. If this finding were to be confirmed in a larger survey, it should cause concern that information is not reaching the population likely to be eligible for its benefits.

It is possible that some potential petitioners may be aware of the Program but have concluded that they do not qualify for compensation. Their decisions not to file a petition may be based on advice from an attorney, a physician, or a parents' organization. Others with retrospective cases may have decided to take their chances in tort litigation, although preliminary interviews with attorneys for petitioners suggest this is unlikely.

One final possible explanation may be that prospective petitioners are waiting to file until the Program is running at full speed in order to move rapidly through the process. However, retrospective cases must be filed on or before October 1, 1990, so the time for waiting and watching is running out. Several petitioners' attorneys reported having additional cases they were preparing for filing before the deadline. The Program Office also reported that it was receiving an average of about five petitions, still largely retrospective cases, a week in June 1990. This is a significant increase, but the numbers fall far short of the 3,500 maximum.

Almost all of the petitions filed by the end of February concerned vaccines administered before October 1, 1988. As of March 1990, only nine prospective cases had been filed, and only one of these had been decided.

It would be unwise to predict the rate of petitions that might be filed for prospective cases from the experience with retrospective cases. After all, all prospective instances of serious adverse reactions must file with the Program first, while retrospective cases may have pursued litigation as an alternative to entering the Program. Prospective cases are likely to be filed at a more consistent annual rate since they must be filed within 2 to 4 years after the injury or death occurs. All the cases relating to pre-October 1, 1988 vaccinations are bunched into two filing years. On the other hand, before the Act was passed, the Centers for Disease Control estimated that perhaps 120 to

150 prospective cases would be filed annually under the Program. The higher estimate is in line with rate of all petitions being filed during the first half of the second year of the Program.

The majority of petitions filed as of February 28, 1990, request compensation for injury. Out of 236 petitions filed, 153 (64.8 percent) cited permanent injury, while 83 (35.2 percent) cited death. Cases of injury have been rising as a proportion of petitions filed since September 1989.

By far the largest proportion of petitions filed (82.6 percent) cite DTP or pertussis as the presumed cause. (See Table VI-2.) The next largest categories cite the MMR combination vaccine (5.9 percent) and polio (5.5 percent) as the presumed cause of death or injury. The remaining covered vaccines together are mentioned in only 6 percent of petitions filed as of February 28, 1990.

TABLE VI-2

*Petitions filed as of February 28, 1990 by Vaccine Type*

<u>Vaccine</u>	<u># of Petitions</u>	<u>percent of Total</u>
DTP (diphtheria, tetanus, pertussis)	176	
DTP/Polio	18	
Pertussis	1	
Subtotal: All with Pertussis	<u>195</u>	82.6
DT	3	1.3
Polio	2	
OPV (oral polio vaccine)	9	
IPV (inactivated polio vaccine)	2	
Subtotal: All with Polio	<u>13</u>	5.5
MMR (measles, mumps, rubella)	14	5.9
Measles	3	1.3
Rubella	5	2.1
Measles/rubella	1	0.4
Mumps	0	0.0
Gammaglobulin	1	0.4
Smallpox	1	0.4
Total:	<u>236</u>	<u>99.9</u>

## Reports by the Special Masters

The special masters began issuing their initial reports on petitions under the original rules within about a month after the full complement of eight Special Masters were in place in March 1989. (See Table VI-3.) Only one report was issued in April 1989, however, and none were issued in May 1989. This may have been attributable to the motion by the Program Office made in April 1989 to place a moratorium on the Program.<sup>187</sup> The Program got back on track in July 1989, and between August 1, 1989, and November 30, 1989, 53 reports were issued.

The special masters issued initial reports in a total of 76 cases as of February 28, 1990.<sup>188</sup> This represents 32.2 percent of the 236 petitions filed by that date. Sixty-five (85.5 percent) of these initial reports were decided by the end of November 1989, about 1 year after petitions formally began to be accepted. Fewer reports were issued each month after November 1989. One might hypothesize that the easier cases were decided more quickly, with those involving more difficult issues of causation or damages requiring more time. Almost all of the special masters and petitioners attorneys interviewed believed that the death cases were more speedily decided. The majority (43 out of 76 or 56.6 percent) of cases decided through February 1990 were cases involving death. But that leaves a substantial proportion (33 cases, or 43.4 percent) involving injury. Of the 11 cases reported between December 1, 1989 and February 28, 1990, 6 involved death and 5, injury. The time required for issuing a report appears to depend upon whether eligibility for or the amount of compensation is contested by the Program Office. Eligibility for compensation has been in dispute in a significant proportion of death cases where the Program Office believed that death resulted from a factor unrelated to the vaccine. Although similar issues were raised in many injury cases, such cases also require detailed, often contested, determinations of the amounts of compensation to be awarded.

Of the 76 cases in which special masters issued a report, Claims Court judges made final decisions in 70 cases, all under the original rules, and remanded 3 additional cases for further consideration by the special masters. Initial reports of the special masters were awaiting judicial review in 3 cases.

Judges adopted the recommendation of the special master for or against compensation in all but two cases. In one case, a recommendation against eligibility for compensation was reversed, and in another a recommendation for compensation was reversed. Judges also accepted the special masters' recommendation as to the amount of compensation in 60 of the 70 (85.7

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<sup>187</sup> See text accompanying note 171.

<sup>188</sup> Reports were not issued in 17 cases in the petitioner voluntarily dismissed the petition.



percent) cases decided by final judgment. In one injury case, a judge awarded more compensation than initially recommended by the special master. Judges awarded a lesser amount in nine cases of injury. The close congruence of the opinions of the special masters and judges suggests that granting special masters final decisionmaking authority, as the Technical Amendments did, is reasonable.

## TABLE VI-3

*Special Master Reports Issued\**

	<u>Monthly Total</u>	<u>Cumulative Total</u>
April 30, 1989	1	1
May 31, 1989	0	1
June 30, 1989	4	5
July 31, 1989	7	12
August 31, 1989	12	24
September 30, 1989	12	36
October 31, 1989	15	51
November 30, 1989	14	65
December 31, 1989	8	73
January 31, 1990	2	75
February 28, 1990	1	76
March 22, 1990	2	78

\* Excludes voluntary dismissals by petitioner

## Disposition of Petitions

The disposition of cases for which a final judgment had been entered as of February 28, 1990, is shown by vaccine and type of injury in Table VI-4. A total of 87 cases had been finally disposed of, with final judgments entered in 70 cases. All but one were retrospective cases and all were decided under the original rules. Final judgments include all final decisions entered by order of a Claims Court judge after review of a special master's report and recommendations. Compensation (exclusive of attorneys fees) was awarded in 71.3 percent (62 out of 87) of final dispositions. Seventeen petitions were voluntarily dismissed by the petitioner, ordinarily because the injury did not qualify as compensable under the Vaccine Injury Table. One of these involved a smallpox vaccine which is not among the vaccines covered by the Program. Petitions voluntarily dismissed by the petitioner are not defined as final judgments because no action was taken on them by a special master or a judge. Two additional cases were involuntarily dismissed by order of a Claims Court judge upon the recommendation of special masters' reports. Moreover, six cases were awarded no compensation, although five of these were granted attorneys fees, which are permitted under the Act where the petition was filed in good faith but the injury is determined not to qualify for compensation. In the aggregate, 25 of the 87 decisions (28.7 percent) were dismissed or awarded no compensation.

Judges made final decisions by court order in 70 cases and awarded compensation in 62 (88.5 percent) of these. They denied compensation or dismissed the petition in 8 (11.4 percent) of these judgments. Of the 87 final dispositions, 71 (81.6 percent) were in cases citing DTP or pertussis as a cause of death or injury. It should not be surprising, then, that DTP cases accounted for the largest number of awards--51 cases, or 82.2 percent of the 62 petitions that received an award. Of these awards in DTP cases, 36 involved death while 15 involved injury. Twenty of these DTP cases received no award or were voluntarily dismissed; this represents 80 percent of all cases that were dismissed or denied compensation.

No other vaccine accounts for more than a handful of decided cases. Only three cases involved polio vaccine. Awards were made in two of those cases; one was voluntarily dismissed. Decisions were made in eight cases involving the combined measles-mumps-rubella vaccine (MMR), with awards granted in all but one. Two cases involved rubella and two cases the diphtheria-tetanus combination vaccine. In both types of cases, an award was made in one case while the other was voluntarily dismissed. No cases decided before March 1, 1990 considered IPV, or diphtheria, measles, or mumps vaccine alone.

**Table VI-4**  
*Final Decision AS OF February 28, 1990*

	Voluntary VaccineDismissal		Involuntary Dismissal		Award of No Compensation		Award of Compensation	
	<u>Death</u>	<u>Injury</u>	<u>Death</u>	<u>Injury</u>	<u>Death</u>	<u>Injury</u>	<u>Death</u>	<u>Injury</u>
DTP or P	4	8	1	1	1	4	34	15
DTP/Polio			1					2
DT			1					1
Diphtheria								
Polio (OPV) 1							1	1
Polio (IPV)								
Measles								
MMR						1	3	4
Rubella			1					1
Mumps								
Smallpox			1					
Subtotals	5	12	1	1	1	5	41	21
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TOTAL		17	2	6	62			

## Compensation Awarded

The Program awarded \$32,495,151.17 in compensation (exclusive of attorneys fees) in final judgments as of February 28, 1990. Of this amount, a total of \$10,250,000 was awarded in cases of death, with the award being \$250,000 in each of 41 cases. The balance of \$22,245,151.17 was awarded in 22 cases of injury. Table VI-5 shows the total and average amounts awarded by vaccine.

In cases of injury, the amount of compensation ranged from a low of \$27,081 to a high of \$2,772,855. The average award was \$1,011,143.21. Nine of the 22 awards were more than \$1 million. All of the compensation in injury cases was awarded for future medical, rehabilitative and custodial care expenses (to be incurred after the date of judgment), since all of these cases were retrospective cases which the Act precludes from receiving past medical expenses. The Act also caps lost earnings and pain and suffering together with attorneys fees at \$30,000. Only one prospective case had been decided by the end of February 1990. It involved death and resulted in compensation in the amount of \$250,000.

The compensation awarded during the first 17 months of the Program has been well within the \$80,000,000 per year appropriated by Congress. At the same time, the number of cases decided has been significantly less than Congress expected. It can be seen that if each successful injury case were awarded \$1 million, fewer than 80 retrospective injury cases per year could be paid, since some awards would be paid in retrospective death cases. There does not appear to be any immediate threat to the funds available for retrospective cases. The amounts of compensation in prospective cases may be expected to be higher since they may include past expenses and will be brought on behalf of younger children. Thus, it will be important to monitor the amount of awards in prospective cases to ensure that the Trust Funds are adequate.

**TABLE VI-5**  
*Compensation (\$) Awarded as of February 28, 1990*

<u>Vaccine</u>	<u>Death</u>	<u>TOTAL</u>		<u>AVERAGE</u>	
		<u>Injury</u>	<u>Death</u>	<u>Injury</u>	
DTP + DTP/P	9,000,000.00	18,058,486.48	250,000.00	1,128,655.03	
MMR	750,000.00	2,637,540.19	250,000.00	659,385.05	
OPV	250,000.00*	499,575.50*	250,000.00*	499,575.50*	
RUBELLA		1,049,555.00*		1,049,555.00*	
DT	250,000.00*		250,000.00*		
<b>TOTAL</b>	<b>10,250,000.00</b>	<b>22,245,151.17</b>	<b>250,000.00</b>	<b>1,011,143.21</b>	

\* Only one award made in category

## Attorneys' Fee Awards

Of the 88 cases decided by the end of February 1990, the final judgment included an award of attorneys' fees in 65 cases (73.9 percent). Attorneys' fees were awarded in 60 (95.2 percent) of the 63 cases in which compensation was also awarded. One fee award remained pending. Attorneys' fees were also awarded in five (83.3 percent) of the six cases which received no compensation award. No fee award was made in the case of voluntary dismissal by the petitioner.

Amounts awarded for attorneys' fees are shown in Table VI-6. Unexpectedly, in DTP cases, the average award is slightly higher where the adverse reaction resulted in death than where permanent injury without death resulted. One possible explanation could be that it has required more time and expense for attorneys to demonstrate that a death resulted from DTP than an injury. This might arise in cases in which the Program Office opposes a petition on the theory that the death did qualify as a Table injury, thereby forcing the petitioner to prove that the death resulted from the vaccine.<sup>189</sup>

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<sup>189</sup> See text preceding note 94.

**TABLE VI-6**  
*Attorneys Fee Awards in Final Judgments as of 2/28/90*

	<u>DTP</u>	<u>MMR</u>	<u>RUBELLA</u>	<u>OPV</u>	<u>DT</u>
<u>Aggregate:</u>					
Death	757,345.62	59,881.00		7,040.00*	16,607.74*
Injury	303,316.73	72,342.37	25,099.00*	25,886.76*	
All	\$1,060,662.35	132,223.37	25,099.00*	32,926.76	16,607.74*
<u>Average:</u>					
Death	21,037.38	19,960.33		7,040*	6,607.74*
Injury	18,957.30	18,085.59	25,099.00*	25,886.76*	
All	20,397.35	18,889.05	25,099.00*	16,463.76*	16,607.74

\* Only one award made in this category



### Attorneys' Representation of Petitioners

Virtually all of the petitioners who pursued a claim in the Program were represented by counsel. All but perhaps two or three have retained an attorney to file their petitions. Those that did not have counsel before filing were afforded the opportunity to retain an attorney by the special masters assigned to their cases.

The overwhelming use of attorneys may be explained in several ways. Few petitioners are confident of their ability to gather and present evidence sufficient to prove their cases without an attorney. Others may prefer to distance themselves from analyzing their children's deaths or injuries in detail, in order to avoid painful memories. It is possible that many petitioners seek the advice of an attorney about whether any remedy is available, perhaps even before they are aware of the Program's existence.<sup>190</sup> Some parents may first contact the parents' organization which may refer them to one or more attorneys.

As of February 28, 1990, the vast majority of attorneys who represented petitioners (103 out of 128 or 80.5 percent) had filed only one case. (See Table VI-7.) Twenty-five attorneys (19.5 percent) had filed two or more cases. Of these, 12 had filed only two cases; 4 had filed three cases; 1 had filed four cases; 2 had filed five cases; 1 had filed six cases; and 1 had filed nine. Only four attorneys had filed 12 or more cases. Of these four, one had filed 12, one 15; one 17; and one 23 cases. One case was filed *pro se* (by the petitioner). The 128 petitioners' attorneys were located in 41 states.

Fewer than half of the cases, 43.6 percent (103 of the 236 petitions filed), were represented by an attorney having only one case. About twenty-nine percent (28.8 percent) of the cases (68/236) were represented by one of four attorneys who had filed 12 or more cases. Twenty-five attorneys together had 128 cases (53.8 percent of all cases). These figures do not indicate any pattern of representation common to all petitioners. However, attorneys with diverse backgrounds and specialties have represented petitioners in concluded cases. Some specialize almost exclusively in vaccine litigation, some are litigators without previous experience in vaccine cases, and others are not litigators. If a wide variety of attorneys are willing to represent petitioners, the Program should be reasonably accessible. However, some attorneys who are not experienced in vaccine litigation say they are likely to refer future cases--at least those that present any problem of proof--to specialists in vaccine litigation. If vaccine specialists are more efficient at presenting cases, such a

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<sup>190</sup> The Act specifies that attorneys have an ethical obligation to advise clients who consult them with respect to a vaccine-related death or injury that compensation may be available under the Program. 42 U.S.C. 300aa-10(b).

development might expedite decisionmaking. It might also concentrate Program cases in the hands of a small number of attorneys. If potential petitioners find it difficult to locate a vaccine specialist, however, they be dissuaded from entering the program.

**TABLE VI-7**  
*Distribution of Petitioners Attorneys by Case Filed  
as of February 28, 1990*

Numbers of Cases Filed (Total 236)	Number of Attorneys (Total 128)
1	103
2	12
3	4
4	1
5	2
6	1
9	1
12	1
15	1
17	1
23	1

## Chapter VII: Summary and Conclusions

The National Vaccine Injury Compensation Program is a creative policy mechanism to compensate persons with vaccine-related injuries and reduce the need for litigation. It establishes a no-fault compensation system that is expressly intended to avoid disputes concerning legal responsibility for injury and make decisions expeditiously. The Program's design fosters these goals in several ways: by substituting a defined list of compensable injuries, the Vaccine Injury Table, for the need to prove the actual cause of injury; by limiting the time within which decisions must be made to a period far less than ordinary litigation; by empowering special masters to determine eligibility for and amounts of compensation; by specifying available compensation that reflects actual financial losses; and by emphasizing procedural flexibility to make the process simple and congenial. Almost everyone involved with the Program recognizes its special function and structure and is committed to making it run smoothly.

Whether the Program's promise will be fully realized remains to be seen. It suffered not only from ordinary difficulties of any new endeavor, but from some confusion both in identifying the Program's objectives and in devising ways to meet them, as well as from limited resources. In consequence, the Program is only now beginning in earnest.

The experience of the Program to date may not be representative of its future operation. Aside from having undergone significant changes, both statutorily and programmatically, the Program has dealt almost exclusively with retrospective cases. The future of the Program lies with prospective cases. The procedures developed to decide retrospective cases should apply reasonably well to prospective cases. But, the Program's acceptability, and consequently its effectiveness, may be affected by prospective cases. Therefore, whether the findings presented in this report will apply in prospective cases can only be assessed by testing them against future Program operations.

To begin to generate hypotheses about how the Program may work, this study surveyed Program participants. Participants in the Program--in the Office of the Special Masters, the Department of Justice, the Program Office at the Department of Health and Human Services, and a nonrandom sample of petitioners' attorneys--were asked what they liked and disliked about the Program.

## Positive Aspects of the Program

Positive features of the Program mentioned most often concerned the Program's design and potential speed and efficiency. Most participants like the fact that the Program establishes a list of compensable injuries and a simplified method for determining entitlement to compensation, although a few questioned the wisdom of including one or two specific injuries in the Table. The use of designated compensable injuries tends to remove many complex questions of causation as a subject of dispute, thereby shortening and simplifying the decisionmaking process. The relative speed, compared with litigation, was seen as especially valuable to all concerned. In general, the special masters were viewed as objective or very objective and as able to move petitions through the review process quickly and efficiently.

Thus, the Program is generally, but not unanimously, viewed as having significant potential for being more efficient than litigation. The Congressional appropriation, made in the 1989 Technical Amendments, to fund Program activities considerably strengthened the commitment to the Program of those charged with administering it. It seems to have generated a new sense that the Program's potential can be realized.

Other positive features from petitioners' point of view include the Program's recognition, by its very existence and by the issuance of judgments awarding compensation, that people have become disabled or have died following vaccination with required vaccines and that the country is willing to provide them with necessary financial assistance. A few also indicated that the amount of compensation awarded under the Program was closer to actual losses and somewhat more generous than that ordinarily obtained in settling litigated cases. Thus, the Program was seen by many as more attractive than litigation.

Additional positive features were mentioned by only one or a few persons but may be corroborated by future research. For example, vesting decisionmaking authority in an impartial person who is neither a physician nor affiliated with immunization programs makes sense to many. Many medical and public health professionals with expertise in immunization have expressed opinions on vaccine reactions and could be seen as insufficiently impartial for purposes of the Program. At the same time, because the special masters hear only Program cases, they can become familiar with the subject matter and begin to render decisions based on specialized knowledge. The fact that the special masters are granted inquisitorial powers to question witnesses and demand the production of necessary evidence was seen by some as a practical advantage for moving cases along. They also have the power to seek advice from independent experts, although few have exercised it, possibly because of the difficulty of locating experts viewed as genuinely impartial by all

concerned. The Technical Amendments clarified who is responsible for producing particular documents and reports and for making decisions, so it is now easier to identify how to correct a problem if one occurs.

In addition, several participants mentioned the utility of having petitions reviewed by medical professionals. While the Program Office was criticized by some, most agreed that HHS was probably the best choice among federal agencies for conducting medical reviews.

### **Difficulties in the Program**

Problems with the Program most frequently mentioned were the earlier lack of participation by the Program Office and DOJ and disagreement in a large proportion of cases in the interpretation of the Vaccine Injury Table or the evidence necessary to prove a Table injury. The DOJ's lack of participation during the last half of 1989 frustrated the course of deciding cases. In the absence of legal representation, the Program Office was unable or unwilling to participate in hearings where evidence of causation could be presented and evaluated. While the Act does not require Program Office participation in determining eligibility, the special masters expected participation. Some special masters felt constrained to consider written Program Office reports as part of the record in order to produce a fair opinion. However, this use of written reports did not provide petitioners with an opportunity to question or challenge the medical reviewer's basis for an objection to eligibility. This was perceived as unfair by some attorneys.

The funding provided as a result of the Technical Amendments should alleviate the problem of lack of participation by allowing the DOJ and the Program office to hire staff. However, the full complement of the DOJ staff attorneys was not in place until April 1990, almost a year after the initial withdrawal of participation. The Program Office has only one full-time physician and is making do with part-time and contract physicians. Cases that had to be decided within the statutory period of (then) 1 year could not benefit from the new funding. It was expected that sufficient staff would have joined the Program Office and become familiar with its requirements by summer 1990 to permit the Program to operate smoothly. When combined with the changes in decisionmaking authority made by the Technical Amendments, however, the recent gearing up of DOJ and, to a lesser extent, the Program Office means, that the Program is only now in full operation--a place where new programs are ordinarily expected to be within 6 months of the effective date.

The second major problem with the Program was disagreement over the function of the Vaccine Injury Table, as described in Chapter III. The Program Office's initial difficulty in appreciating the distinction between legal

causation embodied in the Table and causation-in-fact as more commonly used in medicine increased the proportion of disputed cases. Although it is now clear that the Table sets forth a list of compensable injuries, the Program may be affected by external differences of opinion as to the specific medical conditions that should be included in the Table. A more difficult problem acknowledged by most participants was disagreement on the proof that is or should be required to demonstrate a Table injury. The Act's aids to interpretation have not proved dispositive in many cases. The variation in symptoms experienced by individuals as well as how these are documented often made it difficult to determine whether a Table injury in fact occurred.

A related concern of many participants involved the use of expert witnesses. While experts may be impartial as to the merits of each individual case, many have formed opinions on the more general issue of causation. The repeated use of some experts willing to review cases or testify in Program proceedings may affect the perception of fairness. On the other hand, it is not clear whether participants would be comfortable with substituting independent experts called by special masters for experts of their own choosing.

Other problems mentioned include a perception that there is little public awareness of the Program which may have contributed to the lower than predicted number of petitions being filed. Some felt that this could be attributed to the meager publicity given the Program. If the number of petitions filed increases during the summer of 1990, it may be difficult to process them in a timely fashion with the Program Office's limited staff.

## Conclusions

Although many participants saw difficulties in the Program, most were enthusiastic about its continuation. The difficulties were seen as largely in the past, the future as full of promise. In essence, two programs were being evaluated--the original Program and the new rules included in the Technical Amendments. The Amendments gave the special masters the authority to operate a more informal, flexible process. They also gave the Program the resources needed for full participation. Thus, the Program is now operating with more support and is closer to the simplified streamlined system originally envisioned.

At the same time, the Technical Amendments did not alter the Act's basic programmatic structure for the Program. While it is less adversarial, it remains an adversary format, with a petitioner bearing the burden of proving a claim, a respondent able to object to the claim and its proof, and a special master charged with the duty to reach a decision supported by the evidence. Virtually all decisions under the Program, from interpreting the statute to weighing the evidence to calculating compensation, must be reached by an independent decisionmaker--a special master or Claims Court judge--after hearing from opposing sides. Since there is no administrative entity that can issue general regulations interpreting ambiguous statutory provisions or establishing methods to calculate compensation, such decisions must be made much as common law is made, by the accretion of decisions in individual cases. The one area in which the Secretary may regulate--revising the Vaccine Injury Table--may be too sensitive to permit unilateral action.

The adversary posture of the parties has not hampered the decisionmaking process as much as misapprehension of expected roles did. In the future, the Program may discover the irreducible minimum amount of time required to decide contested cases. Informal procedures are not likely to make it any easier to resolve questions of fact about the nature and cause of an individual's injury. The time needed to resolve such issues is not necessarily wasted, nor is it a sign of programmatic failure. Indeed, the fact of resolution could be considered programmatic success.

It cannot be forgotten that the Program was created not only to provide fair compensation for vaccine-related injuries, but also to quell a seemingly insoluble debate over adverse reactions to vaccines. The fundamental question is whether a decisionmaking process can settle such a controversy. The answer may be yes, if controversial policy issues are removed from the process itself.



## Applying Lessons from the Program

It is reasonably clear that Congress viewed the Program as *sui generis* and not as a precedent for compensating personal injuries from other causes. Representative Waxman made this point quite clearly in introducing the bill in 1986, and has reiterated that position publicly.<sup>191</sup> In discussing a predecessor bill, Senator Hawkins and Deputy Assistant Attorney General Willmore agreed that the compensation system presented a unique situation, primarily because the government requires childhood immunizations.<sup>192</sup>

Many of those who originally opposed the Program did so because they feared it would create a model for dealing with other personal injury problems. The administration was concerned about the potential cost of multiple or expanded compensation programs funded through government, and instead tended to favor limiting the compensation payable in tort actions as an alternative.

In spite of these intentions, the Program has been suggested as a model to solve other policy problems. Congress is considering a compensation system explicitly modeled on the Program to compensate uranium miners and other civilians exposed to above ground nuclear testing.<sup>193</sup> The Program has also been considered, but not explicitly adopted, by private committees as a model for compensating adverse reactions to investigational or approved HIV vaccines, to remove any disincentive that future litigation might pose to HIV vaccine development. In addition, it is conceivable that the Program itself could be expanded to cover additional vaccines, particularly those that are recommended for children. The Program has also been mentioned as a model in alternative proposals for no-fault compensation of injuries related to medical practice.

Such recommendations could pose difficulties for the Program. Adding new vaccines to the Vaccine Injury Table is contemplated by the Act, but could undermine its basic justification if the new vaccines are not required for children. A more practical problem would be developing an acceptable list of compensable injuries to include within the Vaccine Injury Table. Vaccines newly approved by the Food and Drug Administration will not have been in use long enough to identify serious adverse reactions. The Program could cover new vaccines without listing compensable injuries in the Table if petitioners were required to prove that the new vaccines actually caused their

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<sup>191</sup> Remarks of Rep. H. Waxman, Conference on the National Vaccine Injury Compensation Program, Washington, DC, April 27, 1990.

<sup>192</sup> Hearing on S.827, July 18, 1985.

<sup>193</sup> The bill passed the Senate in August 1990, and has been submitted to the President for signature.

injuries. While the Program might be able to handle such a requirement, it could require longer decisionmaking periods and more expensive traditional methods of proof. It would also create a bifurcated system, with legal definitions of compensable injuries for vaccines now covered and requirements for proving actual causation in new vaccine cases. Most important, it could undermine the rationale for and utility of the Vaccine Injury Table for the vaccines currently covered.

It is likely that the Program will receive additional attention as a model for resolving policy problems that involve liability for injury, socially beneficial products or services, and injured persons in need of financial assistance. In the absence of any system of social insurance that covers injuries regardless of cause, narrower cause-based compensation systems offer a source of needed assistance. Whether or not multiple systems are an appropriate policy choice, it seems inevitable that they will be considered. In its current posture, the Program is not likely to be a generic model.

This is not to say, however, that elements of the Program are by their nature nontransferrable. Several structural and procedural components might fruitfully be incorporated in administrative benefit, administrative tribunal or litigation systems. For example, the front-end loading requirement can be used in most decisionmaking systems (where it is not already being practiced) to speed up the collection of all relevant information. Discrepancies and missing information can be identified and remedied early in the process. This gets decisionmaking under way promptly. Of course, there must be an adequate number of decisionmakers to be able to delve into the substance of a claim promptly upon its receipt, since there is little time spent waiting for additional papers to be submitted.

The Rule 5 Conference format can be applied in a variety of settings also. It can be used as a screening mechanism to identify claims that are patently eligible or ineligible for benefits, allowing limited time and resources to be concentrated on the more difficult cases. It also serves to facilitate resolution of claims. Off the record discussions encourage participants to settle disputes. There is little incentive to adopt a negotiating posture for purposes of building a record. Moreover, the special master's reaction to the case, in the form of a nonbinding preliminary opinion, gives the participants an objective assessment of their positions. They can identify any additional proof needed to make their positions persuasive or accept the opinion as properly dispositive of the case. This should encourage both the best presentation of each position and expeditious resolution of claims. Rule 5 Conferences seem especially suitable for administrative tribunals that handle cases involving the same or similar subject matter. For the same reason, they can be used in administrative benefit determination proceedings. They especially could be useful where claimants

deserve an opportunity to explain written claims and supporting documentation, but there is little need for a formal hearing.

The use of telephone conferences is also adaptable to almost any decisionmaking system. They appear particularly advantageous in systems with limited resources, as most are currently. However, they are likely to be most effective where the decisionmaker knows the participants and can assess their credibility. Personal or professional credibility is not always an issue, of course. Telephone conferences are a useful way to conduct informal conferences and formal hearings of all types.

The establishment of a designated unit of special masters or other decisionmakers to decide specific kinds of cases could be adapted for several uses. Although similar in concept, this structure differs from earlier proposals for specialized courts (like a science court or medical malpractice tribunal) in that it could be used within a court of general jurisdiction. Moreover, it can operate more easily as an administrative review mechanism without being bound by the court's rules of practice. Special masters dedicated to one technical subject matter (or several, where the caseload for each is small) have an advantage in understanding and evaluating cases because of familiarity with the subject matter. Their expertise should permit special masters to issue high quality decisions in a minimum amount of time. The dedicated special master unit concept can be applied in courts and in some administrative benefit systems. Among the latter, special masters may be best suited for making decisions that require decisionmakers who are independent of the agency responsible for paying the benefits claimed.

## Recommendations for Evaluation

The findings reported herein are descriptive of the Program's operation during its infancy. The Program's importance and the likelihood that it may operate differently, perhaps more efficiently, in the future, warrant a more comprehensive evaluation of the Program's operation during the next few years. Congress recognized the need for such an evaluation in the Technical Amendments. Moreover, to make a responsible decision whether or not to continue the Program after 1993, Congress should be provided with a careful analysis of the program's operation and effectiveness. The following discussion outlines the major issues that should be addressed in evaluating the Program.

Evaluating the Program requires identifying Program objectives. The task is complicated somewhat in this case because of the breadth, ambiguity, and occasional conflict in the goals of those who supported legislation authorizing the Program. Many members of Congress hoped that the Program could solve

the entire complex of problems affecting immunization rates, the supply of vaccines, the price of vaccines, future improvement of vaccine safety and effectiveness, and the compensation of injured persons. Thus, the Program was expected to contribute to stabilizing, and ideally increasing, domestic vaccine production by private companies.

There are several possible measures of Program effectiveness in meeting this objective--several because the objective is multifaceted. First, one might compare levels of vaccine production before and after the Program took effect. This preliminary evaluation does not attempt such a comparison because it will require several years of Program operation before any long-term effect on vaccine production could arise. Manufacturers may be expected to base future production plans on what they consider to be stable market conditions. The Program has not operated consistently for more than several months at a time as a result of the withdrawal of Program Office and DOJ participation and the Technical Amendments to the Act. Moreover, the Program has handled primarily retrospective cases that are funded out of Congressional appropriations rather than a surtax on vaccine sales. Therefore, the vaccine industry has not yet seen whether the Program will prove more or less costly to it than the risk of litigation. Also, the industry may prefer to wait to pass judgment on the Program until a year or two of prospective cases have been decided, when the incidence of petitioners who reject Program awards in favor of litigation can be empirically determined.

A preliminary estimate of the Program's effect on vaccine production could be attempted after the Program has completed at least 1 year of deciding prospective claims. At that time, it will be important to assess not only the number of doses of vaccine produced, but also the number of manufacturers producing vaccines covered by the Program. The number of vaccine doses must also be adjusted by the birth rate and expected market for immunization.

In addition, in order to evaluate the effect of the Program itself on vaccine production, the analysis must take into account other factors that may influence private sector decisions. For example, the expected future birth rate in the United States and the maximum tolerable price of vaccines will define the domestic market and whether continued production is sufficiently profitable when compared with other activities. New markets for vaccines may open up to encourage production, or old markets may shrink or become unprofitable. The condition of factories and laboratories and the cost of renovation or new construction may influence production plans. The technology used for vaccine production may prove a hindrance if it is suitable for only one product, or a cost-effective investment if it is useful for several lines of products. Thus, the evaluation should be able to collect sufficient data and employ an analytic method that will differentiate the real effect of the Program on industry decisions to produce childhood vaccines.

Determining the effect of the Program on immunization rates presents similar problems, albeit simpler ones. Obviously, any comparison of immunization rates before and after the Program took effect would require adjustment for the size of the population for whom immunization was recommended. Other factors influencing acceptance of childhood immunization would need to be weeded out. These might include the availability of private and medicaid insurance coverage for immunization, the availability of free immunizations at public clinics, a public educational campaign to encourage immunization, any change in the proportion of the population who declined immunization for religious reasons, and especially influential publicity about immunizations or adverse reactions to vaccines.

A second objective of the Program was to provide a mechanism for insuring fair and adequate compensation for injury resulting from vaccination. Parents of disabled children, as well as other supporters of the Act, viewed this as the real, and perhaps most attainable goal. Again, litigation was viewed as a problem, not because it cost too much, but because it resulted in too few instances of compensation.

Evaluating the Program's effectiveness in achieving this objective is also complicated. While adequacy of compensation could be measured by comparing awards against the losses incurred by petitioners, the fairness of compensation is not necessarily measurable by objective standards. Query whether it is "fair" to specify \$250,000 as compensation for a person's death? Does it matter whether a state's wrongful death act prescribes a greater or lesser amount? What is fair compensation for noneconomic losses like pain and suffering? Should it be commensurate with civil litigation awards or established by a schedule of functional losses? Should awards for lost earnings be calculated on the basis of actual individual losses, or be standardized so that everyone is compensated at the same rate? Because the Act specifies the terms of compensations, it incorporates an implicit congressional judgment of what is fair. However, this judgment may be challenged in the future if other changes, such as a recommendation to reduce costs, are proposed.

Estimating the adequacy of compensation is conceptually much easier, but does entail making some assumptions that could prove inaccurate. A survey of petitioners to ascertain their actual expenditures in caring for an injury seems necessary, even though self-reports are often unreliable. A sample of petitioners might be studied in greater depth, either to estimate reliability or to construct an estimate of expenses incurred by all. Estimates of future expenses depend upon the validity of actuarial assumptions, estimates of future economic costs of care, and the inflation rate.

The objective of providing fair and adequate compensation also included the idea that a larger proportion of persons permanently injured as a result of vaccines would receive compensation. This calls for two types of measures.

The first is a measure of whether all those who are injured and desire compensation have access to the Program and file a petition. The higher the ratio of persons filing petitions to persons injured, the more effective the Program. The numerator of the ratio can be taken from Program records. The denominator can only be estimated from CDC reports and the medical literature for retrospective cases. Better estimates should become available as the reporting of adverse reactions required by the Act is implemented.

The second measure of the Program's effectiveness in providing compensation to injured persons is the proportion of the Program's final decisions that is "correct;" that is, decisions that award compensation to petitioners for injuries listed in the Vaccine Injury Table and for unlisted injuries that are demonstrated to be caused by the vaccine. Unless the final judgment is assumed to be correct, this requires an independent assessment of the merits of petitions.

It would also be useful to determine whether the Program provides more or less compensation on average than do awards resulting from judgments or settlements in tort litigation. If the Program offers more compensation than most tort cases, injured persons are more likely to prefer the Program to litigation, and vice versa, of course. However, data on settlements has not been provided voluntarily by industry in the past. For this preliminary evaluation, a sample of petitioners attorneys were asked how Program awards compared with litigation. A similar proxy measure could be used in the future.

A third objective of the Program is impliedly incorporated in the first two--that the Program will reduce tort law claims against vaccine producers by serving as a substitute for litigation. As noted earlier, it is too soon to predict whether the Program will achieve this objective, although there are anecdotal reports that civil law claims have already decreased. In a few years, it may be possible to compare the claims made against vaccine producers after prospective cases have been through the Program with tort claims made in the 1980s, for example. However, to do so, it will be necessary to obtain data on claims made from the vaccine industry or its insurers where relevant. If such information is deemed important, it may be necessary to amend the Act to require it to be furnished if it is not offered voluntarily.

Program costs also influence its comparative advantage over litigation. To estimate the comparative costs of each to industry, it should be possible to calculate the aggregate amount of vaccine surtax costs and estimate the costs of litigation to industry. However, the reluctance of industry to disclose litigation costs may also create an obstacle to collecting this data.

The Program can only serve as a substitute for litigation if injured persons are aware of its existence. Thus, one measure of the Program's capacity to serve in lieu of litigation is the degree to which information about the Program

is available. This can be estimated by identifying informational materials prepared on behalf of the Program and by private organizations, the breadth of their dissemination (geographically and by target populations), and by surveying petitioners and nonpetitioners to determine whether and how they learned about the Program. Here, the major obstacle lies in identifying eligible persons who have not entered the Program.

Realistically, access to the Program is also rationed by access to attorneys willing and able to represent petitioners. So far, virtually all petitioners have sought representation by counsel in order to file and pursue a petition. Unless this changes dramatically, an unlikely event, the availability of attorneys will affect the number and type of petitions filed. The availability of attorneys can be measured in several ways. One is by a survey of attorneys. This has the disadvantage of possible inaccuracy as in any self-report. It may also fail to reach the entire pool of attorneys available unless a nationwide survey of all those admitted to the bar is conducted. Alternatively, attorney availability could be estimated by comparing the amount of attorneys' fees awarded to the costs of representing petitioners. This would entail estimating the costs of representation. In addition, one could infer the adequacy or inadequacy of the level of attorneys' fees from any increase or decrease in representation by attorneys who had filed petitions in an earlier year, although this would require adjustment for specialty and the instances in which an attorney handled only one case as a favor to a client or friend. Finally, since the choice of accepting the decision of the Program or pursuing a tort law claim lies with the petitioner, the petitioners' satisfaction with the compensation awarded will affect the Program's appeal. This can be measured in a survey of petitioners.

Much of the Program's success in achieving the above objectives lies in its effectiveness in operating an efficient administrative process. Here, more numerous and feasible measures of process, both objective and subjective, are available. These include the level of compliance with petition and documentation requirements, and the proportion of petitions to which an objection is filed by the Program Office. These may indicate that Program requirements remain unclear or that participants are misinterpreting the eligibility rules. Another measure of process efficiency is the time required to reach a final decision on petitions, and whether the time is within statutory limits. Lengthy proceedings may indicate either legitimately difficult cases or unnecessary obstructionism or simple inefficiency. Time estimates may also indicate whether statutory limits are realistic, although extending those limits may frustrate other objectives. Costs of administration also affect estimates of efficiency. Such costs, including staff time, can be compared with those of other compensation programs. Staff turnover rates and caseloads can also be studied.

More subjective measures include levels of satisfaction with the Program's process reported by all participant groups, including petitioners and their attorneys. This may include perceptions of efficiency and objectivity on the part of other participants.

Other measures of Program efficiency relate primarily to outcomes. For example, the proportion of awards that are appealed by either petitioner or respondent indicates the degree to which participants believe that the Program is making accurate or defensible decisions. The proportion of the trust fund paid out in awards will also indicate the economic efficiency of the Program and the levels of vaccine surtax.

These objectives of the Program are summarized, but not in any rank order, in Table VII-1. Examples of possible measures of effectiveness in achieving the objectives are also listed in the Table.



**Table VII-1**  
*Program Objectives and Measures of Effectiveness*  
(not rank-ordered)

**Stabilization of Domestic Vaccine Supply**

- Levels of vaccine production per population
- Number of vaccine producers
- Vaccine prices

**Stabilization of High Vaccination Rates**

- Rates of immunization

**Ensuring Adequate Compensation for Adverse Reactions to Vaccines**

- Comparison of compensation amounts with losses incurred
- Proportion of injured persons receiving compensation

**Substituting Program for Litigation**

- Frequency of claims against vaccine producers
- Comparison of vaccine surtax with litigation costs
- Availability of information on Program
- Availability of attorneys to represent petitioners
- Petitioners satisfaction with compensation awarded by Program
- Petitioners satisfaction with decisionmaking process and outcomes

**Efficient Program Administration**

- Level of compliance with petition/documentation requirements
- Proportion of petitions objected to
- Proportion of cases within Vaccine Injury Table
- Use of adversary and independent witnesses
- Proportion of awards appealed
- Time required for final decision
- Proportion of attorneys' costs covered by attorneys fee award
- Petitioners satisfaction with time, process, and participants
- Costs of administration
- Ratio of awards to trust funds

## RECOMMENDATIONS

The National Vaccine Injury Compensation Program (Program), 42 U.S.C. 300aa-10 et seq., is a federal no-fault compensation system for permanent injuries and deaths resulting from vaccines to prevent seven infectious diseases of childhood (diphtheria, tetanus, whooping cough, measles, mumps, rubella, and polio). State laws generally require that children be immunized against such diseases for school entry.

The Program, which became effective October 1, 1988, differs from most federal benefit programs in organizational structure and decisionmaking processes. Petitioners submit petitions for compensation to the United States Claims Court and bear the burden of proving both entitlement and the losses and expenses to be compensated. The Secretary of Health and Human Services (HHS) is designated as respondent. The National Vaccine Injury Compensation Program (NVICP) Office acts on behalf of the Secretary and may oppose compensation in individual cases.

Determinations of eligibility for and amounts of compensation are made by Special Masters within the United States Claims Court. There is no umbrella administrative agency charged with the duty of interpreting the enabling legislation or issuing general regulations. The Advisory Committee on Childhood Vaccines oversees the Program but is empowered only to advise the Secretary of HHS on Program implementation. The Secretary may revise the statutory list of compensable injuries (the Vaccine Injury Table), but has no authority to impose decisionmaking rules on the United States Claims Court.

### I. General Recommendations

#### A. Program Evaluation

This hybrid programmatic structure was created to settle controversies over whether and how compensation should be awarded for adverse reactions to childhood vaccines. It was also intended to contribute to improving immunization rates, stabilizing the supply and price of vaccines, encouraging new and improved vaccines, and reducing the burden and uncertainty of litigation. If the decisionmaking process is effective in resolving a multifaceted scientific and legal debate, it could be applied in other compensation or benefit programs, particularly those in which socially beneficial conduct is encouraged and the attendant risks are uncertain or controversial.

A long-term evaluation of the Program's operation and effects in the near future will be necessary to determine whether the Program could benefit from

administrative changes and whether any of its elements could offer an efficient decisionmaking process in other areas. Congress recognized the need for evaluation and amended the statute in November 1989 to require the Secretary of HHS to evaluate the Program and report to Congress by January 1, 1992. The NVICP Office in HHS began planning for soliciting extramural proposals for such a study, but the solicitation process has not yet begun. It is unlikely that any well-designed new study could be conducted by the original deadline.

Several changes have already been made in the Program's decisionmaking authority and proceedings by statutory amendments. Experience with the Program has demonstrated that some problems are not easily anticipated and that others may be solved informally with relative ease as experience increases. For these reasons, new major or structural changes in the Program should be avoided until an objective evaluation of Program needs is completed.

### **Recommendation 1. Longitudinal Program Evaluation**

An empirical evaluation of the Program's operation and effectiveness during at least fiscal years 1990, 1991, and 1992 should be conducted to collect and analyze sufficient empirical data to determine whether the Program is meeting its objectives. Research questions to be addressed should also include whether the Program serves as an effective substitute for litigation, and the effectiveness of decisionmaking procedures. The evaluation should distinguish between the Program's handling of retrospective and prospective cases to identify effective or problematic administrative processes that may be peculiar to one or the other type of case.

### **B. Opportunities to File Petitions with the Program**

There have been anecdotal reports that some people who may be eligible for compensation for retrospective cases under the Program have failed to file petitions thereunder for lack of awareness of the Program's existence. The deadline for filing petitions with respect to vaccinations administered before October 1, 1988 (retrospective cases) was January 31, 1991. Because the Act requires petitioners to submit all available relevant evidence supporting their eligibility when the petition is first filed, potential petitioners need to be aware of Program requirements well before the limitations period for filing expires. In cases involving a vaccine administered on or after October 1, 1988 (prospective cases), failure to file a timely petition under the Program precludes the individual from filing a civil action for personal injuries arising out of the vaccination.

## **Recommendation 2. Extension of Time for Filing Petitions**

Congress should consider whether section 2116(a) of the National Childhood Vaccine Injury Act should be amended to extend the time for filing petitions with respect to a vaccine administered before October 1, 1988, to September 30, 1991 (36 months after the effective date of the Act), if necessary to ensure that all those eligible for the Program have an opportunity to file a petition if they wish.

## **Recommendation 3. Program Information and Publicity**

The National Vaccine Injury Compensation Program Office, in consultation with the United States Claims Court and the Advisory Commission on Childhood Vaccines, should explore effective ways to disseminate information about the Program, including eligibility requirements and the time within which petitions must be filed, throughout the country in order to ensure that the population is aware of its legal remedies.

### **C. Conforming Time Limitations**

Under the Act, petitioners with prospective cases may not commence a civil action for an injury arising out a vaccination covered by the Act unless they have filed a petition with the Program and elected not to accept the final judgment thereon or the decision on appellate review. The Act tolls the statute of limitations governing the civil action until a final judgment is issued on the petition. This tolling provision was intended to preserve a petitioner's right to commence a civil action after the petitioner had exhausted the remedies under the Act. However, because an election to accept or reject a decision may be made within 90 days after the final judgment issued by the United States Claims Court or a decision on appeal, there is a gap in the tolling provision that could extinguish a petitioner's right to commence a civil action.

## **Recommendation 4. Conforming Time Limitations**

Section 2116(c) of the National Childhood Vaccine Injury Act should be amended to stay the limitations of actions governing civil actions for personal

injuries arising out of a vaccination covered by the Act until the date that the petitioner files an election, or is deemed to file an election, pursuant to section 2121 of the Act, to accept the judgment or to file a civil action.

#### **D. Determination of Eligibility**

The major eligibility criterion entitling a petitioner to compensation under the Program is that an individual has sustained an injury (including death) that either is described in the Vaccine Injury Table within the time specified in that Table or that was caused by a covered vaccine. Petitioners bear the burden of proof on this issue. The Act also requires petitioners to submit all available documentation to sustain their burden on this issue. An award of compensation may be made only if a petitioner has demonstrated by a preponderance of the evidence that the injury is covered by the Act, and if the Special Master finds that there is not a preponderance of the evidence that the injury was caused by factors unrelated to the administrations of the vaccine. The Act does not assign the burden of proof of an alternative cause to either party to the proceeding. The respondent, however, ordinarily raises the issue when it thinks relevant. Since the respondent should have all information relevant to the determination of the cause of injury early in the proceedings and the Special Master can compel the production of any additional necessary information, the respondent ordinarily presents the case for an alternative cause. The time required for the Special Master to make a determination with respect to an alternative cause of injury might be reduced, especially in cases in which there is little controversy as to the cause of the injury, if the burden of proof of this issue were placed on the respondent. The respondent would not be under pressure to present expert opinion on the issue of causation in cases in which there was no dispute simply to create a record for the Special Master's determination. In effect, the issue would operate as an affirmative defense, which the respondent could raise in appropriate cases.

#### **Recommendation 5. Burden of Proof of Causation by Factors Unrelated to Vaccine**

Section 2113(a)(1) of the National Childhood Vaccine Injury Act should be amended to require the respondent to carry the burden of proving that an injury or death described in any petition is due to factors unrelated to the administration of the vaccine. Compensation should be awarded if the special master or the United States Claims Court finds (1) that the petitioner has demonstrated eligibility for compensation by a preponderance of the evidence,

and (2) that the respondent has not demonstrated by a preponderance of the evidence that the injury or death is due to factors unrelated to the administration of the vaccine.

### **Recommendation 6. Independent Experts**

If Recommendation 5 is not adopted, the Office of Special Masters should consider developing a list of independent experts to serve as expert witnesses in cases in which there is no clear preponderance of the evidence favoring either a Table injury or an injury caused by a covered vaccine, or favoring an unrelated cause of injury. Such experts should be generally recognized for their skill and knowledge and should not have any affiliation with any vaccine producer, government agency involved with vaccine research, approval, distribution, or evaluation, or regularly serve as an expert witness on behalf of a party in vaccine-related litigation. The types of cases in which the cause of injury or death is not readily resolved by evidence introduced by the parties should be studied to predict whether and how often such independent experts might prove useful and whether they could in fact assist in creating a fair and expeditious decisionmaking process.

### **E. Determinations of Compensation**

Compensation for permanent injury, other than death, includes the net present value of actual unreimbursable expenses for medical, rehabilitative, and custodial care, actual and anticipated lost earnings, and actual and projected pain and suffering. The determination of the amount of compensation to be awarded to eligible petitioners in cases of injury can be difficult and time consuming. To expedite calculation of the amounts to be paid and to promote their consistency across similarly situated individuals, the Special Masters could apply uniform discount rates to the elements of compensation. This should reduce the need for hearings or submissions to prove future inflation rates to establish the net present value of specific elements of compensation.

### **Recommendation 7. Measures of Net Present Value of Compensation**

The Office of Special Masters, in consultation with the Advisory Commission on Childhood Vaccines and the National Vaccine Injury

Compensation Program Office, should develop uniformly applicable measures, such as discount rates for the value of medical and other services to be purchased in different years, for calculating the net present value of specific elements of compensation to be awarded to petitioners. Such measures could be applied in all cases to compute the amount of awards promptly and with consistency in cases similarly situated. The measures should be reviewed at least annually in order to ensure that they are consistent with reasonable estimates of future economic performance.

## **F. Settlement Authority**

The expeditious settlement of an injury case is sometimes hampered by limitations on the authority of attorneys in the Department of Justice (DOJ) who represent the respondent in the Program to settle cases for more than a specific amount of compensation. The limitation is lower than the average award to an eligible petitioner in an injury case. The time required to obtain approval of a settlement may jeopardize compliance with the Act's deadline for the Program's final decision.

### **Recommendation 8. DOJ Settlement Authority**

The Department of Justice should grant to the chief of the Vaccine Injury Compensation Program section authority to settle cases of injury under the Program in which the compensation award does not exceed \$1.5 million.

## **II. Interim Measures to Ease Temporary Program Burdens**

The Program's capacity to make expeditious decisions is being strained temporarily as a result of the recent filing of more than 3,000 petitions during the 5 months preceding February 1991. This represents about 10 times the number filed in the preceding 2 years. The vast majority of these petitions are retrospective cases representing injuries from vaccinations administered at any time before October 1, 1988. The unusual burden they place on the Program is unlikely to extend to prospective cases brought after January 31, 1991. Prospective cases are expected to be filed in smaller numbers each year and in a more regular pattern because they must be brought within 2 to 4 years after the injury.

The bulge of retrospective cases now in the Program warrants a special response to ease the burden of deciding petitions. Steps should be taken to

expedite the decisionmaking proceedings. Even so, the time needed to make final decisions in this group of cases is likely to extend well beyond the 240 days (plus extensions) now required by the Act. Because the limit is jurisdictional, as a result of a 1990 amendment to the Act, petitions that are not decided within the time limit are dismissed and the petitioners are precluded from proceeding within the Program. To the extent that such petitioners pursue civil actions for the same injuries, one purpose of the Program--to serve as a substitute for litigation--would be undermined.

Existing resources are unlikely to prove adequate to process the temporary bulge of retrospective cases. Therefore, if these cases are to be decided within the next 2 to 4 years, additional Special Masters will be required to serve as decisionmakers for the Program, and the Departments of HHS and Justice may need to obtain additional staff to review petitions and represent the NVCIP Office before the United States Claims Court.



### **Recommendation 1. Deletion of Involuntary Dismissal for Exceeding Time Limits**

Congress should delete section 2121(b)(2) of the National Childhood Vaccine Injury Act, as added by the Vaccine and Immunization Amendments of 1990, which withdraws jurisdiction over any petition that is not decided within the time required by the Act.

### **Recommendation 2. Extension of Time to Decide Claims**

Congress should amend section 2112(d)(3) of the National Childhood Vaccine Injury Act, as amended by the Vaccine and Immunization Amendments of 1990, to permit the chief special master to suspend proceedings on and to extend the time for deciding all or any petitions under the Program for up to 2 years, in addition to all other extensions and suspensions permitted, when the chief special master determines that the number of filings and resultant workload so requires in the interest of justice.

### **Recommendation 3. Number of Special Masters**

Congress should amend section 2112(c)(1) of the National Childhood Vaccine Injury Act to increase the maximum number of special masters from 8 to 12.

### **Recommendation 4. Aids to Interpretation**

Congress should consider whether additional qualifications and aids to interpretation of the Vaccine Injury Table, set forth in section 2114(b) of the National Childhood Vaccine Injury Act should be adopted to further clarify and explain the symptoms and conditions that should be considered evidence of an injury described in the Table, to simplify the process of determining eligibility.

### **Recommendation 5. Compensation Fund Advisor**

The National Vaccine Injury Compensation Program Office in the Department of HHS should engage an advisor to the Trust Fund who could assist in calculating the net present value of elements of compensation and in identifying reasonable sources, kinds, and amounts of annuities and other methods for the payment of awards.

### **Recommendation 6. Compensation Guidelines**

The United States Claims Court, in consultation with the National Vaccine Injury Compensation Program Office and representatives of petitioners, should develop guidelines for the amount of compensation payable with respect to each element of compensation. The guidelines should provide for appropriate variations on the basis of age, severity of injury, intensity of services, and other relevant factors. The guidelines should present a range of values in each category, with flexible ceilings and floors, in order to accommodate special circumstances. The special masters should provide petitioners and respondent with a copy of the relevant guidelines to facilitate the expeditions calculation of compensation. Requests for compensation within the relevant range could be presumed acceptable in the absence of evidence demonstrating that the petitioner's needs are more likely than not to be outside the guidelines.

## EPILOGUE

The National Vaccine Injury Compensation Program (Program) has experienced a new challenge since those described in the Report. In September 1990, the last month for filing petitions for retrospective injuries, about 2,700 petitions were submitted to the U.S. Claims Court, or more than five times the total number filed in the preceding 23 months. Another 700 retrospective petitions were submitted after the October 1, 1990 deadline, and returned by the court for lack of timeliness. The unexpected avalanche of cases helped to persuade Congress to extend the deadline for filing retrospective petitions. In November 1990, President Bush signed into law amendments to the Act that, among other things, extended the deadline for filing petitions for retrospective injuries to January 31, 1991.<sup>194</sup> By the end of January 1991, the Program had received 4034 retrospective petitions and 98 prospective petitions. About 800 retrospective petitions were filed in the month of January alone.

The increased number of cases has created two new problems for the Program. One is concern that the funds appropriated for retrospective cases will be insufficient to pay awards as permitted by the Act. The second is concern that the time required to decide claims will exceed the limits established in the amended Act. Both of these are summarized briefly below.

### Awards in Retrospective Cases

The Report indicated that the average award paid to a petitioner for a retrospective injury was approximately \$1 million as of February 28, 1990. Awards in the case of death were limited to the statutory maximum of \$250,000. By January 21, 1991, the Program had issued final decisions awarding \$87.8 million in 136 cases, including two prospective death cases. Awards in retrospective cases of injury ranged from \$86,000 to \$2.9 million, with an average of \$1.2 million.

While predictions of the cost of awards that will be made in all retrospective cases are necessarily tenuous, it is likely that they will exceed substantially the \$400 million that Congress has authorized for retrospective cases. If awards were made in 71 percent of the 4,034 retrospective cases filed, as they were through February 28, 1990, and in the same ratio of approximately two death cases for every injury case, then total retrospective awards could be made for 955 injuries and 1,909 deaths. This would require

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<sup>194</sup> Vaccine and Immunization Amendments of 1990, Pub. L. No. 101-502, sec. 5(e), 104 Stat. 1285.

\$1.1 billion (955 x \$1.2 million) for injuries and \$477 million (1,909 x \$250,000) for deaths, for a cumulative cost of \$1.6 billion, or four times the amount authorized to be appropriated.

This estimate, however, is both too conservative and too liberal. The number of petitions alleging injury rather than death has risen in recent months, so that the proportion of awards for injury is likely to be higher than that seen during the first year of the Program. For example, only about 300 of the 2,700 petitions filed in September 1990 sought compensation for death. Thus, it may be more realistic to estimate the ratio of death to injury cases as 1:6, which is closer to the estimated incidence of vaccine related deaths and injuries nationally. Using this ratio, of the 4,034 petitions filed, approximately 576 could involve death, while 3,458 could involve injury. This would increase the cost of awards for injury, since injury awards are four to eight times as large as awards for death.

At the same time, it seems unlikely that the Program will approve the same high proportion of petitions that it did during the first year. During the first few months of 1991, only about 60 percent of petitions were approved, and this could decrease further. Assuming that only 50 percent of all petitions (2,017) were awarded compensation, a total of \$2.1 billion could be required to fund all such retrospective awards (\$72 million for death cases and \$2.07 billion for injuries cases).

These are very crude estimates and need refinement with more complete data. The range of \$1.6 to \$2.1 billion in total costs is consistent with an earlier rough estimate of \$2 billion made by the U.S. Claims Court Office of Special Masters. This represents eight times the total funds actually appropriated by Congress for retrospective cases so far. If the Program is to pay out awards to all eligible petitioners, something must change. The number of awards may decrease, the proportion of awards for injuries may decrease, the amount awarded per petitioner may decrease, Congress may appropriate more money to fund retrospective awards, or other sources of funds may become available.<sup>195</sup>

## Time to Determine Claims

The Report on the Program's first year noted that the time required to assess and determine the amount of compensation to be awarded to successful petitioners in injury cases was occupying an increasing proportion of the claims determination process. This trend has continued. The Office of Special

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<sup>195</sup> For example, the Act permits the Trust Fund to seek subrogation from parties responsible for injuries for which an award has been made. 42 U.S.C. 300aa-17.

Masters reports that compensation determination consumes about half the time required to decide claims. The time appears to be spent largely by the petitioners and the respondent seeking expert assessments of the future costs of medical and rehabilitative care for injured children, eligibility for federal and state assistance, present values of future living and medical expenses, and calculating appropriate annuities. In a significant proportion of cases, the amount of compensation is contested, even when there is no real dispute over eligibility.

Given the large numbers of new retrospective claims, the Program is already experiencing difficulty handling the petitions within statutory time limits. The number of staff that was sufficient to process 300 petitions in mid-1990 is not likely to be able to decide 4,000 new claims in the same timeframe. The Office of Special Masters, for example, had six special masters in August 1990. It is now actively recruiting two additional special masters to return to its original total of eight. But, it is limited to eight special masters by the amended Act. The Program Office within the Department of Health and Human Services and attorneys in the Department of Justice (DOJ) are similarly understaffed. It is possible that the Program Office and the DOJ may feel compelled to withdraw from participating in some cases, as they did in May 1989. Yet, their withdrawal would not eliminate the need for determining awards for successful petitioners.

Several options exist to minimize the time pressure faced by the Program. The most obvious is to amend the statute to extend the time for reaching a final decision in retrospective cases. The November 1990 amendments to the act added a new provision permitting the Chief Special Master to "suspend proceedings on any petition for up to 180 days in addition to the suspension time" already permitted by the Act, if the workload created by the number of petitions created an "undue burden."<sup>196</sup> In the absence of increases in Program staff, the extension period might need to be longer than 6 months, even a year. A lengthy extension, however, may undermine one of the Program's greatest attraction to petitioners--its speed.

A second option is to increase the number of staff at all three entities involved in the Program. This would require additional appropriations to fund new staff, adding more costs to the Program. It would also require amending

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<sup>196</sup> Vaccine and Immunization Amendments of 1990, Pub. L. No. 101-502, sec 5(b)(1), amending 42 U.S.C. 300aa-12(d)(3). The Amendments also permit a petitioner, upon 30-days' notice to the court, to withdraw a petition if it is not finally decided within the 240-day time limit (plus extensions). Moreover, if a decision is not made within 30 days after such notice is filed, the petition is deemed withdrawn. Thus, the Program would no longer apply in any case in which a decision could not be made within the statutory time limits. A petitioner who withdraws a petition under these circumstances may pursue litigation.

the Act to permit more than eight special masters. However, authorization and recruitment of new reviewing physicians for the Program Office and new DOJ attorneys could take several months. Cases being processed during that period are likely to need an extension of time for decision.

A third option is to establish more uniform standards of compensation for eligible petitioners with injury cases to reduce the time required to calculate awards. This could be accomplished in several ways. The simplest, least attractive to petitioners, and probably least equitable, would be to establish a fixed dollar amount for all injuries, as the British Vaccine Damage Payments Act does.<sup>197</sup> An alternative would be to establish a fixed dollar amount for each type of injury, based on average estimates of future medical and rehabilitation expenses. More elaborate schedules of compensation are also possible, with fixed amounts specified for particular ages, conditions, geographic locations, and insurance status. These can be tailored to individual circumstances without extensive investigations of individual needs. Scheduled compensation has the advantage of permitting special masters to award compensation without extensive hearings on damages. It may also eliminate the need for the Program to pay the costs of expert witnesses for individual petitioners. Scheduled compensation also has disadvantages. It would require several months at best to develop a reasonable schedule. It is not likely to appeal to petitioners. Most troublesome, it materially alters the Act, which provides for compensation of actual estimated future expenses to all eligible petitioners who have already filed a petition. Thus, it would require an amendment to the statute, and an opportunity for those who do not want scheduled compensation to opt out of the Program and pursue litigation. The implications of such a change, for the Program, the supply of vaccines, and immunization in general are not easily predictable. Similar standards in the form of nonstatutory guidelines, however, could be used by the special masters without amending the Act.

An alternative to fixed or scheduled compensation is a procedural device known as "final-offer adjudication." The special masters could require both the petitioner and the respondent each to submit one first-and-final statement of the compensation thought appropriate and the special master would choose one

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<sup>197</sup> If the \$400 million in authorized funds were spread equally among 2,000 eligible applicants, each could receive \$200,000. Since more than \$88 million has already been awarded, only about \$312 million is available for the remaining eligible petitioners, who could number almost 2,000. That would permit approximately \$165,000 per person, less than the \$250,000 Act provides in death cases. The British Vaccine Damage Payments Act pays 20,000 pounds to an eligible claimant, but the amount, which has been criticized as woefully inadequate, is not intended as compensation. Mariner, *Compensation Programs for Vaccine-Related Injury Abroad: A Comparative Analysis*, 31 St. Louis L.J. 599, 626 (1987).

or the other as the final award. A similar statutory decision rule in Wisconsin's workers compensation program governs decisions on disability ratings and requires the administrative law judge to make a determination within 5 percent of either rating.<sup>198</sup> Splitting the difference is not permitted, so extreme estimates by partisan experts is discouraged. Such an approach could be required by amending the statute or implemented by the special masters. It would save time, although the parties would still have to spend considerable effort developing a realistic estimate.

Finally, it might be possible to eliminate much of the immediate decisionmaking with respect to long-term care by making successful petitioners eligible for institutional or home care services under the Medicare or Medicaid programs. This would enable petitioners to obtain services as and when needed in future years, without necessitating an estimate of total lifetime costs. Moreover, it would reduce the current pressure on Program funds. Medicare appears to be attractive because it already offers assistance to some disabled persons, and, like the Program, is federally administered. However, it is not structured to provide general nonacute care, and would require an amendment to authorize eligibility for appropriate services for petitioners. Medicaid programs do cover some long-term care. But because Medicaid is administered by the states, consistent coverage for Program petitioners could not be assured without some federal intervention. The statute would also require amendment to permit appropriate home care services.

The options sketched above are merely suggestive of the types of responses available. It will be important to ensure that any alteration of the existing statutory scheme be consistent with the original goals of the Program and that they garner the general support that made the Program possible.

## Conclusions

Just as the Program was setting into a more comfortable mode of operation, a large influx of petitions has necessitated reconsideration of the decisionmaking process. The new petitions seem to confirm the appeal of and need for the Program. Thoughtful consideration is required to develop ways to decide a larger number of claims without losing the benefits of the Program.

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<sup>198</sup> L. I. Boden, *REDUCING LITIGATION: EVIDENCE FROM WISCONSIN* (1988).