

Use of Expert Testimony, Specialized Decision Makers, and Case-Management Innovations in the National Vaccine Injury Compensation Program

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I. Introduction

In recent years courts have seen an increase in cases involving scientific and technical evidence. Many of these cases, such as those involving asbestos or silicone breast implants, fall into the category of “mass torts,” where numerous injuries are alleged to have been caused by the same product or event. Calls for the study of procedures for managing such cases have been coming from a number of sources over the past several years.¹

This report describes the National Vaccine Injury Compensation Program (VICP), which was established by the National Vaccine Injury Act of 1986² (hereinafter “the Act”) to handle claims of injury or death from the administration of certain vaccines.³ Persons claiming that injury or

1. For example, in 1990 the Executive Committee of the Judicial Conference of the United States requested that the Federal Judicial Center study how courts handle scientific and technological complexity in litigation. Memorandum of Action of the Executive Committee of the Judicial Conference of the United States 5 (May 18, 1990) (on file with the Federal Judicial Center, Research Division). The final report of the Federal Courts Study Committee suggested that, for instances in which a high number of injuries may have been caused by a single product or event, the Center should “analyze and disseminate information about tailored procedures to avoid undue re-litigation of pertinent issues and otherwise facilitate prompt, economical and just disposition of claims.” Report of the Federal Courts Study Committee 46 (1990). Finally, a 1993 report of the Carnegie Commission on Science, Technology, and Government, prepared by its Task Force on Judicial and Regulatory Decision Making, suggested studying alternative mechanisms that judicial systems might use to cope with science and technology issues in the courts. Carnegie Comm’n on Science, Tech., & Gov’t, Science and Technology in Judicial Decision Making: Creating Opportunities and Meeting Challenges 40 (1993).

2. 42 U.S.C.A. §§ 300aa-1 to -34 (West 1991 & Supp. 1996). The statute was enacted on November 14, 1986, and became effective on October 1, 1988. All subsequent statutory citations are to this act unless otherwise noted.

3. Vaccines included in the statute are those for diphtheria, tetanus, pertussis (whooping cough), polio, measles, mumps, and rubella. *Id.* § 300aa-14. On March 24, 1997, vaccines for hepatitis B, Hemophilus Influenzae Type B (Hib), and varicella were added to the program’s coverage. Other modifications to the table and the qualifications and aids to interpretation were also made at that time. *See* 62 Fed. Reg. 7685 (1997). Effective August 6, 1997, a flat tax was enacted to provide funds for compensation for injuries related to the additional vaccines. *See infra* note 26.

death was caused by a vaccine covered by the statute, and whose claims arose after the effective date of the Act, are diverted from filing a civil lawsuit against a vaccine manufacturer or provider in state or federal court unless their claims have first been adjudicated in the program. Under the VICP, the federal government (through the Secretary of Health and Human Services) assumes liability for vaccine-related injuries, and the task of proving causation for those seeking to recover is simplified. Claims, many of which rest largely on scientific and medical evidence, are initially decided by special masters who hear only vaccine-injury cases and who operate under relaxed rules of evidence and procedure. Only after final judgment is entered can a party choose to reject the special master's judgment and file a civil action for damages against a vaccine manufacturer in state or federal court. Funding for the program comes in part from appropriations and in part from an excise tax on vaccine purchases.

Some have suggested the VICP as an alternative dispute resolution model for future mass tort cases.⁴ Thus, one goal of this report is to describe the structure and operation of the program so that its suitability as a model for other classes of cases can be evaluated by policy makers. In addition, some of the case-management procedures employed to manage scientific and medical evidence in the VICP could conceivably be utilized in the context of traditional tort litigation. Another purpose of this study, then, is to describe these specific case-management procedures so that their potential usefulness in more traditional litigation of cases involving scientific evidence can be evaluated.

A. Research Questions

To learn more about the VICP we examined the following questions:

- Why was the program initially created, and what were the main issues involved in its design?
- How is the program structured and implemented?
- What have filing and termination rates been over the course of the program? How long do cases in the program take to resolve, and what proportion of petitioners are compensated?

4. E.g., Denis J. Hauptly & Mary Mason, *The National Childhood Vaccine Injury Act: The Federal No-Fault Compensation Program That Gives A Booster For Tort Reform*, 37 Fed. B. News & J. 452 (1990). Mr. Hauptly is a former special master for the VICP, and Ms. Mason is a former law clerk.

- How are cases managed in the program, and what procedures are used to facilitate resolution of scientific and medical issues?
- What are participants' views of the program, particularly its case-management procedures and handling of expert evidence? Do participants think the program has achieved its goals?
- For what other types of cases might the VICP structure or procedures be appropriate?

B. Research Methods

We used several approaches to obtain information relevant to our research questions. First, we reviewed a number of documents, including the Act, its legislative history, and relevant law review articles.

Second, we obtained statistics about the program from databases maintained by the Office of Special Masters of the U.S. Court of Federal Claims and the Division of Vaccine Injury Compensation (DVIC) of the Department of Health and Human Services. Unfortunately, a good deal of information pertinent to this study is not included in the databases, and therefore we were unable to conduct a number of relevant analyses.

Third, we interviewed all current (seven) and former (four) special masters. Interviews with the seven current special masters were held in person, while three of the four former special masters were interviewed by telephone. We also interviewed by telephone eight attorneys from the Department of Justice office that defends cases in the VICP. These attorneys were selected (based on information provided by supervisors) to represent a range of years of experience under the VICP, as well as a range of experience in litigation contexts outside the program.

Fourth, we sent a written questionnaire to all petitioners' attorneys (131) who were identified in U.S. Court of Federal Claims Clerk's Office records as having participated in three or more cases in the VICP as of spring 1995. We were unable to locate 5 of the selected attorneys. Of the remaining 126 questionnaires, 69 were completed and returned, for a response rate of 55%.⁵ Although this is a reasonably high response rate from attorneys, the fact that almost half of those to whom the questionnaire was mailed did not respond means that we cannot be confident that the responses represent the views of experienced practitioners as a group.

5. In addition, one attorney who had handled a number of vaccine cases as an associate of an attorney who received the questionnaire completed a copy of the questionnaire and returned it to us; because he had handled more than three vaccine cases, we included his responses in the analysis.

We have no reason to believe, however, that those who did not respond differ in notable ways from those who did respond.

Finally, we observed sixteen hearings involving expert testimony, mostly on causation issues. At least one hearing was observed before each special master.

C. Summary of Findings

The following are our overall findings:

- The program was designed to keep manufacturers from leaving the vaccine market, while at the same time compensating those individuals injured by vaccines. Issues debated during its development included where the program would be located, whether it would be an exclusive remedy for those seeking compensation for vaccine-related injuries, and how the program would be funded.
- The program is located in the U.S. Court of Federal Claims, where cases are heard by special masters who hear only vaccine cases. Respondent to petitions is the Secretary of Health and Human Services, as represented by attorneys in a special office at the Department of Justice. Claims must be decided within statutory time limits and are subject to limitations on compensation amounts and attorneys' fees.
- By August 1997, 5,176 petitions had been filed, 82% of which were for compensation for injuries that had occurred prior to the effective date of the Act. Of the cases that had terminated, just under 30% had resulted in an award of compensation to the petitioner (including settlements).
- Innovative case-management procedures employed in the program include: (1) a requirement that virtually all documentation supporting claims or defenses accompany the initial pleadings; (2) use of expert reports; (3) informal status conferences; (4) bifurcation of causation and damages issues; (5) telephonic hearings; (6) hearings limited to expert testimony; and (7) direct examination of expert witnesses by the special master.
- Overall, petitioners' attorneys who responded to our questionnaire think that resolution of cases in the VICP is less expensive than litigation in state or federal court, but that it takes the same amount of time or longer. Delays appear to be attributable to a backlog of pre-Act cases that is steadily being reduced.

- Participants are generally satisfied with the operation of the VICP, although petitioners' attorneys appeared somewhat less enthusiastic than did respondent's attorneys and special masters. Petitioners' attorneys were particularly concerned with the length of time to resolve cases, the sometimes adversarial nature of case resolution, and the inadequacy of statutory attorneys' fees provisions.
- Most participants (special masters and attorneys) think the VICP, or elements of it, could apply to other categories of cases, particularly those with well-defined issues that are litigated repeatedly.

D. Overview of the Report

In Part II we provide a thorough description of the background and structure of the Vaccine Injury Compensation Program. Part III provides statistical information about the program, including filing and compensation rates. Part IV describes case-management procedures used in the program, focusing on those for handling scientific and medical testimony. Part V discusses participants' overall assessments of the program and its potential suitability for other mass tort cases. Part VI sets forth the authors' conclusions about the VICP.

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II. Description of the National Vaccine Injury Compensation Program

A. Background of Program

Most states require proof of vaccination against certain childhood diseases before a child is able to enroll in school.⁶ The federal government plays an important role in vaccine policy as well, by providing grants to states for immunization services, by conducting vaccine research and development, and by testing and licensing vaccines.⁷ Childhood vaccination in the United States has been an extremely successful program, with the incidence of many of the diseases vaccinated against—such as polio and whooping cough—greatly reduced, if not eradicated, since large-scale public vaccination began.⁸ At the same time, scientific research has suggested that, while adverse reactions to vaccines are rare, a small fraction of the population may experience adverse reactions and become seriously ill or die as a result of being vaccinated.⁹

As public awareness of the link between childhood vaccination and certain injuries grew in the early 1980s, increasing numbers of lawsuits were filed against vaccine manufacturers to recover damages for injuries

6. Staff of Subcomm. on Health & the Env't, House Comm. on Energy & Commerce, 99th Cong., 2d Sess., Report on Childhood Immunizations 103 (Comm. Print 1986) [hereinafter *Childhood Immunizations*].

7. *Id.* at 43.

8. *See, e.g.*, H.R. Rep. No. 99-908, at 4 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6345 [hereinafter *Legislative History*] (“Vaccination of children against deadly, disabling, but preventable infectious diseases has been one of the most spectacularly effective public health initiatives this country has ever undertaken.”).

9. *See* Institute of Medicine, *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality* 16–17 (Kathleen R. Stratton et al. eds., 1994) [hereinafter *Adverse Events*].

that were allegedly vaccine related. Because of these lawsuits, the threat of future lawsuits, and the resulting difficulty in obtaining liability insurance, a number of vaccine manufacturers left the market.¹⁰ In 1986 there was only one manufacturer of the polio vaccine, one manufacturer of the measles, mumps, and rubella (MMR) vaccine, and two manufacturers of the diphtheria, pertussis, and tetanus (DPT) vaccine.¹¹ Liability insurance costs for vaccine manufacturers grew rapidly, causing prices for some vaccines to rise by over 300% between 1980 and 1986.¹²

These developments created concern that a continued supply of vaccines was at risk.¹³ Furthermore, parents of children injured by vaccines were frustrated by the time and expense involved in litigating vaccine-injury cases in court and by the difficulty of establishing causation in situations where the vaccine was administered long ago and the manufacturer of the vaccine in question could not be identified. A number of these parents formed groups, such as Dissatisfied Parents Together, that lobbied Congress to change the way vaccine-injury claims were handled.

This situation led to the development of the VICP. To ensure vaccine production by manufacturers—which benefits the public as a whole¹⁴—the government assumed liability under the program for injury or death associated with the administration of designated vaccines. At the same time, the program encompassed features to make it attractive to those seeking to recover for vaccine-related injuries—including a presumption of causation if certain facts are established; expeditious, less adversarial processing of claims; and the option of rejecting a judgment received under the program and pursuing the claim in federal or state court.

10. Legislative History, *supra* note 8, at 6–7, *reprinted in* 1986 U.S.C.C.A.N. at 6347–48.

11. *Id.* at 6348.

12. Childhood Immunizations, *supra* note 6, at 63.

13. Exacerbating the risk of vaccine shortages was the fact that the nation's supply of vaccines had never reached the six-month reserve levels recommended by the Centers for Disease Control. *See* Legislative History, *supra* note 8, at 7, *reprinted in* 1986 U.S.C.C.A.N. at 6348.

14. The success of vaccination programs depends on a high percentage of the population participating, so that transmission of the disease vaccinated against will be limited or prevented. This concept is called “herd immunity.” *See* Arnold W. Reitze, Jr., *Federal Compensation for Vaccination Induced Injuries*, 13 B.C. Env'tl. Aff. L. Rev. 169, 208 (1986).

1. Issues in Program Design

a. Location in the U.S. Court of Federal Claims

Although the VICP resembles administrative compensation schemes in many respects, cases in the program are heard not by administrative law judges but by special masters within the U.S. Court of Federal Claims (hereinafter, the “Claims Court”). The decision to locate the program in a court of law rather than an executive agency was in part a response to the concerns of parents of children with vaccine-related injuries, who thought that the Department of Health and Human Services—which would have been the most obvious location for an administrative program—was too heavily involved in overseeing childhood immunization programs to administer the VICP objectively.¹⁵

Under initial versions of the legislation, cases in the program were to be filed in U.S. district courts. A district court judge receiving a petition was to appoint a special master to hear the case as an adjunct to the court. After this proceeding was completed, the district court would enter a judgment which the petitioner could either accept or reject. If the judgment was rejected, the petitioner could go on to file a traditional civil action. The provision that allowed petitioners to reject a district court’s judgment raised a problem under the “case or controversy” requirement of Article III of the Constitution, which has been interpreted to prohibit federal courts from rendering advisory opinions.¹⁶ This and other concerns, including questions about the best use of judicial resources, were raised by the Judicial Conference of the United States, the American Bar Association, and others.¹⁷

In response, Congress amended the Act in 1987 as part of the Omnibus Budget Reconciliation Act (P.L. 100-203) to transfer jurisdiction over vaccine-injury cases to the U.S. Claims Court,¹⁸ an Article I court. In addition to avoiding the “case or controversy” problem, the Claims

15. See Wendy K. Mariner, *Innovation and Challenge: The First Year of the National Vaccine Injury Compensation Program*, 1991 Admin. Conf. U.S. 409, 454.

16. *Muskrat v. United States*, 219 U.S. 346 (1911).

17. H.R. Conf. Rep. No. 100-495, at 771 (1987), reprinted in 1987 U.S.C.C.A.N. 2313-1245, at 2313-1517.

18. The U.S. Claims Court was renamed the U.S. Court of Federal Claims on October 29, 1992. Federal Courts Administration Act of 1992, Pub. L. No. 102-572, § 902(a), 106 Stat. 4506, 4516 (1992). No claims under the VICP were ever heard in the district courts since petitions were first considered beginning February 1, 1989, long after jurisdiction was placed in the Claims Court. Office of the Inspector Gen., Department of Health & Human Servs., *The National Vaccine Injury Compensation Program: A Program Review* 2 (1992) [hereinafter Program Review].

Court was a desirable alternative because its jurisdiction is nationwide and judges can travel throughout the country to accommodate the needs of parties and witnesses.¹⁹ In addition, the Claims Court has specific authority to appoint special masters²⁰ and is not bound by the Seventh Amendment to hold jury trials in suits brought against the United States.²¹

b. Election to Reject Judgments

Vaccine manufacturers wanted the VICP to be an exclusive remedy for those seeking to recover for vaccine-related injuries or death. At the same time, parents of injured children did not want to forgo entirely their right to bring a civil action. As a compromise, the Act allowed petitioners to reject a judgment received under the program and pursue the claim in federal or state court, but also addressed manufacturers' concerns in several ways.

First, because compensation under the program was intended to be more expeditious, generous, and certain than compensation obtained through tort litigation, Congress expected that few petitioners would reject a special master's judgment in favor of litigation.²² Second, the Act places limits on the legal theories that can be pursued in state or federal court litigation. Specifically, the Act shields vaccine manufacturers from strict product liability by providing that manufacturers shall not be liable for vaccine-related injury or death caused by unavoidable side effects as long as the manufacturer properly prepared and labeled the vaccine with proper warnings.²³ In addition, the Act adopts the learned intermediary doctrine, allowing manufacturers to satisfy their duty to warn by providing information to the treating physician rather than directly to the per-

19. H.R. Conf. Rep. No. 100-495, *supra* note 17, at 772, *reprinted in* 1987 U.S.C.C.A.N. at 2313-1518.

20. 28 U.S.C. § 798(c) (1994).

21. The U.S. Court of Appeals for the Federal Circuit, which hears appeals from the Claims Court, has held that its review of vaccine cases does not contravene the "case or controversy" requirement of the Constitution. *Hines v. Secretary of Health & Human Servs.*, 940 F.2d 1518, 1521 (Fed. Cir. 1991).

22. *See* Legislative History, *supra* note 8, at 13, *reprinted in* 1986 U.S.C.C.A.N. at 6354 ("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.").

23. 42 U.S.C.A. § 300aa-22(b)(1) (West 1991 & Supp. 1996).

son receiving a vaccine.²⁴ Finally, the Act creates a presumption that warnings that are in compliance with FDA standards are adequate.²⁵

c. Financing of Program

The Act as originally passed specified that funding for the VICP was to come from an excise tax on vaccine sales. The tax was not enacted until 1987, leaving the program without a source of funding for more than a year after its enactment. In 1987, an excise tax was imposed on the sale of childhood vaccines through amendments to the Internal Revenue Code. These taxes, which are based on the number of anticipated doses and current scientific views about the relative risk from each vaccine,²⁶ are placed in a trust fund for compensation of victims whose injuries arose after October 1, 1988, the effective date of the Act.²⁷ For those whose injuries arose before that date, compensation comes from appropriated funds. Congress appropriated \$80 million per year for pre-Act cases through 1992 and \$110 million per year after that until no further compensation is required for pre-Act cases.²⁸

In addition, the Department of Justice, the Department of Health and Human Services, and the Claims Court each receive appropriations from the trust fund for administrative expenses associated with the VICP. The total paid from the fund for expenses of program administration has been approximately \$10 million for all three entities combined for each of the last several fiscal years.²⁹

24. *Id.* § 300aa-22(c).

25. *Id.* § 300aa-22(b)(2). See Daniel A. Cantor, *Striking a Balance Between Product Availability and Product Safety: Lessons from the Vaccine Act*, 44 Am. U. L. Rev. 1853 (1995) (discussing the effect of the Act on state and federal law).

26. Until recently, the tax per dose was \$4.56 for the diphtheria, pertussis, and tetanus (DPT) vaccine, \$.06 for diphtheria and tetanus (DT), \$4.44 for measles, mumps, and rubella (MMR), and \$.29 for polio. 26 U.S.C. § 4131(b)(1) (1994). Effective August 6, 1997, the excise tax structure was revised to a flat rate of \$.75 per dose for each vaccine covered under the program. Taxpayer Relief Act of 1997, Pub. L. No. 105-34, § 904(a), 111 Stat. 788, 873 (1997).

27. See 26 U.S.C. § 9510 (1994).

28. 42 U.S.C.A. § 300aa-15(j) (West 1991 & Supp. 1996).

29. Source: Thomas E. Balbier, director, Vaccine Injury Compensation Program, Department of Health and Human Services.

B. The Statutory Scheme and Its Implementation

1. Parties in Cases Brought Under the Act

A petitioner in the VICP may be a person who sustained a vaccine-related injury, the legal representative of this person if the person is a minor or is disabled, or the legal representative of one who died as the result of the administration of a vaccine covered by the statute.³⁰ Petitioners may proceed pro se or with counsel, but virtually all are represented by counsel. The Secretary of Health and Human Services (HHS) serves as the respondent,³¹ and is represented by about eighteen attorneys in the Vaccine Litigation Group of the Office of Constitutional and Specialized Torts at the Department of Justice (hereinafter, “respondent’s attorneys”).

2. Types of Cases Brought

The Act distinguishes two categories of vaccine-injury cases: (1) those in which the petitioner received a vaccination prior to the October 1, 1988, effective date of the Act (these are referred to as “pre-Act” or retrospective cases); and (2) those where the petitioner received a vaccination after that date (“post-Act” or prospective cases). In addition to the fact that compensation awards are funded in different ways depending on this classification (see *supra* Part II.A.1.c.), pre-Act and post-Act cases are subject to different limits on compensation. Recovery for post-Act cases can include expenses incurred up to the date of judgment as well as expenses for future care, compensation for lost earnings,³² an award for pain and suffering up to \$250,000, and an award for reasonable attorneys’ fees and costs, without cap.³³ In contrast, compensation available for petitioners in pre-Act cases does not include any expenses incurred before the date of the judgment. Compensation may include only future care and treatment for the injured party, without dollar limitation, plus a capped total of \$30,000 for pain and suffering, lost earnings, and reasonable attorneys’ fees and costs combined.³⁴ For both types of cases, where a vaccine-related death has occurred, the statute caps damages at

30. 42 U.S.C.A. § 300aa-11(b)(1)(A) (West 1991 & Supp. 1996).

31. *Id.* § 300aa-12(b)(1).

32. For a petitioner injured before the age of eighteen, awards for lost earnings are capped by a formula. For one injured after age eighteen, there is no cap for lost earnings. *Id.* § 300aa-15(a)(3).

33. *Id.* § 300aa-15(a), (e).

34. *Id.* § 300aa-15(b).

\$250,000 for the estate of the deceased, plus attorneys' fees and costs.³⁵ In addition, punitive or exemplary damages are prohibited in both types of cases.³⁶

Attorneys' fees are calculated using the lodestar method,³⁷ under which the number of hours reasonably expended is multiplied by a reasonable hourly rate.³⁸ Fees may be awarded whether or not the petitioner receives compensation under the program if the special master or court determines that "the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought."³⁹

3. The Vaccine Injury Table

One of the unique features of the program is the statutory scheme for handling causation issues. Petitioners are entitled to a presumption of causation if they can prove by a preponderance of evidence that certain injuries, disabilities, illnesses, conditions, or death occurred or were significantly aggravated within specified time periods after the administration of a vaccine listed in the vaccine injury table, which is reproduced in the Appendix.⁴⁰ Injuries included in the table, and thus eligible for the causation presumption, are referred to by participants in the program as "table" injuries. Presumptive causation shifts the burden of proof to the respondent, who must then show an alternate cause for the petitioner's injury in order to defeat an award of compensation. The statute also lists specific qualifications and aids to the interpretation of the table to assist the parties.⁴¹

A petitioner may also allege causation-in-fact in the case of an injury not listed in the vaccine table or not occurring within the time periods set forth in the table. In such cases, the petitioner has the burden of proving causation by a preponderance of the evidence utilizing traditional tort standards of proof. Petitioners often allege a table injury or, in the alternative, causation-in-fact, to preserve both causes of action.

The vaccine table was derived based on epidemiological studies of adverse reactions to the covered vaccines and reports of the American

35. *Id.* § 300aa-15(a)(2).

36. *Id.* § 300aa-15(d).

37. *E.g.*, *Edmondson v. Secretary of Health & Human Servs.*, No. 90-3060V, 1992 WL 88017 (Cl. Ct. Apr. 13, 1992).

38. *Blanchard v. Bergeron*, 489 U.S. 87, 94 (1989).

39. 42 U.S.C.A. § 300aa-15(e)(1) (West 1991 & Supp. 1996).

40. *Id.* § 300aa-14(a). The vaccine injury table may be—and has been—revised in accordance with administrative procedures set forth in § 300aa-14(c). *See supra* note 3.

41. *Id.* § 300aa-14(b).

Medical Association and the American Academy of Pediatrics.⁴² Congress explicitly recognized that some petitioners would be compensated erroneously through the use of this table and its presumption of causation⁴³ and mandated that the table be updated in the future to reflect evolving scientific information.⁴⁴

4. Special Masters as Decision Makers

Cases in the program are adjudicated by seven special masters appointed by the U.S. Court of Federal Claims. The special masters are appointed for an initial term of four years, subject to reappointment by a majority of the judges of the U.S. Court of Federal Claims. They have jurisdiction to determine both whether petitioners are entitled to compensation under the VICP and the amount of any such compensation.⁴⁵ When the program was first established, special masters made recommendations to the Claims Court, which then had to review the special master's recommendation and make the final decision in a case. Amendments to the Act in 1989, however, transferred final decision-making authority to the special masters, subject only to the appellate process.⁴⁶

Although Congress contemplated that non-lawyer scientists could serve as special masters in the VICP,⁴⁷ all of the special masters to date

42. Mariner, *supra* note 15, at 430–31.

43. Legislative History, *supra* note 8, at 18, *reprinted in* 1986 U.S.C.C.A.N. at 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.”).

44. In fact, the statute called for a review of scientific information on the possible adverse consequences of the pertussis and rubella vaccines. 42 U.S.C.A. § 300aa-1 note (West 1991 & Supp. 1996). An advisory committee of the Institute of Medicine (IOM) was asked to conduct this review, and its findings were published in 1991. *See* Institute of Medicine, *Adverse Effects of Pertussis and Rubella Vaccines: A Report of the Committee to Review the Adverse Consequences of Pertussis and Rubella Vaccines* (Christopher P. Howson et al. eds., 1991). The statute also mandated a review of the possible adverse events associated with other vaccines commonly given in childhood, and the IOM published this report in 1994. *See* *Adverse Events*, *supra* note 9. The changes to the vaccine table discussed in note 3 were based on the findings published in these IOM reports.

45. 42 U.S.C.A. § 300aa-12(a) (West 1991 & Supp. 1996).

46. Vaccine Injury Compensation Technicals, Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6601, 103 Stat. 2285 (1989).

47. *See* H.R. Conf. Rep. No. 101-386, at 515 (1989), *reprinted in* 1989 U.S.C.C.A.N. 3018, 3118 (“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.”).

have been lawyers. Nine of the eleven current and former special masters we interviewed previously worked for the federal government, three at the Department of Justice and two at the U.S. Court of Federal Claims. All have law degrees; three have master's degrees, one in social work and two in English. Three had previous legal experience in health-related issues. The eight special masters who had been appointed to the program at its inception attended a two-day educational program sponsored by the Federal Judicial Center to familiarize them with the medical issues they would encounter in the program. Those who were appointed later did not receive any specialized training.

5. Time for Case Processing

The Act as originally passed required a final judgment by the Claims Court within 365 days after filing. Under amendments to the statute, in cases filed after January 19, 1990, the time period is shortened to 240 days. However, this deadline does not include allowable suspension time. In both pre-Act and post-Act cases, the assigned special master can suspend proceedings upon motion of either party for an aggregate total of 180 days.⁴⁸ Furthermore, after a large influx of pre-Act case filings in 1990 and 1991, the Act was amended to provide that in pre-Act cases the chief special master may suspend the proceedings on any petition for up to thirty months (but not more than six months at a time) if he or she finds that the number of filings and resultant workload place an undue burden on the parties or special master involved.⁴⁹ Thus, if all available suspension periods are used, the total case-processing time can total more than one year in post-Act cases and more than three and one-half years in pre-Act cases. If final judgment is not entered within the applicable time period, a petitioner may choose to either continue in the program or withdraw his or her petition and file a civil action in state or federal court.⁵⁰

6. Conduct of Proceedings

The Act requires that the rules governing the management of cases in the VICP shall:

(A) provide for a less-adversarial, expeditious, and informal proceeding for the resolution of petitions, (B) include flexible and informal standards of admissibility of evidence, (C) include the opportunity for summary judgment, (D) include the opportunity

48. 42 U.S.C.A. § 300aa-12(d)(3)(C) (West 1991 & Supp. 1996).

49. *Id.* § 300aa-12(d)(3)(D).

50. *Id.* §§ 300aa-11(a)(2)(A)(ii), 300aa-21(b).

for parties to submit arguments and evidence on the record without requiring routine use of oral presentations, cross examinations, or hearings, and (E) provide for limitations on discovery and allow the special masters to replace the usual rules of discovery in civil actions in the United States Court of Federal Claims.⁵¹

Thus, neither the Federal Rules of Civil Procedure nor the Federal Rules of Evidence apply to cases in the VICP. As mandated by the Act, the Vaccine Rules of the Office of Special Masters, set forth in Appendix J of the Rules of the U.S. Court of Federal Claims, provide for many informal procedures for the resolution of vaccine cases, including an early off-the-record conference at which the special master orally presents tentative findings and conclusions (Rule 5); a provision prohibiting formal discovery as a matter of right, accompanied by a requirement that a party seeking formal discovery file a motion explaining why informal discovery has not been sufficient (Rule 7); a provision allowing the special master to consider all relevant, reliable evidence, governed by principles of fundamental fairness to both parties (Rule 8); and a provision allowing argument or hearing testimony to be taken by telephone (Rule 8).

As a supplement to the Vaccine Rules, the Office of the Special Masters issued practice guidelines in 1990 (revised in September 1996) to familiarize practitioners with the unique conduct of proceedings in the program and to underscore the ultimate goal of prompt and efficient resolution of claims.⁵² In describing the role of the special master, the guidelines note that “. . . in recognition of Congress’ intent that the special masters be more ‘inquisitorial’ than in typical litigation, the special master will question witnesses where appropriate, ask for more documents when such a need is determined, and keep the parties informed at all stages concerning what further proof is necessary to prove their cases.”⁵³

The specific case-management procedures used by the special masters are discussed in more detail in Part III.

51. *Id.* § 300aa-12(d)(2).

52. See Guidelines for Practice Under the National Vaccine Injury Compensation Program of the Office of Special Masters 1 (1996) [hereinafter Guidelines for Practice] (“Practitioners are encouraged to suggest creative ways of resolving their cases in the most efficient manner.”).

53. *Id.* at 9.

7. Appeals Process

Within thirty days of a final decision by a special master, either party may file a motion for review by the U.S. Court of Federal Claims. If no motion for review is filed within this time frame, the clerk of the U.S. Court of Claims enters judgment in accordance with the special master's decision.⁵⁴ Cases that are appealed at this stage of the process are argued to an individual judge of the U.S. Court of Federal Claims rather than an appellate panel. The judge hearing the appeal may (1) uphold the special master's opinion, (2) set aside any of the special master's findings of fact or conclusions of law found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law, and issue new findings of fact and conclusions of law, or (3) remand the opinion to the special master for further action.⁵⁵ Either party may appeal the Claims Court determination to the U.S. Court of Appeals for the Federal Circuit, where the case is heard by a three-judge panel and the legal issues are reviewed *de novo*. Final appeal from the Federal Circuit is to the U.S. Supreme Court, and the Supreme Court has heard one case under the VICP.⁵⁶

A petitioner may elect to reject a special master's judgment if no motion for review is filed or when the appeal process has been completed and final judgment entered. If an election to reject is filed within ninety days after entry of judgment, the petitioner may proceed to file a civil action for damages against a vaccine manufacturer or provider in state or federal court.⁵⁷ If the petitioner does not file an election, he or she is deemed to have accepted the judgment.

54. 42 U.S.C.A. § 300aa-12(e)(3) (West 1991 & Supp. 1996).

55. *Id.* § 300aa-12(e)(2). The level of review on appeal has been described by the Claims Court as "very limited." *Walker v. Secretary of Health & Human Servs.*, 33 Fed. Cl. 97 (1995).

56. *See Shalala v. Whitecotton*, 514 U.S. 268 (1995) (ruling that in order to make out a *prima facie* case under the Act, claimant must show not only that she experienced an injury during the period specified in the vaccine table, but also that no evidence of the injury appeared before the vaccination).

57. 42 U.S.C.A. § 300aa-16(c) stays state statutes of limitation for a civil action beginning on the date a petition is filed with the VICP and ending on the date (1) an election is made to file a civil action or (2) an election is made to withdraw a petition pursuant to § 300aa-21(b).

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III. Program Statistics

Little published statistical information exists about cases in the VICP. In addition, because the program is relatively young and filing patterns will no doubt change over time (e.g., pre-Act cases can no longer be filed), it is difficult to make generalizations from available data about termination times and other caseload characteristics.

To get a general idea of the filing trends, outcomes, and appeals or rejections, we analyzed information from automated databases maintained by the Division of Vaccine Injury Compensation (DVIC) of the Health Resources and Services Administration at HHS and the Office of Special Masters in the Claims Court.

A. Case Filings and Terminations

In projecting the costs of the VICP, the Congressional Budget Office estimated that 1,500 pre-Act cases would be filed, and that post-Act cases would be filed at the rate of approximately 185 per year.⁵⁸ As shown in Table 1, these projections underestimated the number of pre-Act petitions actually filed.

Table 1 shows, for each fiscal year beginning in 1988, how many pre- and post-Act cases were filed in the program during that period, how many were adjudicated, and how many were pending at the end of the period. The filing rate appears fairly steady over the course of the program at between about 110–190 filings per year, except for fiscal years 1990 and 1991. This time period includes the original September 30, 1990, deadline for pre-Act cases and a deadline extension to January 31, 1991, for the filing of pre-Act cases.⁵⁹

58. Legislative History, *supra* note 8, at 39, *reprinted in* 1986 U.S.C.C.A.N. at 6380.

59. 42 U.S.C.A. § 300aa-16(a)(1) originally allowed petitioners twenty-four months from the effective date of the statute (October 1, 1988) to file all pre-Act cases. This deadline was September 30, 1990. The 1990 amendments to the Act added four more months to this jurisdictional time frame, changing the final deadline to file pre-Act cases to Janu-

Table 1. Filings and adjudications, 1988-1997

Time Period	Cases Pre-Act	Filed Post-Act	Adjudications		Cases Pending at End of Period
			Pre-Act	Post-Act	
FY 1988	24	0	0	0	24
FY 1989	147	1	22	0	150
FY 1990	3,199	49	124	3	3,271
FY 1991	864	98	524	28	3,681
FY 1992	3	186	531	68	3,271
FY 1993	3	137	623	72	2,716
FY 1994	1	106	503	81	2,239
FY 1995	1	179	636	100	1,683
FY 1996	0	84	421	127	1,219
FY 1997	1	93	235	100	978

Note: The numbers in this table come from the Monthly Statistics Report (through August 31, 1997) of the Division of Vaccine Injury Compensation at the Department of Health and Human Services. The report is available on the department's web page at <<http://www.hrsa.dhhs.gov/bhpr/vicp/monthly.htm>>.

The majority of pending cases are pre-Act cases, most of them filed close to the deadlines. Table 1 shows that as of August 1997 a total of 5,176 cases had been filed, 4,243 (82%) of which were pre-Act cases.

The special masters have adjudicated cases at a fairly steady rate of approximately 500-650 cases per year. Because this rate has remained relatively constant, following the large influx of pre-Act cases the adjudication time has grown steadily as only a portion of those cases can be adjudicated each year, while the others remain on the docket. Thus, some cases from the 1990-1991 influx were still pending in 1997, when they were nearly seven years old. The number of pending cases has decreased in recent years, as virtually no new pre-Act cases are entering the system.

B. Outcomes

A case filed in the vaccine program can have one of several outcomes: (1) a voluntary dismissal by petitioner; (2) a dismissal by the special master; (3) a decision by the special master to compensate petitioner; or (4) a decision by the special master to deny compensation. If the parties agree to settle the case, the special master must approve the settlement and enter judgment in accordance with it before compensation can be paid. This stems from the statutory requirement that no compensation may be paid until the petitioner has made an election, or is deemed to have made an election, to accept the final judgment.⁶⁰

1. Overall Case Outcome Statistics

Unfortunately, the available databases are missing a good deal of information about case outcomes. The most recent information from the DVIC indicates that of 4,198 cases that had been adjudicated as of August 1997, 1,183 (28%) were compensated and 3,015 (72%) were dismissed or not compensated.⁶¹ Although the current DVIC database does not distinguish among voluntary dismissals, special master dismissals, or decisions denying compensation, two earlier sources suggest that overall about half of the terminated cases are dismissed by the petitioner or a special master, about one-third result in a decision to compensate, and the remaining cases have ended with a decision not to compensate.⁶²

Compensation has been awarded more frequently in post-Act cases than in pre-Act cases. Specifically, out of 579 post-Act cases with judgment entered as of August 1997, 257 (44%) were compensated; out of 3,619 pre-Act cases with judgment entered, 909 (26%) were compensated.⁶³

60. 42 U.S.C.A. § 300aa-15(f)(1) (West 1991 & Supp. 1996).

61. Monthly Statistics Report (through August 31, 1997) of the Division of Vaccine Injury Compensation <<http://www.hrsa.dhhs.gov/bhpr/vicp/monthly.htm>> [hereinafter Monthly Statistics Report].

62. An earlier (December 1993) version of the HHS database, which did distinguish among cases dismissed, compensated, and not compensated, revealed that 33% of cases were compensated, 55% were dismissed, and 13% resulted in a special master decision not to compensate. Similarly, a 1992 evaluation of the program by the Office of the Inspector General at HHS reported that as of August 1991, 40% of terminated cases had been compensated, 45% had been dismissed, and 15% ended with a special master decision not to compensate. Program Review, *supra* note 18, at C-3.

63. Monthly Statistics Report, *supra* note 61.

2. Settlements

Because all settlements must be approved by the special master, compensated cases would include those in which the parties negotiated a settlement. Settlement as to the amount of damages to be awarded can occur at any of three stages: (1) after early concession on the merits by respondent; (2) as a result of compromise between the parties based on “litigative risk” when entitlement is open to some question; or (3) during negotiation following a decision on entitlement by a special master.⁶⁴

The settlement process is fairly complicated, because most awards are paid not as a lump sum but through a structured settlement consisting of a small lump sum and an annuity owned by the government with the injured person as the beneficiary.⁶⁵ To determine an appropriate award amount, the parties hire experts to devise life care plans setting forth projected medical, rehabilitative, and residential needs.⁶⁶ Once the attorneys handling the case have reached agreement on an award amount, the proposed award must be approved by officials at HHS and the Department of Justice.

Despite this rather complicated settlement process, information from the Department of Justice indicates that, in fiscal years 1996 and 1997, the parties negotiated a settlement as to the amount of damages to be paid in approximately 70% of all cases in which compensation was awarded.⁶⁷

C. Awards

As shown in Table 2, compensation awards have varied widely in both pre-Act and post-Act cases. Awards in pre-Act cases have ranged from \$4,000 to \$4,092,999, with a median award of \$490,671. In post-Act cases, the awards have ranged from \$2,000 to \$7,495,419, with a median of \$271,674. The highest award amounts have been in injury cases, as death cases are subject to a \$250,000 cap plus reasonable attorneys’ fees.

64. Letter from John Lodge Euler, deputy director, Torts Branch, Civil Division, Department of Justice, to Molly Treadway Johnson (Dec. 29, 1997) (on file with the Federal Judicial Center, Research Division).

65. Vaccine Litig. Group, U.S. Dep’t of Justice, Steps to Streamlining Damages Under the Vaccine Program 4 (1994).

66. Letter from John Euler, *supra* note 64, at 5.

67. *Id.* at 4.

Table 2. Award amounts (in dollars)⁶⁸

		Pre-Act cases		
		All	Injury	Death
Range	Low	4,000	4,000	45,000
	High	4,092,999	4,092,999	280,000
Median		490,671	765,603	265,960
		Post-Act cases		
		All	Injury	Death
Range	Low	2,000	2,000	46,128
	High	7,495,419	7,495,419	304,116
Median		271,674	384,564	267,648

Note: Figures are based on 886 pre-Act and 240 post-Act cases in which an award has actually been paid as of July 1997, and include amounts for attorneys' fees. These figures do not include cases in which only attorneys' fees were awarded.

D. Appeals

Data from the Special Masters' Office indicate that, as of June 1997, a total of 286 appeals of special master decisions had been made to the U.S. Court of Federal Claims since 1990. Based on the adjudication data in Table 1, this would appear to represent roughly 7% of cases in which a special master decision was issued. More than three-quarters (81%) of the appeals were taken by petitioners, 18% by respondents, and 1% by both. Over the same time period (1990–June 1997), 52 appeals were taken to the Federal Circuit, 39 by petitioners and 13 by the respondent.⁶⁹

E. Rejections of Special Master Decisions

Data from the DVIC as of December 1995 indicated that in the 3,337 cases in which a special master's judgment was entered, twenty-six petitioners

68. Letter from Jerilyn Thornburg, chief, Records Management Branch, Division of Vaccine Injury Compensation, to Molly Treadway Johnson (July 3, 1997) (on file with the Federal Judicial Center, Research Division).

69. Letter from Gary Golkiewicz, chief special master, Office of Special Masters, U.S. Court of Federal Claims, to Molly Treadway Johnson, Attachment A (Oct. 24, 1997) (on file with the Federal Judicial Center, Research Division).

overall had filed elections to reject the special master's judgment.⁷⁰ Similarly, only six petitioners' attorneys we surveyed indicated they had at least one client who rejected a judgment and went on to file a civil lawsuit, and most reported that only one client had done so.

⁷⁰. This database no longer tracks elections to reject, so updated information is not available.

IV. Case-Management Procedures

The empirical portion of our study focused on case-management procedures, particularly those used to manage expert testimony. Our description of case-management procedures is based on interviews with special masters and respondent's attorneys, a written questionnaire to petitioners' attorneys, and observation of a number of hearings with expert testimony.

A. "Front-End Loading"

As a substitute for formal discovery, and to speed up the processing of claims, the Act requires that most of the information necessary to rule on a petition be provided at the time the petition is filed. In addition to setting forth allegations supporting petitioner's entitlement to compensation, the petition must be accompanied by an affidavit and documentation supporting the allegations as well as medical records related to petitioner's case.⁷¹ Petitioners must identify any of these records that are unavailable and the reasons for their unavailability. This production of documents at the outset of a case is known among program participants as "front-end loading."

Similarly, pursuant to Vaccine Rule 4, respondent's first response to petitioners' filings must be in the form of a report and must include a medical analysis of petitioners' claims.⁷²

71. Required medical records include "maternal prenatal and delivery records, newborn hospital records (including all physicians' and nurses' notes and test results), vaccination records associated with the vaccine allegedly causing the injury, pre- and post-injury physician or clinic records (including all relevant growth charts and test results), all post-injury inpatient and outpatient records (including all provider notes, test results, and medication records), if applicable, a death certificate, and if applicable, autopsy results." 42 U.S.C.A. § 300aa-11(c) (West 1991 & Supp. 1996).

72. "Within 90 days after the filing of the petition, respondent shall file a report that shall set forth a full and complete statement of respondent's position as to why an award

We asked petitioners' attorneys how much time, on average, they and/or members of their staff spend gathering and compiling records and other documents to comply with the front-end loading requirement. The responses ranged from 4 to 300 hours, with a mean (average) of 33 hours and median (midpoint) of 24 hours. The majority (56%) of those who responded said they generally consult with experts in preparing their petitions and supporting documents.

According to special masters and respondent's attorneys, petitions often are not accompanied by all of the specified documents at the time of filing. Several respondent's attorneys noted that in some pre-Act cases the deadlines required petitioners to file before they had the opportunity to complete searches for medical records. Other respondent's attorneys and special masters indicated that the rate of compliance with this requirement could be linked to the amount of experience an individual attorney had with the vaccine program. One respondent's attorney stated that in his experience, petitioners' attorneys do not always realize the extent of the documentation required. The most common way respondent's attorneys handle petitions they believe to be incomplete is to ask for the additional information and request an extension of time to file their initial reports with the special master until the information is provided.⁷³

The special masters and respondent's attorneys agreed that the front-end loading process is helpful, particularly when all relevant documents are included. One respondent's attorney described the process as being "unlike traditional tort litigation where a skeleton complaint and a skeleton answer might be filed"—front-end loading allows the parties and the special masters to "get to the meat of the issues" as soon as possible. Similarly, a special master referred to front-end loading as "the opposite of notice pleading." One special master described the process as very successful in that it allowed him⁷⁴ to identify all the issues in the case before meeting with the parties. Another noted that the process puts him well on the way towards recognizing what further information is needed in any particular case.

should or should not be granted. The report shall contain respondent's medical analysis of petitioner's claims. It shall also present any legal arguments that respondent may have in opposition to the petition. General denials are not sufficient." Rules of the U.S. Court of Federal Claims, Appendix J, Vaccine Rule 4(b).

73. To lessen the adversarial nature of this process, the Special Masters' Office has recently issued a permanent order modifying Vaccine Rule 4(a) to provide for a conference call with the parties forty-five days after a petition is filed to discuss information needed to complete the petition without a formal request from the respondent.

74. To preserve anonymity, all special masters we interviewed are referred to with masculine pronouns.

When we asked petitioners' attorneys whether they think front-end loading is an efficient procedure, fifty-four of the sixty-six (82%) who responded said yes. Those who said no (twelve attorneys, 19%) indicated that it is sometimes time-consuming and difficult to locate medical records, particularly in older cases, and that sometimes records must be gathered that turn out not to be relevant to petitioners' claims. In written comments, four petitioners' attorneys said they thought the respondent asks for irrelevant or excessive amounts of information during the front-end loading process.

We asked respondent's counsel to describe how they prepare their initial Rule 4 reports and whether they work with experts to prepare this report. All of the respondent's counsel we interviewed indicated that in addition to their own review of the case file and the medical records, they rely on the medical analysis done by the doctors employed by their client, the Department of Health and Human Services. These doctors review the petitioner's medical submissions and provide a medical analysis of petitioner's claims.

B. Expert Reports

Virtually all cases in the VICP that survive early dismissal require expert reports from both sides. Vaccine Rule 2(e) provides that if a petitioner's claim "does not rely on medical records alone, but is based in part on the observations or testimony of any persons, the substance of each person's proposed testimony in the form of an affidavit executed by the affiant must accompany the petition. . . ." The Vaccine Guidelines clarify that vaccine cases require affidavits because most petitioners rely on the diagnosis of an expert medical witness as part of their proof; therefore, any such petition is to be accompanied by an affidavit setting forth the expert's opinion and reasoning. This affidavit of a petitioner's medical experts, whether it be from a treating physician or an independently hired medical expert, constitutes petitioner's initial expert report. Vaccine Rule 4(b) similarly requires that respondent's initial report contain respondent's medical analysis of petitioner's claims.

We asked the special masters several questions about petitioners' and respondent's initial expert reports to learn more about when the reports are received, how they are used by the special masters, how often they need to be supplemented, and what they are supplemented with.

1. Petitioners' Expert Reports

When asked at what point in the proceedings the special masters receive petitioners' initial expert reports, most indicated that while they were supposed to receive the reports with the initial petitions, the reports frequently are not provided at that time. Two special masters said they do not need a petitioner's expert report if the records alone prove petitioner's case. This is consistent with the Act.⁷⁵

The special masters' views of the importance of petitioners' expert reports varied. When asked how they use these reports, the majority of the special masters indicated that the reports provide the initial explanation of petitioner's case, with one special master referring to these reports as "perhaps the most important document for petitioner." Two special masters indicated they look for the "magic words" regarding whether the expert's opinion on causation is held to "a reasonable degree of medical certainty." Three special masters placed less emphasis on these reports, saying that they were generally helpful, but that some were conclusory and therefore less helpful. When asked in what proportion of cases the reports must be supplemented with additional information, the special masters' answers ranged from 10% to 70%, with the majority of the special masters indicating that about 20% to 40% of petitioners' initial expert reports required supplemental filings.

The special masters said that when these reports have to be supplemented, they are supplemented by additional medical expert reports that provide more detail. Such detail may include more information about specific symptoms, detailed medical literature supporting petitioner's allegations, or answers to specific questions, such as whether there is a possible alternative cause for a petitioner's injuries. In some cases the special masters require opinions from an entirely new expert, either because the reports have been written by a repeat expert whom the special master does not find credible or because the special master wants an opinion from a medical expert with a particular specialty, such as pediatric neurology.

2. Respondent's Expert Reports

We asked the special masters several questions related to respondent's initial expert report. First, we asked at what point in the proceedings they receive respondent's initial expert report. Most special masters indicated that while respondent's initial expert report is supposed to be filed

75. 42 U.S.C.A. § 300aa-13(a)(1) provides that a petitioner can prove his or her case with medical records *or* expert testimony.

with the Rule 4 report, it frequently is not. There was general agreement that when the expert reports were not filed with the Rule 4 report this was primarily because the petitioner failed to make a *prima facie* case at the outset. One special master indicated that he only receives the report after asking for it. The special masters' answers were fairly consistent regarding the usefulness of respondent's experts' reports, indicating that they were helpful, usually had more detail than petitioners' experts' reports, and helped to narrow the issues. One indicated that he believed respondent's expert reports were less trustworthy than petitioners'. The special masters generally agreed that they rarely had to supplement respondent's reports, and that if they did, they supplemented with additional reports from experts or with medical articles and studies.

C. Initial (Rule 5) Status Conferences

Vaccine Rule 5 requires that the special master schedule an initial status conference to be held within thirty days of the filing of the respondent's Rule 4 report. The rule provides that this be an off-the-record conference at which the special master reviews petitioner's and respondent's cases, evaluates the respective positions, and presents tentative findings and conclusions. This conference's timing corresponds to a pretrial conference in traditional civil litigation and is structured to expedite case resolution.

We asked the special masters we interviewed several questions about the process and use of the Rule 5 status conference. We asked first how much time the special masters generally spend familiarizing themselves with the record prior to this status conference. Responses indicate that the special masters spend, on average, anywhere from thirty minutes to five hours preparing for the Rule 5 status conference, with the majority typically spending from two to three hours. Four special masters explained that they have their law clerks do an initial and thorough review of the case file, including the medical records, and provide them with a summary of the case file.

The responses to our questions about how the Rule 5 conference is used indicate that all special masters use this status conference to advise the parties of the special master's perspective on the case, to identify what the issues are, where the gaps in the record are, and to devise a plan for resolution of outstanding issues and the case itself. In most instances, parties are told what information they must provide to complete the record. If the record is substantially complete at the time of the Rule 5 conference, the special master might set a date for the first hearing in the

case. More commonly, a second status conference is scheduled to encourage quick compliance with requests for more information. On occasion a case will be dismissed or settled at or immediately after the Rule 5 conference.

Several petitioners' attorneys noted in comments that they found this informal status conference helpful with respect to getting a feel for the special master's view of the case, and said they used this information to help prepare their witnesses for later hearings in which they might be examined directly by the special master.

D. Hearings with Expert Testimony

One of the main reasons for studying the VICP is the central role played by scientific and medical experts. Thus, the case-management procedure we studied most in-depth was the use of hearings with expert testimony. Most special masters we interviewed said they hold hearings in a high percentage of their cases, with estimates ranging from 30% to 80%. The most frequently addressed issues in hearings are the compensability of petitioners' claims, such as the time of onset of symptoms; the strength of medical evidence supporting petitioners' claims; or whether there is an alternative possible cause for petitioners' injuries. These issues normally require expert testimony.

One special master indicated that, in addition to bifurcating entitlement and damages issues (which most special masters do routinely), some special masters further bifurcate the entitlement phase of a case and hear fact witnesses prior to medical testimony on causation. Thus, a number of hearings involve expert testimony exclusively. In this section we present findings on hearings with expert testimony in the VICP from special master interviews, respondent's attorney interviews, petitioners' attorney questionnaires, and our observations of hearings with expert testimony.

1. Number of Experts

The hearings we observed generally included a testifying expert for each side. This is consistent with interview responses from special masters and respondent's attorneys, who indicated that each side generally presents one or (occasionally) two experts on entitlement and the same number on damages. The lowest number of testifying experts we observed was one (generally because there had been a previous hearing with another expert testifying), and the highest number we observed was five.

2. Selection of Testifying Experts

We asked both petitioners' and respondent's attorneys how they find and select scientific or medical experts to testify in the event a case proceeds to an entitlement hearing.

Almost three-quarters (73%) of petitioners' attorneys indicated that they use the petitioner's treating physician as an expert in entitlement hearings. Half (50%) retain experts who have testified previously for them in a vaccine program case, and over a quarter (27%) rely on referrals from other attorneys who have litigated in the vaccine program.⁷⁶

Of the eight respondent's attorneys we interviewed, four said they normally find their testifying expert witnesses through referrals from their client agency, the Division of Vaccine Injury Compensation at HHS, or use the doctor from that agency who helps them prepare their initial expert report. Two said they never use DVIC experts at hearings, with one noting concern about the credibility of these experts with the special masters. Finally, two respondent's attorneys said they use both DVIC experts and outside experts fairly frequently. Those who use outside experts said they find experts by using the same methods one would in civil litigation—for example, by talking to other witnesses or calling hospitals for referrals.

3. Types of Testifying Experts

In our observations of expert hearings we noted the types of experts who testified. We also asked special masters and respondent's attorneys (in interviews) and petitioners' attorneys (in the questionnaire) what types of experts they found most useful for entitlement and damages hearings.

At entitlement hearings we observed, the most frequent testifying experts were pediatric neurologists. This is consistent with the preferences of special masters and respondent's and petitioners' attorneys, each of whom most frequently cited pediatric neurologists as the most used and/or most useful type of testifying expert for entitlement hearings. Other areas of expertise relating to pediatrics were also well represented at hearings, including general pediatrics, pediatric pathology, and pediatric immunology. Treating physicians (i.e., those who had treated the patient who received the vaccine) also testified at several hearings. In hearings on damages issues, the most frequent experts were life-care planners and rehabilitation consultants, who testified about the likely

⁷⁶. Because most petitioners' attorneys use more than one approach for selecting experts, these percentages do not total 100%.

future care needs of petitioners and the projected costs of filling those needs.

4. Court-Appointed Experts

Congress anticipated that the special masters would retain independent medical experts to help them resolve causation and compensation issues. The House Conference Report accompanying the 1989 amendments to the Act indicated the following:

[T]he masters may, in some cases, be well-advised to retain independent medical experts to assist in the evaluation of medical issues associated with eligibility for compensation and the amounts of compensation to be awarded. In cases where petitioners assert a theory of vaccine causation of injury and respondents claim other causation, the master may find it most expeditious to receive outside advice rather than attempt a full adversarial proceeding on the question of causation. The Act authorizes such action by the master and the Conferees would encourage its use as appropriate.⁷⁷

The Act provides that a special master may “require the testimony of any person . . . as may be reasonable and necessary” to determine if the petitioner is entitled to compensation.⁷⁸ The Vaccine Rules do not address the appointment of experts by the special master, but the practice guidelines issued by the Special Masters’ Office note that “[i]n unusual instances, special masters may hire and utilize their own expert witnesses to resolve difficult medical issues, or suggest the hiring of a neutral medical expert”⁷⁹

In our interviews we asked special masters about the frequency with which they had directed parties to present specified expert testimony or had appointed their own experts. Most special masters indicated they had directed parties to present expert testimony on particular issues, but that they had done this only rarely. Two of them emphasized that, while they could direct that expert testimony be presented on an issue, they could not direct the parties to present a particular type of expert. One special master also had on occasion directed parties *not* to present expert testimony on a specific issue.

When asked about whether they had ever appointed their own experts, all the special masters we interviewed said that while they had

77. H.R. Conf. Rep. No. 101-386, *supra* note 47, at 516, *reprinted in* 1989 U.S.C.C.A.N. at 3119.

78. 42 U.S.C.A. § 300aa-12(d)(3)(B)(iii) (West 1991 & Supp. 1996).

79. Guidelines for Practice, *supra* note 52, at 9.

considered doing this and were not opposed to the idea, they had never actually appointed an expert. Two special masters said they had identified a need and proposed hiring an independent expert in a specific case, but encountered opposition from the parties.

Several explanations were offered for the lack of use of court-appointed experts. Six of the eleven special masters we interviewed said that the funding mechanism for such appointments was unclear. Others explained that they thought the presentation of expert testimony was the parties' responsibility and that the parties did an adequate job. One special master said there was a "policy" in the Special Masters' Office against appointing experts. In response to a separate question, two special masters cited the lack of clarity about the authority of special masters to appoint experts and about the mechanism by which such an appointment could be made as a weakness of the program.

Another plausible explanation, although it was mentioned by only one special master, is that the special masters have sufficient expertise in the scientific and medical issues at stake that they are better able to resolve conflicting medical evidence than a generalist judge might be. Interestingly, however, even generalist federal judges make infrequent use of court-appointed experts,⁸⁰ although Rule 706 of the Federal Rules of Evidence authorizes them to appoint experts.

Finally, special masters have a good deal of latitude in consulting outside sources, such as medical textbooks, to assist them in their decision making. Most special masters we interviewed report that they read medical textbooks and other medical literature to learn more about specific medical topics relating to vaccine cases. All indicated that they sometimes consult information not presented by the parties to resolve questionable or conflicting scientific or medical testimony, and two special masters pointed out that this practice has been upheld by the U.S. Court of Federal Claims on appeal.⁸¹ It may be, then, that this ability to consult outside references lessens the need for court-appointed experts in the VICP.

80. Joe S. Cecil & Thomas E. Willging, *Court-Appointed Experts: Defining the Role of Experts Appointed Under Federal Rule of Evidence 706*, at 18-23 (Federal Judicial Center 1993). According to this study, several of the judges' reasons for such infrequent appointments are similar to those provided by the special masters: infrequency of cases requiring extraordinary assistance; respect for the adversarial system; difficulty in identifying an expert suitable for appointment; securing compensation for an expert; lack of early recognition that appointment is needed; and lack of awareness of the procedure.

81. *Hines v. Secretary of Health & Human Servs.*, 21 Cl. Ct. 634 (1990).

5. Location of Hearings

All of the expert hearings we observed occurred in the Washington, D.C., area, either in the U.S. Court of Federal Claims building or at the Special Masters' Office. For each expert hearing we observed, a court reporter was present at the special master's location to record the proceedings.

We asked the special masters how frequently they travel to hold hearings outside of the Washington, D.C., area. Responses to this question varied widely, with about half of the special masters indicating they travel for the majority of their entitlement hearings, while one special master said that he does not travel, and that all of his hearings are held in Washington, D.C. Those who do travel generally cited two circumstances under which they travel: (1) if the hearing hinges on a fact issue and they have to assess the credibility of witnesses; and (2) if the petitioners and their witnesses cannot afford to travel to Washington.

6. Telephonic Hearings

Many hearings in the VICP, including most of the hearings we observed, occur with at least some parties or witnesses participating by telephone. We asked special masters what proportion of their hearings are held over the telephone. Responses varied somewhat, but most indicated that, while they normally hear fact witnesses in person, they frequently hear expert testimony over the telephone. They also said that damages hearings are more frequently held by telephone than are entitlement hearings. Two special masters expressed frustration with telephone hearings, noting that it is harder to concentrate and there are frequent technical difficulties.⁸²

In most of the hearings we observed in which parties or witnesses participated by telephone, there were some technical and logistical problems relating to the telephone connection. Most frequently, other participants (including the court reporter) had difficulty hearing certain witnesses who were testifying by phone. Sometimes responses were cut off at the end and had to be repeated. Occasionally participants could not be located at the telephone number where they were supposed to be, and at other times participants were unexpectedly disconnected from the phone line.

82. The Special Masters' Office reports that it has begun using videoconferencing for many of these hearings, providing "a useful compromise between the need to view witnesses and the practical problems of scheduling busy doctors and expensive travel." Letter from Gary Golkiewicz, *supra* note 69, at 2.

7. Conduct of Hearings with Expert Testimony

Although the procedures used in the hearings we observed varied in a number of respects, certain generalizations can be made about how they were conducted. Where applicable, we supplement the descriptions from our hearing observations with relevant questionnaire or interview responses from special masters and attorneys.

a. Forms of Address to Special Master

Attorneys most frequently referred to the special master presiding over a hearing as “Special Master” or “Your Honor.” Other forms of address used were “Sir” or “Ma’am,” and occasionally “Judge.”

b. Opening Statements

At the beginning of most hearings, after some introductory remarks by the special master, the attorneys were given the opportunity to present opening statements. They often waived this opportunity, although a few hearings did have opening statements from one or both attorneys, and one hearing had lengthy opening statements from both. In two hearings the special master did not ask the attorneys if they wanted to give opening statements.

c. Steps Taken to Expedite the Proceedings

Several approaches were taken to speed up the conduct of the hearings. For example, in about one-third of the hearings we observed, attorneys stipulated to the qualifications of testifying experts. In several hearings we observed, the special master noted that any exhibits previously submitted would automatically become part of the hearing record and did not have to be formally entered into evidence at the hearing. Other approaches, such as limiting the time for questioning or asking attorneys to speed up their examinations of witnesses, were used in only one or two hearings.

d. Examination of Witnesses

Both fact and expert witnesses generally were sworn in before testifying. Examination of experts generally followed a fairly standard course, with direct examination by the attorney presenting the witness, cross-examination by the opposing attorney, and occasionally re-direct and re-cross. After the attorneys had finished asking their questions of a witness, the special master would normally further examine the witness about issues of particular interest. In one hearing, the special master asked all of the questions of the expert witness. In another, the special master ordered that the direct examination of both petitioner’s and re-

spondent's experts occur before cross-examination of either one. In all of the hearings we observed, attorneys for both sides, as well as the special master, frequently asked leading questions of their own and other witnesses. Few objections were raised, and when there was an objection, the special master would often either rephrase the question to make it unobjectionable, or allow the question with the assurance that he would give the resulting testimony only as much weight as it deserved.

The routine questioning of experts we observed was consistent with responses from our special master and respondent's attorney interviews and the petitioner's attorney questionnaire, all of which indicated that special masters directly examine experts in virtually every hearing with expert testimony. In describing the circumstances under which they do this, several special masters indicated that a lot depends on the quality of the attorneys and whether they are able to elicit the critical information. One special master explained that it was his responsibility to "have a record I can understand," and that the only way to do this was to ask questions directly of the witness.

We asked attorneys (both petitioners' and respondent's) whether they thought direct questioning of experts by the special master is an efficient procedure. The majority (six of eight respondent's attorneys and forty-three of fifty-four petitioners' attorneys who answered the question) thought this was efficient, particularly when the special master waits until direct and cross-examination are completed and merely asks questions to clarify particular points. Those who did not favor the procedure generally pointed out that it should be left up to the lawyers to elicit testimony and that they are in the best position to do so.

Several attorneys also expressed concern that by asking questions the special masters risked becoming advocates. As one petitioner's attorney who opposes the procedure said, "Let [the special master] act as judge, not advocate." Two respondent's attorneys and one petitioner's attorney said they thought some special masters use their examination to assist the other side's case. One of these respondent's attorneys expressed concern that by asking questions a special master could, for example, "create a case or medical theory" that petitioner had not thought of on his or her own.

About half of the attorneys said they prepare their experts specifically for the special master's examination, usually by thoroughly reviewing the medical records with them, informing them that they can expect questions from the special master, and letting them know of previous comments or rulings by that special master that suggest the issues he is most interested in. Other attorneys do not do anything special to prepare their

experts for the special master's examination beyond their routine hearing preparation, which includes preparing the expert for cross-examination by the opposing attorney.

e. Outcome of Hearings

We were able to observe in their entirety fourteen of the sixteen hearings we attended.⁸³ At four of these hearings, the special master ruled from the bench—twice in favor of petitioner, twice in favor of respondent. In five hearings, the special master indicated that he would deliberate further and issue a written opinion. Two hearings were continued, and in three hearings a further case event, such as a status conference or the filing of written closing arguments, was scheduled. At the end of two hearings (one on entitlement, one on damages) the special master strongly encouraged the attorneys to reach agreement on damages and attorney fee issues without need for a further hearing.

We asked special masters about the frequency with which they rule from the bench at hearings. The majority indicated they do this at least sometimes, particularly if the case hinges on the resolution of a factual issue, though most rule from the bench only rarely. Advantages cited for ruling from the bench include saving time (for the special master and parties) and reaching a decision at the time when the relevant evidence is freshest in the mind of the special master.

f. Consistency of Conduct of Hearings

We asked both respondent's and petitioners' attorneys whether the procedures used in hearings held by the different special masters were fairly consistent. The majority of each group thought the procedures were generally consistent, especially with respect to relaxed evidentiary rules, but they did note several differences in approach. These differences include:

- some special masters bifurcate fact witness hearings from expert testimony hearings, while others hear both types of testimony in one hearing;
- special masters hold the hearings with different levels of formality (one respondent's attorney called the damages hearings held by one special master "almost like a roundtable discussion" rather than a hearing);
- some special masters do not travel for hearings, while most do; and
- some special masters appear to "take sides" during a hearing.

83. The two hearings we did not observe in their entirety were lengthy sessions that extended into the evening hours.

This last difference was noted by seven of the forty petitioners' attorneys who answered the question, but none of the respondent's attorneys.

As revealed by the following comments, two petitioners' attorneys said that the differences between special masters' conduct during the hearings can affect the outcome of the case:

"Unfortunately, the biggest factor in winning or losing a case in this program is which special master is assigned your case."

"Some special masters are control freaks, and will not allow counsel to develop their own theories and arguments. Some are so pro-government that they try the case for the DOJ, and act as another 'expert' for the Secretary. Some are scrupulously fair. Outcome often depends on assignment."

These comments are consistent with earlier-reported comments in which both respondent's and petitioners' attorneys said they thought some special masters assisted the other side through their examination of witnesses. Such comments are relatively subjective, and we were not able to substantiate or refute these allegations through our observation of hearings.

8. Use of Repeat Experts

About half of the experts whose testimony we observed had testified previously in a vaccine program case.⁸⁴ This is again consistent with questionnaire and interview results: Special masters indicated that the majority of expert witnesses they now hear have testified previously in the vaccine program. Respondent's attorneys also generally reported that a majority of witnesses they present are witnesses who have testified previously in a VICP case. Similarly, when asked to estimate the percentage of experts they present that have previously testified in at least one vaccine case, the median (midpoint) response from petitioners' attorneys was 80%.

We asked special masters and attorneys about the advantages and disadvantages of having the same experts testify routinely in vaccine cases. As far as advantages, the repeat experts' familiarity and knowledge—of the medical issues, the applicable law, and the procedures used in the program—were cited most frequently. Several attorneys also emphasized that having repeat experts saved time and costs because the attorneys did not have to spend as much time preparing the experts to testify. Four petitioners' attorneys mentioned that some repeat experts have estab-

84. This number would be considerably higher were it not for the fact that the petitioner's treating physician testified as an expert in a number of hearings.

lished credibility with the special masters. This is confirmed by the response of one of the special masters, who indicated that it's "good to have an expert you know if you have some confidence in him." Finally, two petitioners' attorneys indicated that they use experts who have previously testified to help them "screen" cases and determine whether a petition should be filed in the program.

With respect to disadvantages, attorneys most often noted concerns about the experts' credibility with the special masters, fearing that the special masters perceive repeat experts as advocates or "hired guns." Some attorneys expressed their own concerns about repeat experts becoming biased. A number of petitioners' attorneys also said they believe special masters do not listen as well to repeat experts because they think they know what the expert will say. Eight petitioners' attorneys said they saw no disadvantages of using experts who had previously testified in the program.

The special masters tended to agree with the disadvantages cited by attorneys, such as credibility problems with repeat experts. As one special master said, those experts who repeatedly testify for respondent lose credibility because they are "not willing to find an encephalopathy if it hits them in the face." Another special master acknowledged that if "you know what an expert is going to say, you pay less attention to them."

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V. Participants' Views of the Vaccine Injury Compensation Program

We asked special masters, respondent's attorneys, and petitioners' attorneys several questions about their overall views of the VICP, including the advantages and disadvantages of participants' familiarity with the specific scientific and medical issues involved; what they consider to be the strengths and weaknesses of the program; how they thought the program could be improved; and whether they thought the VICP, or aspects of it, would be useful for other categories of cases. We also asked petitioners' attorneys about their clients' satisfaction with the program and about how the attorneys thought the time and cost of case resolution in the VICP compared to more traditional civil litigation.

A. Familiarity of Program Participants with Scientific and Medical Issues

In contrast to traditional civil litigation, where the specific scientific or technical issues being disputed in a case are often foreign to the attorneys and judges, the special masters and attorneys involved in the VICP develop extensive familiarity with the scientific and medical issues that recur in these cases. We asked participants several questions about this familiarity and how it affects the way they handle cases. We also asked attorneys their views of having cases heard by specialized decision makers who hear vaccine cases exclusively.

The special masters generally said that increased familiarity with the scientific and medical issues was very helpful, particularly with respect to helping them focus in on the critical issues in a case. For example, one special master said that "by now I'm more familiar with developmental milestones, so I can ask more about what was happening with the child [around the time of the vaccination]." Three special masters noted the

benefit of being able to assess how expert testimony in a current case squares with what they have heard in other cases. As one said, “in the real world, judges can’t take judicial notice of very much, but we’re supposed to be inquisitorial. I have no qualms in referring to testimony from other cases.” Similarly, a former special master noted that “I was in a better position to challenge or question an expert, because I had a base of experts I’d heard previously.”

Most of the respondent’s attorneys we interviewed said that their familiarity with the scientific and medical issues, developed through handling numerous vaccine cases, helps them greatly and reduces the amount of time it takes them to prepare, particularly when dealing with expert witnesses.

Attorneys cited both advantages and disadvantages to the fact that the vaccine cases are heard by specialized adjudicators who hear only these cases. The primary advantage cited was the special masters’ familiarity with both the legal and scientific issues, with several attorneys pointing out that this increases efficiency because the special masters are able to focus on the most pertinent issues at an early stage of a case. As one petitioner’s attorney said, the special masters’ increased knowledge enables them to “cut to the chase” and render a decision expeditiously. Another petitioner’s attorney cited the specialized knowledge required to handle these cases and stated that “No trial judge would understand the issues.”

The disadvantage of specialized adjudicators most frequently cited by petitioners’ attorneys (eighteen) was development of bias, particularly in favor of the government’s position. For example, one petitioner’s attorney noted the “development of defined bias in all Special Masters over time (such as which witnesses they believe, weight given medical records, etc.).” A second disadvantage noted by six petitioners’ attorneys and four respondent’s attorneys was that, as a result of the specialized nature of the proceedings, special masters begin to think they know more than they actually do, to the extent that they do not give appropriate deference to expert testimony. Illustrative comments on this issue include the following:

“Some (one in particular) seem to believe they are experts and know better than the real experts. Some have gone so far as to denigrate an expert witness.”

“The Special Masters have heard so much medical testimony that they sometimes start thinking they know more than the physicians who are testifying do.”

“After 5 years of hearings the special masters think they know more medicine than the M.D.’s—and will not listen.”

“A specialist adjudicator may substitute perceived knowledge for evidence.”

Another disadvantage, cited by six petitioners’ attorneys and two respondent’s attorneys, is that the special masters, as one attorney put it, “become jaded to the severity of the injuries the petitioners are testifying about,” because they hear similar cases so frequently. Another attorney wrote that “petitioners lose the ‘sympathy factor’ since most of the cases involve severe injuries, and the special masters are accustomed to such injuries.” One petitioner’s attorney referred to the use of specialized judge adjudicators as “an abrogation of the fundamental right to trial by jury . . . irrespective of the right of claimants to pursue a jury trial at their election.”

Although they cited a number of disadvantages, when we asked petitioners’ attorneys whether overall the advantages of specialized adjudicators outweighed the disadvantages, forty-two said yes and fourteen said no.

B. Program Strengths and Weaknesses

We asked respondent’s attorneys and special masters about the strengths and weaknesses of the VICP. The primary strengths they cited are the informality of the proceedings and the relative lack of legal “wrangling,” which they attributed to the liberal discovery and evidence rules. They also noted that the program provides a quicker, more streamlined way for those injured by vaccines to be compensated for their injuries. Other strengths cited by one or more participants included the following: allowing petitioners to get a “day in court”; use of adjudicators with specialized expertise; the fact that the program pays attorneys’ fees and costs; the use of the Vaccine Injury Table; and the fact that the existence of the program encourages vaccine manufacturers to continue producing vaccines.

No weakness was named by more than four special masters or respondent’s attorneys. Four special masters indicated that the program takes too long in many cases and two special masters said they considered the lack of a mechanism for court-appointed experts to be a weakness. Two respondent’s attorneys said they think the program is *too* relaxed with respect to evidence rules. Other weaknesses named by one or more participants were: difficulty in preparing for hearings because of limited dis-

covery (one respondent's attorney); not enough control by the program of how funds are expended after judgment (one respondent's attorney); the reliance on telephonic hearings (one respondent's attorney); special masters who are too sympathetic toward petitioners (two respondent's attorneys); variation in special master decisions (one respondent's attorney); not enough special masters to handle cases (one respondent's attorney, one special master); obstructionist attitude of respondent's attorneys (one special master); the lack of a defined government role (one special master); inconsistency in rulings arising from the fact that only a single judge, rather than a panel, hears cases at the Claims Court level (one special master); and inexperienced attorneys in some cases (one special master).

When asked for suggestions about how the VICP could be improved, the most frequent suggestion was to make the program less adversarial and litigious. Several special masters expressed the view that the respondent is "over-litigating" and "behaving like an adversary," contrary to the intent of the program. Other suggestions for improvement include: providing for some limited discovery; greater consistency in special master decisions; greater ability to amend the Vaccine Injury Table to reflect changes in scientific and medical knowledge; hiring special masters with more litigation experience; holding more live hearings; applying some evidentiary rules; and hiring more special masters and support staff for them.

Petitioners' attorneys also cited a number of strengths and weaknesses of the VICP in response to an open-ended question asking for general comments about the program. Of the thirty-nine attorneys who provided narrative comments, ten provided general positive comments about the program (e.g., "So far, so good!" "All-in-all, I think the Vaccine Program fairly answered a very real need" "The system works remarkably well considering the limited staffing and heavy work load") or about the special masters (e.g., "In my opinion the special masters are competent, fair, and qualified" "The special masters have shown genuine concern with helping us (who are less experienced with these specialized procedures)" "Special Masters have been extremely fair, willing to devote time necessary to understand case and obtain all available evidence, helpful, courteous, and write well-reasoned opinions").

The most frequent type of negative comment, provided by twelve petitioners' attorneys, had to do with the way attorneys' fees are handled in the program. The comments in this area tended to fall into three categories: (1) attorneys' fees are too low; (2) attorneys' fees take too long to process; and (3) a procedure under which government attorneys are per-

mitted to review and comment on petitioners' attorneys' fee petitions is unfair. Five attorneys suggested in comments that they or other attorneys have decided not to take additional cases in the program because of the problems with attorneys' fees. Example comments include:

"Because of the restrictions on attorney fees there are few experienced attorneys willing to handle these unusual cases."

"The low fees awarded to attorneys discourage claims under the Act."

"Special masters routinely cut attorney fee requests by 50%, even though the statute allows for larger fees. This may chill the program."

"My fees and costs were handled in such a way that my firm had to 'carry' me for years and we lost a great deal of money by virtue of my participation in the Program."

This focus on attorney fee issues was somewhat surprising, because our questionnaire to petitioners' attorneys stated that we were asking about entitlement and damages portions of vaccine cases and not attorneys' fees. Although we have only comments and not systematic data on the issue, it would appear from these comments that petitioners' attorneys are gravely concerned about the program's handling of attorneys' fees, to the extent that some of them will no longer handle cases in the program.

Seven petitioners' attorneys wrote negative comments about the length of time it takes for cases to be processed in the VICP (e.g., "Delays are a very real problem, and delays get compounded by the program process" "The pace is unbelievably slow" "The process is too slow" "The delay in resolving cases is doing a great deal of damage to the program"). Another problem cited by seven petitioners' attorneys, which was also noted by some of the special masters in interviews, was the litigiousness of respondent's attorneys. Comments include:

"I feel the respondent has never embraced the spirit of the Vaccine Program or tried to properly implement it in the manner Congress intended. Every vaccine attorney has [his or her] own horror story about how the respondent has perverted the system. The respondent has done everything he can to circumvent and narrow the scope of the Program."

"The intent of the program has been lost because the government lawyers want to defeat every claim at all costs and for any reason . . . There is now no difference in the level of litigation than if the case were in state or federal court."

In contrast, one petitioner's attorney wrote:

"The respondents have made a good effort (in most instances) to minimize the adversarial atmosphere of the proceedings."

Other problems cited by two or more petitioners' attorneys were: (1) the special masters place too much reliance on contemporaneous medical records as compared to witness testimony; (2) proposed changes to the vaccine injury table are unfair to petitioners;⁸⁵ (3) the program effectively deprives petitioners of their jury trial rights; and (4) various problems with one or more of the special masters.

C. Differences Between the VICP and Traditional Civil Litigation

We asked respondent's attorneys and special masters what they saw as the primary differences between the handling of cases in the VICP and in traditional civil litigation. We also asked petitioners' attorneys to compare the litigation of cases in the VICP with traditional civil litigation with respect to cost and time to disposition.⁸⁶

The differences most frequently cited by respondent's attorneys and special masters were: use of a specialized fact finder and decision maker; the informality of the proceedings in the VICP, especially the use of lower evidentiary standards and the virtual absence of formal discovery; and expedited resolution of cases in the VICP.

When asked to compare the costs of having a case resolved in the program with the costs of litigating vaccine injury cases in state or federal court, more than two-thirds (69%) of the petitioners' attorneys who answered the question said the costs of litigating in state or federal court would be "much higher" or "higher" than in the VICP (see Table 3 below), with almost half (48%) saying they would be "much higher." Twenty-one percent said the costs in court would be "higher," 18% said the costs would be "about the same," and 13% said the costs in court would be "lower" or "much lower."

85. Some of these changes were promulgated, after a comment period, in February 1997. *See supra* note 3.

86. Only 7% of the petitioners' attorneys responding to our survey named vaccine cases as their primary area of practice. The most common practice areas were personal injury (41%) or general civil litigation (24%). Thus, these attorneys generally had a basis for comparing the handling of cases in the vaccine program to other types of civil litigation.

Interestingly, a different pattern emerged when petitioners' attorneys were asked to compare the time from filing to disposition in the VICP relative to traditional litigation (see Table 3). Almost a third (31%) of attorneys who answered this question said the time to disposition would be "about the same" in traditional litigation, while more than a third (38%) said the time to disposition in court would be "shorter" or "much shorter." Only about one-quarter (27%) of petitioners' attorneys said the time to disposition in traditional litigation would be "longer" or "much longer" than in the VICP. Thus, while petitioners' attorneys generally thought that proceeding in the VICP was less expensive than traditional litigation, they also generally thought that—contrary to the intent of the statute—the program took the same amount of time or longer to dispose of a case. This is in contrast to the views of several special masters and respondent's attorneys, who cited expedited proceedings as one way in which VICP cases differ from cases in state or federal court.

Table 3. Petitioners' attorneys' views on the cost and time of vaccine cases compared to litigation in state or federal court*

Q30a. Compared to litigating cases in the vaccine program, the total costs of litigating vaccine injury cases in a state or federal court would be:	Much higher	Higher	About the same	Lower	Much lower	I can't say
	48%	21%	18%	9%	4%	0%
Q30b. Compared to cases litigated in the vaccine program, the time from filing to disposition of vaccine injury cases litigated in a state or federal court would be:	Much longer	Longer	About the same	Shorter	Much shorter	I can't say
	12%	15%	31%	13%	25%	3%

*Note: Table cell entries reflect the percentage of respondents selecting each response. The total number of attorneys responding to these questions was sixty-seven.

D. Petitioner Satisfaction with Program

In our questionnaire we asked petitioners' attorneys several questions about their and their clients' satisfaction with the VICP, including how

fair they thought the procedures used in the program are for their clients; how satisfied they have been with the outcome of cases in the vaccine program; and whether their clients who have been involved in cases in the vaccine program feel they have had the opportunity to have their “day in court.”

Responses to the questions about fairness of procedures and satisfaction with outcomes are presented in Table 4.

Table 4. Petitioners’ attorneys’ views on the fairness of procedures in the VICP and satisfaction with case outcomes*

Q25. Overall, how fair do you think the procedures used in the vaccine program have been for your client or clients?	Very fair	Some-what fair	Neither fair nor unfair	Some-what unfair	Very unfair
	28%	28%	7%	22%	13%
Q27. Overall, how satisfied have you been with the outcomes of your cases in the vaccine program?	Very satisfied	Some-what satisfied	Neither satisfied nor dissatisfied	Some-what dissatisfied	Very dissatisfied
	16%	34%	19%	20%	11%

*Note: Numbers in each cell reflect the percentage of respondents choosing that response. Sixty-seven attorneys responded to Question 25, and sixty-four attorneys responded to Question 27.

As the table shows, the majority of petitioners’ attorneys (56%) think the procedures used in the program are somewhat or very fair for their clients, although a substantial minority (35%) think the procedures are unfair. Similarly, half of petitioners’ attorneys report being somewhat or very satisfied with case outcomes in the program, while just under a third (31%) are somewhat or very dissatisfied. When asked whether their clients felt they had an opportunity to have their “day in court” in the program, 70% of the attorneys who responded said yes, and the remaining 31% said no.

Taken together, these results suggest that a majority of petitioners’ attorneys who responded to our questionnaire believed their clients received fair treatment in the VICP, while a sizable minority did not. When

compared to results of a similar question asked of attorneys in a separate study, the percentage of attorneys reporting that the vaccine program procedures are fair is relatively low: in a study of case-management and alternative dispute resolution procedures in five Civil Justice Reform Act demonstration programs, researchers found that more than 60% of responding attorneys in each district rated the court's procedures as very fair (compared to 28% of vaccine attorneys), while fewer than 15% of them rated the procedures as somewhat or very unfair (compared to 35% of vaccine attorneys).⁸⁷

It should be noted that there was a statistically significant association between petitioners' attorneys' ratings of fairness and of their satisfaction with case outcome ($\chi^2 = 31.9, p < .05$). Thus, these attorneys may have had difficulty separating their evaluation of case-management procedures from their view of the case outcome.

E. Suitability of Program for Other Types of Cases

The VICP, or specific aspects of it, is often mentioned for use as a model in other categories of cases where aggregate injuries are alleged, or where the government accepts responsibility for liability.⁸⁸ In our interviews

87. Donna Stienstra et al., *A Study of the Five Demonstration Programs Established Under the Civil Justice Reform Act of 1990: Report to the Judicial Conference Committee on Court Administration and Case Management* 24-25 & Table 11 (Federal Judicial Center 1997). In another study, 80% of attorneys participating in court-annexed arbitration reported those procedures as fair. Barbara S. Meierhoefer, *Court-Annexed Arbitration in Ten District Courts* 63, 64 Table 15 (Federal Judicial Center 1990).

88. *See, e.g.*, 136 Cong. Rec. S12115, S12118 (daily ed. Aug. 3, 1990) (statement of Senator Charles E. Grassley arguing against the repeal of a ban on litigation against private contractors brought by victims of the government's Atomic Weapons Testing Program: "If the Government is responsible, and the evidence strongly suggests that it is, then let's create a compensation system outside of the courts to provide relief—faster, without litigation expenses, without having to prove fault, and without lengthy appeals. In recent years, we have shown a preference for compensation over litigation, with enactment of the child vaccine compensation legislation, the Radiation-Exposed Veterans Compensation Act of 1988, and the Veterans Dioxin and Radiation Exposure Act . . . among others."). *See also* 142 Cong. Rec. H3656, H3656 (daily ed. Apr. 22, 1996) (statement of Representative Porter J. Goss, arguing in favor of the Ricky Ray Hemophilia Relief Fund Act to provide compensation for hemophiliacs who received blood products tainted with the virus that causes AIDS: "I have sponsored legislation to provide compassionate assistance to these victims from the Government. It is my conclusion—and one reached by a distinguished panel of objective experts from the Institute of Medicine (IOM) at the National Academy of Sciences—that Government shares responsibility for this tragedy.... As part

with both the special masters and attorneys at the Department of Justice, we asked for their thoughts on the applicability of the VICP model, or aspects of it, to other categories of cases.

Of the eleven special masters we interviewed, all thought the VICP, or aspects of it, would be useful in other categories of cases. Two special masters qualified their answers by indicating that causal issues must lend themselves to narrow definition for this kind of program to work. When asked what types of cases the VICP model would be useful for, they suggested several, including product liability and mass tort cases, such as breast implants, toxic shock, asbestos, and Agent Orange, and cases where the government accepts possible liability as a public policy decision, such as radiation exposures alleged to cause injury to civilians living downwind of government atomic weapons testing sites, harm to Japanese citizens interned during World War II, or chemical exposures to members of the military during Operation Desert Storm, and issues related to specific government benefit programs, such as Medicare disability issues.

Aspects of the program the special masters enumerated as most useful for other categories of cases included many of the procedural innovations of the VICP, such as: eliminating “hide and seek” discovery; eliminating the applicability of the Federal Rules of Evidence and the Federal Rules of Civil Procedure; allowing hearsay; eliminating juries in favor of specialist decision makers with an inquisitorial role; the use of a table to define injuries; and the imposition of strict time frames for case resolution.

Of the eight respondent’s attorneys we interviewed, all thought this type of program, or aspects of it, would be useful for other categories of cases. As with the special masters, two qualified their answers by suggesting that the vaccine model would be useful only if issues in a group of cases could be tailored narrowly. One attorney further stated that the method of determining and awarding petitioners’ attorneys’ fees would need to be improved for future application to be successful. Among the types of cases mentioned as possible candidates for application of specific aspects of the vaccine program or the establishment of similar compensation programs were product liability cases and occupational exposure cases, including breast implant cases, cases brought against drug manufacturers for specific drug products, asbestos cases, and radiation cases. Interestingly, one attorney suggested that the program, or aspects of it, was more suited for less complex cases, where factual issues were more

of its concluding recommendations for changes in the system to prevent this type of crisis from recurring, the IOM panel suggested a compensation program involving the government—one similar to that which exists for vaccines.”).

straightforward and an intricate knowledge of medical or scientific issues was not necessary.

Specific aspects of the program that were suggested by the respondent's attorneys as useful to retain in potential future applications of the VICP model included: having knowledgeable fact finders and a single fact finder as opposed to a jury; having limited discovery; eliminating the applicability of the Federal Rules of Evidence; holding informal hearings; and placing caps on damages. One attorney mentioned the importance of retaining petitioner's right to elect to pursue civil litigation. Another attorney noted that the use of lay witnesses' affidavits to explain gaps in medical records should not be continued, as their use sometimes leads to inadvertent issues of perjury at a hearing.

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VI. Conclusions

Although our study was intended primarily to be descriptive rather than evaluative, we had the opportunity during the course of this study to make some observations about the generalizability of the VICP as well as its strengths and weaknesses.

First, it seems plausible that a number of problems participants cited with the VICP resulted from the large and unexpected influx of pre-Act cases that occurred during 1990 and 1991. As these cases are steadily resolved, the caseloads should become much more manageable, and presumably cases will be resolved more quickly. Furthermore, the pre-Act cases have a much stricter limitation on attorneys' fees than do post-Act cases, so it might be expected that problems with attorneys' fees will lessen also as the pre-Act cases leave the system. Thus, further evaluation of the VICP after the pre-Act cases are concluded is warranted.

Second, most of the problems participants cited concerning the VICP had to do with day-to-day practice as it evolved rather than design. In particular, the program was intended to be expeditious and less adversarial than litigation, but a number of participants report that attorneys approach the cases in an extremely adversarial manner, causing them to take a long time to be resolved. Although Congress in 1989 encouraged participants to "re-dedicate" themselves to the goal of nonadversarial resolution of cases in the program,⁸⁹ perhaps stronger measures are needed to ensure the program in practice meets its goals.

Could the VICP serve as a model for handling other types of cases? Because vaccines are governmentally mandated and their use by individuals benefits society as a whole, they are quite unique relative to other consumer products. There are probably very few other areas in which the government will have incentive to assume liability for harm caused by a manufactured product in order to prevent the manufacturers from ceasing production. Thus, the full structure of the VICP is likely to have limited applicability in other areas. Some of the case types cited by special

89. H.R. Conf. Rep. No. 101-386, *supra* note 47, at 512-13, *reprinted in* 1989 U.S.C.C.A.N. at 3115-16.

masters and respondent's attorneys would be likely candidates for being handled through a similar structure.

Whether or not the full program structure can be applied to a large number of cases, several of the specific case-management innovations employed in the VICP appear promising and could be applied in the context of traditional litigation or other alternative case-management systems. One example is "front-end loading" of relevant information in lieu of traditional discovery processes. Most of the VICP participants we surveyed thought the idea of front-end loading was a good one. In fact, a number of federal district courts have adopted various versions of disclosure, pursuant to which parties share certain categories of information without awaiting discovery requests from the other side. The idea of disclosing expert reports has also been adopted in some federal courts,⁹⁰ and a recent study indicates that nearly one-half (47%) of attorneys in cases with expert disclosure believe that it increases procedural fairness, while only 8% believe it decreases fairness.⁹¹

Another case-management procedure that most participants found useful was the early, off-the-record status conference at which the special master shares his or her view of the case and helps parties to define and narrow the issues. Again, this procedure could be used in traditional litigation—although the benefits might be lost if the judicial officer participating in the conference is not the one who will try the case.⁹²

Finally, most participants in the VICP also thought there were many advantages to the use of specialized decision makers to hear vaccine cases. The drawbacks they cited had to do primarily with the fact that the special masters hear the same types of cases over and over again and might develop either indifference or bias as a result of this continual exposure. The idea of specialist decision makers or advisors has been proposed and tried in other contexts, however, in which the specialist serves in only one case—for example, a special master appointed in an individual case to advise the judge on the resolution of technical matters.⁹³ In

90. See Donna Stienstra, Implementation of Disclosure in Federal District Courts, with Specific Attention to Courts' Responses to Selected Amendments to Federal Rule of Civil Procedure 26 (Federal Judicial Center 1994).

91. Thomas E. Willging et al., Discovery and Disclosure Practice, Problems, and Proposals for Change: A Case-based National Survey of Counsel in Closed Federal Cases 29 Table 20 (Federal Judicial Center 1997).

92. Judges' practices differ in the extent to which they express their views of a case in discussions with the parties prior to trial. See William W. Schwarzer & Alan Hirsch, The Elements of Case Management 10 (Federal Judicial Center 1991).

93. See generally Margaret G. Farrell, *Special Masters*, in Reference Manual on Scientific Evidence 575 (Federal Judicial Center 1994).

these instances, the benefits of the expert's familiarity with complicated issues might be realized without some of the reported problems that arise when a specialist decision maker is exposed to multiple cases involving similar issues.

Overall, the case-management innovations and handling of expert testimony, which were the focus of this report, apparently function relatively well in the VICP. Other program aspects—such as attorneys' fee provisions, overly adversarial behavior by attorneys, possible bias on the part of some special masters, and the long time to disposition for many cases—appear to be more problematic. As the pre-Act cases are resolved steadily and removed from the special masters' dockets, many of the problems cited can be expected to improve. The resolution of other problems may require clarification of the roles of various program participants.

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Appendix

National Vaccine Injury Compensation Program Vaccine Injury Table

(Effective date: March 24, 1997)

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
I. Vaccines containing tetanus toxoid (e.g., DTaP, DTP, DT, Td, or TT)	A. Anaphylaxis or anaphylactic shock	4 hours
	B. Brachial neuritis	2–28 days
	C. 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. Vaccines containing whole-cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (e.g., DTaP, DTP, P, DTP-HiB)	A. Anaphylaxis or anaphylactic shock	4 hours
	B. Encephalopathy (or encephalitis)	72 hours
	C. 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

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
III. Measles, mumps, and rubella vaccine or any of its components (e.g., MMR, MR, M, R)	A. Anaphylaxis or anaphylactic shock	4 hours
	B. Encephalopathy (or encephalitis)	5–15 days (not less than 5 days and not more than 15 days) for measles, mumps, rubella, or any vaccine containing any of the foregoing as a component
	C. 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. Vaccines containing rubella virus (e.g., MMR, MR, R)	A. Chronic arthritis	7–42 days
	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
V. Vaccines containing measles virus (e.g., MMR, MR, M)	A. Thrombocytopenic purpura	7–30 days
	B. Vaccine-strain measles viral infection in an immunodeficient recipient	6 months
	C. 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

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
VI. Vaccines containing polio live virus (OPV)	A. Paralytic polio —in a non-immunodeficient recipient —in an immunodeficient recipient —in a vaccine-associated community case	30 days 6 months Not applicable
	B. Vaccine-strain polio viral infection —in a non-immunodeficient recipient —in an immunodeficient recipient —in a vaccine-associated community case	30 days 6 months Not applicable
	C. 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
VII. Vaccines containing polio inactivated virus (e.g., IPV)	A. Anaphylaxis or anaphylactic shock	4 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
VIII. Hepatitis B. vaccines	A. Anaphylaxis or anaphylactic shock	4 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
IX. Hemophilus influenzae type b polysaccharide vaccines (unconjugated, PRP vaccines)	A. Early-onset Hib disease	7 days
	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

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
X. Hemophilus influenzae type b polysaccharide conjugate vaccines	No condition specified	Not applicable
XI. Varicella vaccine	No condition specified	Not applicable
XII. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by the secretary of a notice of coverage	No condition specified	Not applicable

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