Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM: A PROGRAM REVIEW

DECEMBER 1992

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DECEMBER 1992 02-91-01460

EXECUTIVE SUMMARY

PURPOSE

The purpose of this inspection is to review the structure and operations of the National Vaccine Injury Compensation Program (VICP).

BACKGROUND

The VICP is a Federal "no-fault" system which was intended to stabilize the vaccine manufacturing industry and to establish a streamlined process to compensate persons who have suffered injuries due to certain vaccines. The VICP involves three government entities: the Public Health Service (PHS) in the Department of Health and Human Services (HHS), the Department of Justice (DOJ), and the United States Court of Claims (Claims Court). After a claim is submitted to the Claims Court, physicians at PHS review each case based on the Vaccine Injury Table and send their recommendations for or against compensation to the Claims Court, where a hearing takes place. With DOJ attorneys representing the government and private attorneys representing petitioners, a special master, appointed by the Claims Court, makes a final ruling and determines the amount of the award.

In conducting the inspection, policies, written procedures and operational guidelines for the program were reviewed to determine how the program is organized and how it attempts to meet its legislative and regulatory goals. Flow charts of the processes were constructed. Next, from the universe of 2,347 cases in the PHS database a statistical analysis was done and 90 cases were selected for review. The team also interviewed 23 key government officials and 31 petitioners and their attorneys.

FINDINGS

The Program is Currently Struggling To Handle A Large, Unanticipated Influx of Retrospective Cases

At the current production level of approximately 37 cases a month, it will take approximately seven years to complete all of the retrospective cases. As of February 1992, 739 retrospective cases had been completed, leaving 3,356 cases to handle. Some government officials feel that the current production rate will increase due to changes in legislation, the increased experience of the program staff, and an anticipated increase in case dismissals.

Cases are Delayed Due To a Front-end Backlog Resulting From Scheduling Constraints and Lack of Resources

The large influx of retrospective cases has necessitated that the chief special master control intake into the system, resulting in a backlog. No guidelines exist for the

special master's scheduling of cases. They are not necessarily assigned in order of filing. Approximately 2,500 cases have not been scheduled and are backlogged.

Respondents identify specific resources which they consider insufficient to handle the backlog. The chief special master recommends more staff attorneys at the Claims Court and the chief medical officer suggests additional reviewers. The PHS staff also cite a shortage of both pediatric neurologists and infectious disease specialists willing to testify.

The Case Process is Efficient Except for the Front-End Backlog

An analysis of the flow of cases in the PHS database shows that once a case is assigned, it is handled efficiently. Delays exist only at the front end for retrospective cases. The program is meeting deadlines for prospective cases, handling them in a timely and efficient manner.

Our review of program policies and procedures, reinforced by the responses of government officials, shows the program to be well-organized. Each step in the process is clearly delineated and no unnecessary duplication is apparent. Coordination and communication among the Federal agencies is strong. Their roles and responsibilities are clearly defined. Petitioners and their attorneys are generally satisfied with their experience in the program.

A Significant Portion of PHS Medical Review Recommendations Not To Compensate are Overturned by the Special Masters

A review of all completed cases, as of August 1991, reveals that 58 percent of the cases that the PHS medical staff recommended not be compensated were compensated. Several government officials cite two major factors which account for the reversal rate: lack of corroboration of evidence and various interpretations of the Vaccine Injury Table.

The Present Vaccine Injury Table Does Not Reflect The Latest Scientific Evidence

A recent Institute of Medicine (IOM) study found a lack of causal relationship between certain vaccines and injuries on the existing Vaccine Injury Table. Some government officials estimate that if future cases are decided only on the basis of the latest scientific evidence, the compensation rate would be significantly lower.

Government Officials We Interviewed Support Annuities and The Use of Brokers

Most government officials believe annuities are the best way to pay the award and brokers are needed to buy the annuities. Annuities assure long-term benefits, avoid mismanagement of funds, and are less expensive for the government.

RECOMMENDATIONS

The PHS, DOJ and Claims Court should:

Inventory the Backlog to Set Priorities and Better Estimate Future Resource Needs

The Claims Court, in consultation with PHS and DOJ, should evaluate the existing workload to determine which cases it should handle first, what mix of resources will be needed to handle them, and how best to handle more complicated cases.

Further Streamline the Process

Some suggestions include: assuring more complete filing of petitions, appointing one objective expert witness per case, processing damage determinations more quickly, and using past damage decisions as a basis for future ones.

Use Latest Scientific Information

The HHS should support proposed legislation to revise the Vaccine Injury Table to reflect the latest scientific information available, particularly changes recommended by the IOM.

Improve Contact with Petitioners and their Attorneys

Emphasize Use of Annuities

COMMENTS

Comments on the draft report received from PHS, the Assistant Secretary for Planning and Evaluation and the Assistant Secretary for Management and Budget generally concur with the recommendations of this report. However, PHS pointed out that its role in the process is a limited one. We agree. We have directed our recommendations to the Department of Justice and the Claims Court as well as PHS. Suggestions for changes in the wording, clarifications of the text and any technical changes have for the most part been incorporated into the final report. The actual comments received are in Appendix D.

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INTRODUCTION

PURPOSE

The purpose of this inspection is to review the structure and operations of the National Vaccine Injury Compensation Program (VICP).

BACKGROUND

Immunization Goals and Vaccine Injuries

State laws generally require that children be immunized against seven infectious childhood diseases (diphtheria, tetanus, pertussis [whooping cough], measles, mumps, rubella and polio) before entering day care or school. If a large enough proportion of the population is immunized, the disease will not spread significantly and the entire population will benefit. Thus, it is important that vaccines in this country remain in adequate supply and be fairly priced.

Since the advent of these vaccines the occurrence of the diseases they prevent has decreased substantially in the general population. People are often no longer aware of the dangers of the diseases. Before the vaccines, epidemics of the diseases they prevent caused widespread death and disability.

Immunization is not entirely without risk, however. While severe adverse reactions rarely occur, they are a tragedy for the individual children and families who suffer them. Parents of these injured and deceased children originally sought damages from vaccine manufacturers through tort litigation. Tort law requires that the plaintiff prove negligence on the part of the manufacturer or person who administered the vaccine. This process often took years and consumed inordinate amounts of money.

The rapid growth of lawsuits and the increased manufacturer liability adversely affected the vaccine supply. Vaccine prices rose and some manufacturers left the business. By the mid-1980s there was only one manufacturer for polio vaccine, one for measles, mumps and rubella (MMR) vaccine, and two for diphtheria, tetanus and pertussis (DTP) vaccine.

Legislation

In response to this mounting public health concern, several bills were introduced and debated in congressional hearings on the issues of fair compensation and adequate vaccine supply. Ultimately, the National Childhood Vaccine Injury Act of 1986 (the Act) became law. This legislation attempted to ensure both fairness to injured persons and protection for the Federal immunization program. It was designed to serve two vital public purposes: (1) to provide prompt and fair compensation to the few children who died or were injured as a result of routine immunization; and (2) to

reduce the adverse impact of the tort system on vaccine supply, cost and innovation.

To fulfill the part of the Act that deals with fair compensation, the VICP (Subtitle 2 of Title XXI of Public Health Service Act) became effective on October 1, 1988. Subtitle 2 was later amended by the Omnibus Reconciliation Act (OBRA) of 1987, by the 1988 and 1989 amendments, by the Vaccine and Immunization Amendments of 1990, and most recently by the Health Information, Health Promotion, and Vaccine Injury Compensation Amendments of 1991, signed into law on November 26, 1991.

Subtitle 1 of Title XXI of the PHS Act also establishes the National Vaccine Program (NVP) to achieve prevention of infectious diseases through immunization and prevention of adverse reaction to vaccines. The National Vaccine Advisory Committee (NVAC) (Section 2105 of the PHS Act) advises and makes recommendations to the director of the NVP.

Another legislated activity, the Advisory Commission on Childhood Vaccines (Section 2119 of the PHS Act) advises the Secretary on how the VICP is being implemented and how it is accomplishing its goals. It has prepared a policy paper which discusses options to be considered for the future direction of the program.

The Assistant Secretary for Health has also established a PHS-wide task force to make recommendations on the future direction of the VICP, including proposing legislation to deal with the influx of claims, as well as the long-range future of the program.

Program Description

The VICP is a Federal "no-fault" system which compensates families whose children have had serious adverse reactions to vaccines for the following childhood diseases: diphtheria, tetanus, whooping cough, poliomyelitis, measles, mumps and rubella.

The program, which began to consider petitions as of February 1, 1989, differentiates between claims based on immunization prior to the Act's effective date of October 1, 1988 (retrospective cases), and those based on immunizations on or after that date (prospective cases). A deadline of January 31, 1991 was set for filing claims in retrospective cases.

Retrospective and prospective cases are subject to different rules and remedies as described in Table I below. Compensation for retrospective cases comes from an annual appropriation of $80 million. Compensation for prospective cases is given to a maximum of 150 claimants per year, and is financed through an excise tax on childhood vaccines. In both types of cases, awards for death cases are fixed at $250,000 plus attorney fees and costs.

TABLE I: COMPARISON OF RETROSPECTIVE AND PROSPECTIVE CASES

	RETROSPECTIVE	PROSPECTIVE
DATE OF VACCINE	Prior to 10/1/88	On or after 10/1/88
SCHEDULING	Non-sequentially	Sequentially
DEADLINE FOR DECISION ON CASE	32 months	14 months
# OF CLAIMS FILED BY 2/18/92	4,095	220
# OF DECISIONS BY 2/18/92	789	50
COMPENSATED	303 (38.4%)*	21 (40%)**
NOT COMPENSATED	90 (11.4%)*	7 (14%)**
DISMISSED	396 (50.2%)*	22 (44%)**
AWARDS BY 2/18/92	$192 million	$10.5 million
FUNDING SOURCE	Annual Congressional appropriation of $80,000,000	Vaccine Injury Compensation Trust Funded by vaccine excise tax
ALLOWED AWARD AMOUNTS:		
INJURY	Unlimited	Unlimited
DEATH	$250,000 plus attorney fees & costs	Up to $250,000 after pain and suffering + attorney fees & costs
ATTORNEY'S FEES & COSTS	$30,000***	Unlimited
BASIS OF AWARDS	Estimated future unreimbursable rehabilitative and related medical expenses; actual and future loss of earnings; attorney's fees & costs.	Actual past and estimated future unreimbursable rehabilitative and related medical expenses; actual and future loss of earnings; actual and projected pain and suffering; attorney's fees & costs.

* Percentage of completed retrospective cases.

** Percentage of completed prospective cases.

*** This amount also includes petitioner's actual and projected pain and suffering and loss of earnings.

The VICP consists of three government entities: the Public Health Service (PHS) in the Department of Health and Human Services (HHS), the Department of Justice (DOJ), and the United States Court of Claims (Claims Court) which work together to process the cases.

Families of injured or deceased children submit petitions for compensation to the Claims Court which sends a copy to the PHS. The petitioner must prove program entitlement as well as losses and expenses. After a petition is filed, the chief special master in the Claims Court assigns the case to a special master and puts it on the schedule of upcoming cases.

The PHS medical experts, in the Division of Vaccine Injury Compensation (DVIC), evaluate the case and offer an opinion as to whether or not the petitioner is eligible. The PHS Office of General Counsel (OGC) reviews this opinion and forwards it to DOJ. Within 90 days of the original filing, DOJ writes a report incorporating the PHS medical evaluation with a legal response; extensions may, however, be requested and due to the backlog of retrospective cases almost always occur for these. Attorneys from the DOJ and petitioner attorneys then argue the case before a special master in a formal hearing. Prior to the hearing, a great deal of factual and expert preparation is undertaken by the DOJ attorneys and petitioner's attorneys in order to present the case.

Both the PHS medical experts and the special masters are required by statute to use the Vaccine Injury Table when deciding whether an injury is compensable. This table outlines the injuries compensable under the program and the time-frames in which they must have occurred. This table is intended to avoid controversy over which disabilities are potentially caused by vaccines. It is accompanied by "Qualifications and Aids to Interpretation" to allow for easier interpretation.

The final decision on a case is made by a special master of the Claims Court. This decision will become a final judgement if no motion for review is filed within 30 days or if the Claims Court affirms the decision of the special master. A case may be compensated or not compensated or it may be dismissed. When a case is dismissed it is no longer under consideration for a potential award. Their judgement is final, unless either the claimant or HHS requests a review by a Claims Court judge. Further review is available in the United States Court of Appeals.

The Act gives special masters a great deal of leeway as decision-makers. They are not bound by common law or statutory rules of evidence, but are guided by them. They can tailor each hearing to the individual circumstances as they choose, but are constrained by the principle that their decisions may be reversed.

Once a decision is made to compensate, the award amount is negotiated. A life-care planner assesses the present and future needs of the disabled person and their costs, and recommends an award amount. The special master determines the actual amount. The entire process for retrospective cases, from time of initial petition to

final decision, originally was to occur in 14-months, was increased to 20-months in 1990 and, since the 1991 amendments to 32 months. The entire process for prospective cases must occur in 14 months.

It should be noted that compensation for retrospective cases begins at date of judgement and the petitioner is not paid for any expenses incurred before then. However, compensation for prospective cases is for past and estimated future expenses.

Amendments to the Act signed November 1991, delete a provision which terminates the entire program if funding is insufficient. These amendments also change the due date for an evaluation report on the program to January 1, 1993; extend the adjudication time for retrospective cases an additional 12 months for a total of 32 months; allow for compensation to be paid in one installment instead of four; and give the petitioner the option to stay in the program if the deadline is not met. Before the latter change, the Claims Court lost jurisdiction over the case and the petitioner could then seek recourse only in the tort system.

The January 31, 1991 deadline for filing retrospective cases resulted in more than 3,500 cases being filed in the five preceding months. As of February 1992, 4,095 pre-1988 and 220 post-1988 petitions were filed. Of these, 739 retrospective cases have been adjudicated: 281 in favor of the petitioner, 84 against and 374 dismissed. Individual awards total $192 million. Of the 220 prospective cases filed, 50 have been adjudicated: 21 in favor of the petitioner, 7 against, and 22 dismissed. Individual awards total $10.5 million, well within the amount in the trust fund.

Reports

A Boston University recently completed a report for the Administrative Conference of the United States, which summarized the first year of the VICP program and included recommendations for its improvement. Also, the Committee on Governmental Processes of the Administrative Conference as a result of the Boston University study has made a series of recommendations for improvements in the VICP. Some call for more effective dissemination of information, simplification of the eligibility process, new guidelines for determining award amounts, and extensions in time frames for completing cases.

In 1991, the Assistant Secretary for Planning and Evaluation (ASPE) contracted with an actuarial firm to generate estimates on the costs of retrospective awards. The estimates reflect different assumptions with respect to the number of cases compensated, but uniform assumptions on award amounts by claim type and vaccine category. The estimates range from a high of $2.6 billion to a low of $1.6 billion.

The Secretary, as mandated by law, requested the Institute of Medicine (IOM) to form a committee to conduct a review to determine whether pertussis and rubella vaccines cause adverse effects and what those effects are. Its report, completed in

August 1991, found a lack of causal relationship between these vaccines and certain injuries on the vaccine table.

Finally, the Office of Inspector General (OIG) Office of Audit Services (OAS) conducted two related studies. The first looked at the timeliness of attorney fee payments in the VICP. It found the average time for PHS to process attorney payments was 22.6 days. The second reviewed an alleged conflict-of-interest involving the above mentioned IOM committee. The OAS initially verified the conflict-of-interest of two committee members. One person resigned. After further review in the second case, it was determined that no conflict actually existed, although there was an appearance of possible conflict-of-interest.

Concerns about several program operation issues which have direct impact on the program's cost, prompted ASPE to request the OIG to review the program's operations. Additionally, OGC requested the OIG to examine PHS's use of brokers.

METHODOLOGY

We reviewed policies, written procedures and operational guidelines for the program to determine how the program is organized and how it attempts to meet its legislative and regulatory goals. A flow chart was constructed to show the agency roles and processes involved in handling cases. Another flow chart was created to show the process of damage determination.

The universe of 2,347 cases in PHS's database as of August 1991 (1,800 petitions filed had not yet been entered into the database) was stratified by whether the case was open or closed. A random sample of 45 cases was then selected from each strata. The inspection team reviewed these 90 case files to: verify data contained in the PHS's database; get a clearer understanding of how the VICP process works, including the operational process used for decision-making in each case; and identify specific attorneys and petitioners to be interviewed during the study. The 90 cases are described in greater detail in Appendix B.

A survival analysis of all 2,347 cases included in PHS's database through August 1991 was done to evaluate timeliness of decisions and trends in awards. See Appendix C. With respect to this analysis, it should be kept in mind that this data set did not include all the cases received by PHS. Eighteen hundred cases filed had not yet been entered into the computer. Therefore, the results of this analysis should be interpreted with caution. Once a complete data set is developed, the relationships noted here may change appreciably.

The team interviewed 23 key government officials or those acting on behalf of the government from HHS, DOJ, the Claims Court, and the National Vaccine Advisory Commission. They include five administrators, four physicians, five agency attorneys, two special masters, three other government officials, two brokers and two life-care

planners. They were asked their views of and their experience with the program and their recommendations for its improvement.

Additionally, the team interviewed by telephone 31 non-government individuals. These included 17 petitioners' attorneys, 12 parents (6 of whom represented themselves, known as pro se) selected from the closed cases reviewed, a medical expert, and a parents' advocate. They were asked their views of the program and their recommendations for its improvement. Although an effort was made to interview all 33 attorneys and their clients identified from the closed cases, 16 attorneys could not be reached or did not want to be interviewed. Also, many attorneys did not agree to having their clients interviewed for a variety of reasons. For example, some attorneys had lost contact with their clients, some clients spoke no English, and some clients did not want to speak with us. Many attorneys said their clients would become unnecessarily distraught if they had to discuss the painful subject of their disabled children.

FINDINGS

THE PROGRAM IS CURRENTLY STRUGGLING TO HANDLE A LARGE, UNANTICIPATED INFLUX OF RETROSPECTIVE CASES

At the current production level it will take approximately seven years to complete all of the retrospective cases.

The program is currently struggling to deal with a large, unanticipated influx of retrospective cases. An analysis of PHS's FY 1991 and 1992 program output status reports shows that the VICP adjudicates an average of 37 retrospective cases a month. This includes compensated, not compensated and dismissed cases. As of February 1992, 739 retrospective cases had been completed, leaving an additional 3,356 cases to handle. If the number of cases completed monthly does not change, it will take approximately seven years to complete all the retrospective cases.

However, some government officials feel that the production rate will increase due to changes in legislation, the increased experience of the program staff, and an anticipated increase in dismissals. The chief special master believes the production rate has already increased since he has accelerated the assignment of cases. More experience will be needed to ascertain the effects. However, if this increase continues, the time needed to complete the retrospective cases would be substantially reduced.

Although the statutory deadline was extended for an additional 12 months, the program will only be able to complete one-third of the retrospective cases by the new deadline.

Because the greatest number of retrospective cases were filed in September 1990, we used June 1993, 32 months, later as the deadline for completion of all these cases. With an average adjudication rate of 37 cases a month, 1,368 retrospective cases of the total 4,095 filed will be adjudicated by the deadline, leaving 2,727 cases to be completed. Were the deadline to be extended another twelve months, an additional 444 cases would be completed within the deadline.

If program output were to double, half the retrospective cases would still not be completed by the deadline; if it were to triple, 35 percent would not be completed. Actually, completing 95 percent of the retrospective cases by the statutory deadline would require a five-fold increase in the production rate.

These projections are approximations based simply on experience. Completed cases have been scheduled and adjudicated in a variety of ways which may not necessarily be typical of future case development.

Although most government respondents feel positive about having time requirements for handling cases, almost one-half consider these requirements unrealistic in light of the large number of pending cases.

Almost one-half (43 percent) of government officials could not even give an estimate of how long it will take to complete the cases. Those who answered offered estimates ranging from two to five years.

The delays are of concern to petitioners and their attorneys because of the lack of retrospective payment.

The time required to process the remaining cases will depend in part on the case mix.

The results of the survival analysis indicate that, for the cases found on the PHS data set as of August 26, 1991, the median time to completion of a case is approximately 15 months, well within the statutory time frames. Further, the results indicate that some aspects of the cases, including whether the patient died, the type of vaccine involved, when the case was filed, and whether the case was handled pro se or not, significantly affect the length of time it takes to handle a case.

It should be kept in mind that this data set did not include all of the cases filed. A number of cases had yet to be entered into the computer. It is possible that the addition of these cases may increase the median time to completion if it were found that cases were entered into the data set in a differential manner. This may indeed be the case given the large influx of cases that occurred during September 1990.

CASES ARE DELAYED DUE TO A FRONT-END BACKLOG RESULTING FROM SCHEDULING CONSTRAINTS AND LACK OF RESOURCES

The large influx of 3,500 retrospective cases has necessitated that the chief special master control intake into the system.

This large influx of cases, filed in or around September 1990 and January 1991, has compelled the chief special master to decide the order in which they are handled. No guidelines exist for this ordering and cases are not necessarily assigned in order of filing. The chief special master must consider available resources throughout the program when scheduling cases.

In order to handle the large number of cases, the chief special master has: held several informal meetings with representatives from DOJ and PHS and petitioner's counsel to develop a schedule; grouped cases according to type of vaccine; grouped cases geographically so that attorneys with many cases can have them heard at the same time in the same place; and dismissed many cases for lack of information.

The approximately 2,500 cases which have not been scheduled make up the front-end backlog. In March 1992, the chief special master estimated that the Claims Court had begun assigning 40 to 60 cases a month and dismissing an additional 40 a month after preliminary review of the petitions. As this preliminary review is a new development in the process, its effect is not yet reflected in any available data.

It is not yet clear what will happen if this front-end bottleneck is opened. We can anticipate the system would get backed up in other places, but cannot predict exactly where or how much.

Specific resources considered insufficient to handle the backlog are staff attorneys, pediatricians, pediatric neurologists, and infectious disease specialists.

According to the chief special master, more staff attorneys at the Claims Court would be a key addition. Staff attorneys conduct preliminary reviews of cases to determine whether or not they meet statutory requirements and to ensure that complete case files are forwarded to the chief special master. This facilitates scheduling and leads to appropriate dismissal of cases at an early stage.

According to the PHS chief medical officer, the medical review staff of six pediatricians reviews approximately 60 cases a month, an average of two days per case per doctor. The time needed for this initial review, further review required after additional information is submitted, discussions with DOJ, and for other activities leaves no buffer in the system. Additional reviewers would be necessary if the case load increases. Difficulty recruiting competent pediatricians has currently left three positions vacant. The PHS staff attribute these vacancies to the unwillingness of many physicians to do such work, because it removes them from patient care and requires them to make review decisions in a controversial area.

The PHS staff cite a shortage of both pediatric neurologists and infectious disease specialists willing to testify. The PHS staff also believe the small number of available expert witnesses is and will continue to be a limiting factor. Recently, five cases were dismissed in one month because the petitioners could not find experts to testify in support of their cases. Some petitioners also mention difficulty in finding attorneys willing to represent them.

THE CASE PROCESS IS EFFICIENT EXCEPT FOR THE FRONT-END BACKLOG

Once a case is assigned, it is handled efficiently.

An analysis of the flow of cases in the PHS database as of August 1991, from the date the claim was filed to the date of judgement, shows that delays exist with retrospective cases only at the front-end of the process. Once filed, entered into the PHS database and scheduled for review, the median time for both retrospective and prospective cases to reach a special master decision is 15 months. However, our analysis indicates that most of the processing time appears to be absorbed in the early stages, from the time a case is filed to the PHS OGC report date. This analysis is explained further in appendix C.

This 15-month completion period is well ahead of the current 32-month statutory deadline for retrospective cases. Of the 594 retrospective cases adjudicated by August

1991, fifty-four percent were completed within 10 months; 91 percent within 15 months; and 96 percent within 20 months.

The program is meeting deadlines for prospective cases and handling them in a timely and efficient manner. Of the 126 prospective cases filed before August 1991, none have missed the 14-month statutory requirement.

While agreeing that cases are handled in a timely manner, government officials, petitioners and their attorneys mention factors which delay a case once it is in the system. Most frequently mentioned is the long time it takes for a case to be assigned and to get into the system, because of the large influx of retrospective cases.

Government officials often cite incomplete records submitted with the initial petitions as a cause of delay. Petitioners and their attorneys agree that delays in getting evidence and medical records occasionally slow the process. Ninety percent of petitioners and attorneys say they were required to submit additional material or evidence after the case was filed. Sixty-two percent of petitioners and attorneys report that getting medical records was the most common problem they encountered in preparing their petition.

The review of 90 cases shows that additional information, mostly medical records, was requested in fifty-six percent of the closed cases.

A PHS official reports cases are sometimes stalled at the point where damages are determined. Another government official reflects the views of many when he says, "Once entitlement is determined, damage determination should not go through this lengthy process. Too much time is taken here."

The program appears to be generally well-organized with good procedures.

Our review of program policies and procedures shows the program structure to be well-organized, with each step in the process clearly delineated. This is demonstrated in flow chart I.

Three-quarters of government officials and half the petitioners and their attorneys consider the program to be well-organized with a sound and logical structure. Government officials most frequently mention that the program has developed effective procedures and guidelines, that roles have evolved more clearly over time, and that staff have gained more experience. Petitioners' attorneys note that the program is less costly and faster than State and Federal courts; some also feel that it has improved over time with better procedures. Thirty-five percent of petitioners and their attorneys say that the program is not well-organized, most frequently mentioning that the Claims Court is overrun.

Almost three-quarters (74 percent) of government officials feel the program is operating efficiently. They most frequently cite the program's effective processes.

Some also mention that under the circumstances, with limited staff and a large caseload, the system is working as well as it can.

Half the petitioners and their attorneys agree the program is operating efficiently. Several say that it works better than the Federal and State court systems; others remark that, in their experience, the process has been relatively smooth. Those who do not think the program is operating efficiently (32 percent) voice concerns about its lack of consistency, timeliness and overly bureaucratic process. The remaining respondents did not render an opinion.

No unnecessary duplication of effort exists.

A review of program policies and procedures reveals very little duplication of effort. It is, however, required at certain points in the process. For example, PHS, DOJ, and the Claims Court each review a case. This is necessary since each party must come to an independent conclusion in order to negotiate and resolve the case.

Most government officials who believe duplication of effort exists agree it is necessary to fairly adjudicate a case. Some government officials, however, identify areas where duplication of effort is perhaps not necessary, such as double data entry and the flow of paperwork between the PHS and DOJ.

Roles and responsibilities are clearly defined.

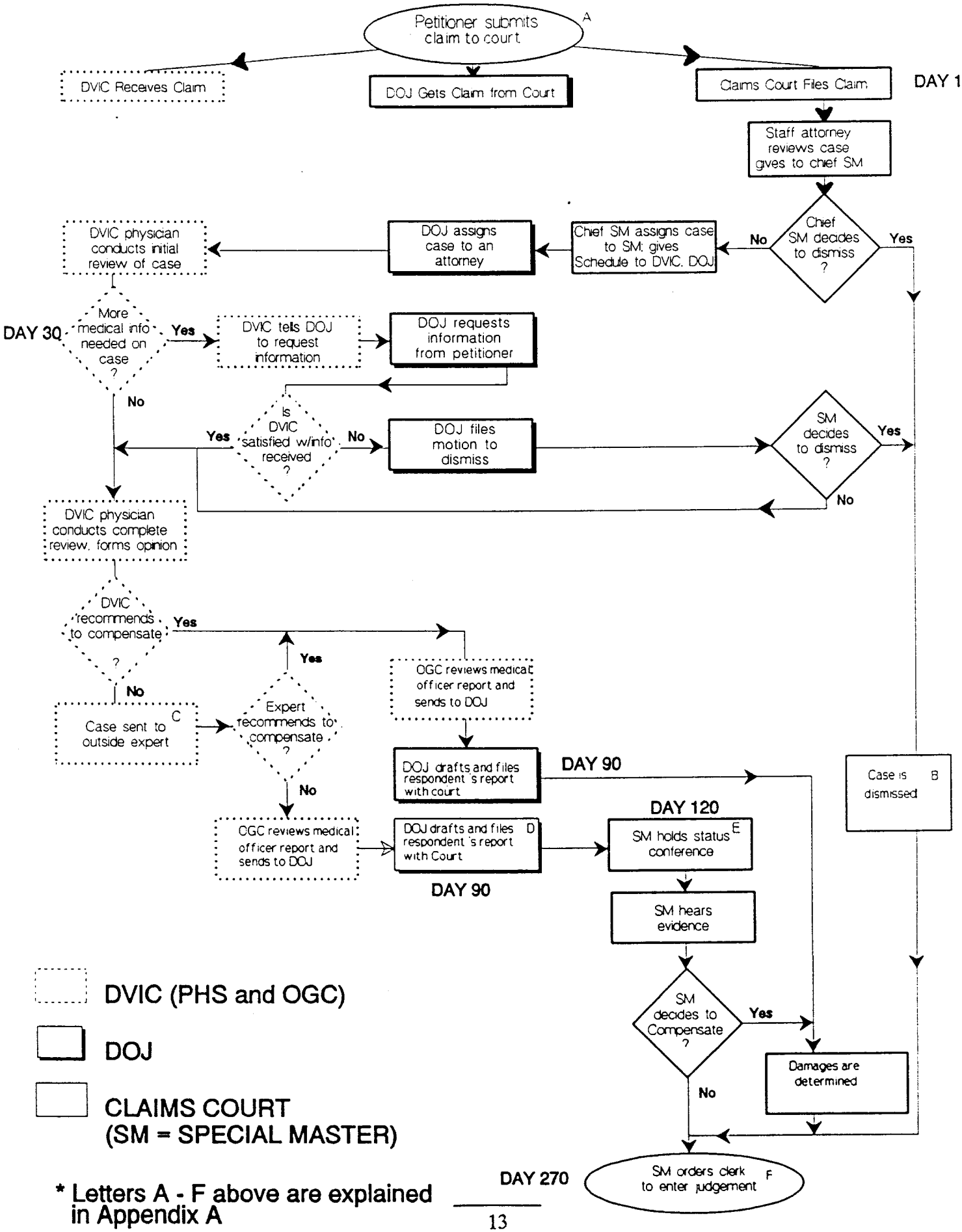
Flow chart I shows that the functions and responsibilities of each government entity are, for the most part, clearly outlined.

All government officials, except the special masters, feel their office role is clearly defined. Most say the Act is very specific and that clear written procedures are available.

The special masters interviewed do not feel their office role is clearly defined. One asks, "Should [I] be inquisitor or traditional judge?" Special masters can question witnesses, call their own expert and generally be more involved throughout the whole process than a judge usually is.

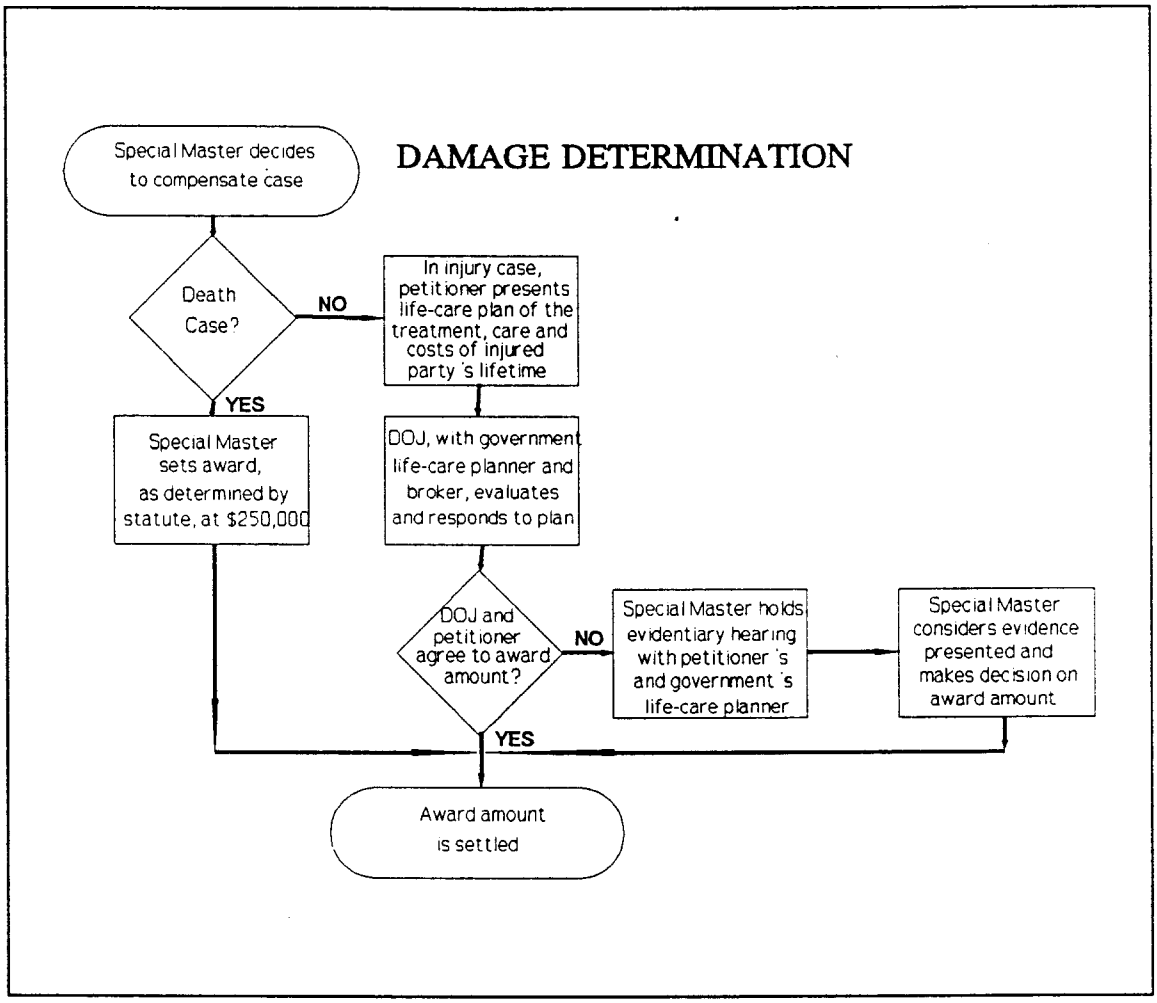
All government officials, including the special masters, think that their individual roles in the program are clearly defined. All feel they have clear job descriptions and performance plans and know what is expected of them. Although the special masters say the role of their office may not be well-defined, they believe their personal responsibilities in the program have evolved more clearly because of their increased case experience.

FLOW CHART I



* Letters A - F above are explained in Appendix A

FLOW CHART II



Coordination and communication among the Federal agencies is strong.

Flow chart I demonstrates clear-cut avenues for coordination. For example, should a PHS doctor require additional records to complete the medical review, the request will be made to the petitioner through DOJ to help assure compliance.

Almost three-quarters (74 percent) of government officials rate communication among all parties as good (22 percent) or excellent (52 percent). The PHS staff feel particularly positive about communication within their own division. Many government officials say that, while there is room for improvement, they respect each other's efforts and work at keeping communication open. One states, "there are real attempts by the heads of different parts to keep communication open." Several consider the new total quality management (TQM) group, which includes members from PHS, DOJ, and OGC, an excellent mechanism for communication and cooperation.

Status conferences between the special master and both sides involved in the case also facilitate open communication. Once a case is assigned, these conferences are held to speed up and simplify the decision-making process. The special master conducts these informal conferences with the petitioners' attorneys, possibly the petitioners, and the DOJ attorneys, either by telephone or in person, to focus issues and to give each party the opportunity to address the other's position.

A majority of government officials rate coordination between government agencies good or excellent. They know where responsibilities lie and who to call on specific issues.

Petitioners and their attorneys are generally satisfied with their experience in the program.

The experience of petitioners and attorneys has been positive. Seventy-six percent say that government officials have been generally helpful. They mention that the representatives were cooperative, readily available and promoted a good working relationship. A majority (79 percent) also say they were kept informed about their case while it was being decided. On the other hand, some petitioners and their attorneys report that before a case is assigned to a DOJ attorney, they are unable to find out its status. They would like a contact person for that purpose. Other petitioners believe that the program should be better publicized.

A SIGNIFICANT PORTION OF PHS MEDICAL REVIEW RECOMMENDATIONS NOT TO COMPENSATE ARE OVERTURNED BY THE SPECIAL MASTERS

A review of all completed cases as of August 1991 reveals that 58 percent of cases that the PHS medical staff recommended not be compensated were compensated. During the seven-month period from June 1989 to January 1990 (when DOJ was not representing the government), eighty percent of the medical review recommendations not to compensate were compensated. In contrast, when DOJ has argued the case, 52 percent of recommendations not to compensate have been compensated.

One special master believes the reversal rate is currently lower than 52 percent. He feels that, with experience, the special masters have become more comfortable in their role and in making decisions, leading to fewer compensated cases. Additionally, he believes that cases which had more substantive evidence submitted with the original petition were put into the system first, and were more likely to have been compensated.

Several government officials cite two major factors which account for the reversal rate: lack of corroborating evidence and differing interpretations of the Vaccine Injury Table. Disputes occur over what constitutes appropriate evidence. Additionally, the character of expert witnesses and the potential conflict between testimony and records or legal evidence also lead to disagreement. A related reason is the interpretation of the Vaccine Injury Table. Although the Aids to Interpretation assist with the

interpretation of the table, there is still room for differences of opinion. Therefore, each special master may interpret the table differently. The DOJ and HHS both support stronger corroboration of evidence requirements.

Of those who have an opinion, government officials are almost evenly divided about whether they believe cases have generally been decided appropriately. Many government officials who feel cases have been decided appropriately mention that, with DOJ's involvement, decisions are more balanced and fairer. Some also believe that decisions have been appropriate within the framework of the present Vaccine Injury Table and the evidence presented.

Most government officials who feel cases have not generally been decided appropriately do not believe all compensated decisions have been scientifically based. Many also think that too much emphasis has been given to petitioners' testimony, as opposed to medical records. One government respondent notes that PHS medical decisions and special master decisions are based on two different sets of factors: the former relies primarily on medical records, while the latter additionally considers testimony and affidavits.

Of those petitioners and their attorneys with an opinion, a majority (78 percent) feel that, based on their own experience, cases have generally been decided appropriately. More than half feel satisfied with the final decision in their own case. However, none of the petitioners who represented themselves (pro se) are satisfied: all of their cases have been dismissed for lack of evidence.

Only a small percentage of cases are appealed which could be interpreted to mean petitioners and their attorneys are generally satisfied with their case outcomes. To appeal a case after the special master decision, either party files a motion for review with the Claims Court judge. As of November 1991, 86 motions for review were filed, 60 by the petitioner and the remaining 26 by DOJ. After the judge's decision either party has 60 days to file a further appeal to the United States Court of Appeals for the Federal Circuit. Since the program's inception, very few cases have actually gone to the next appeal step. Currently, there are approximately five DOJ appeals and 15 petitioner appeals at this level.

THE PRESENT VACCINE INJURY TABLE DOES NOT REFLECT THE LATEST SCIENTIFIC EVIDENCE

A recent Institute of Medicine (IOM) study found a lack of causal relationship between certain vaccines and injuries on the existing Vaccine Injury Table.

The IOM committee sponsored a public meeting to solicit medical and scientific data and comments on the nature, frequency, and circumstances of adverse events following pertussis and rubella vaccines. It then reviewed existing research about 17 adverse events for pertussis vaccine and three adverse events for rubella vaccine. The

committee organized its conclusions into five categories reflecting the causal relationships between the vaccines and the adverse events.

Based on the study findings the HHS and the Advisory Commission have made recommendations for changes. The primary changes would remove seizure disorder and shock-collapse from the presumption of causation for pertussis vaccines. On the other hand, chronic arthritis would be added for rubella vaccine, but only on a showing of vaccine involvement. Some government officials estimate that if future cases are decided only on the basis of the latest scientific evidence, the compensation rate would be significantly lower.

GOVERNMENT OFFICIALS WE INTERVIEWED SUPPORT ANNUITIES AND THE USE OF BROKERS

Of those government officials offering opinions, almost all believe that annuities are the best way to pay the award. Eighty-three percent say annuities alone are best; the remaining 17 percent think that the award should be paid in a combination of lump sum and annuity. According to those who favor annuities, annuities assure long-term benefits for the child, avoid mismanagement of funds, are less expensive for the government because the insurance company assumes some of the risk, and give the petitioner tax benefits.

Although all government officials agree certified brokers are necessary to buy the annuities, some express concerns that their costs are too high. Many mention that brokers perform a necessary function by shopping for the best deal, actually servicing the annuity during the course of the petitioner's life, and providing support to DOJ during damage determinations.

The brokers have recently demonstrated their value. Originally, the program had to pay compensation in death and injury cases in four equal installments. This restriction limited the number of insurance companies willing to sell annuities to PHS. Those companies charged higher than normal rates because they were not getting the full cost of the annuity up front. The November 1991 Amendments to the Act, which allow for compensation to be paid in one installment instead of four, have made it possible for the brokers to renegotiate several annuities. Brokers were able to arrange for the program to make the remaining payments on several annuities and to renegotiate many annuity proposals. In total, the PHS has reportedly saved $7.7 million through these actions. The brokers' fees had already been paid by the insurance companies, so PHS did not incur any additional costs to achieve the savings. If annuities are to be the preferred payment approach, brokers are essential since insurance companies only deal with credentialed individuals.

APPENDIX A

FLOW CHART NOTES

TIME FRAMES

Generally, prospective and retrospective cases should be resolved in 420 days (14 months): 240 days from filing date to the special master's decision plus the maximum allowable suspension time of 180 days. However, the special master can suspend proceedings in any case several times and at various stages in the process. Also, due to the unexpected influx of retrospective cases, the retrospective cases have been given the 420 days plus additional extensions of 18 months, for a total of 32 months from filing date to the special master decision. Since the suspension times may differ from case to case, the time frames incorporated into this flow chart do not include any suspensions.

A: SUBMITTING CLAIMS AND "FRONT-LOADING"

The VICP was designed to get all the case information at the time of filing (called "front loading" the information) so all the issues and evidence are presented at the start. The petitioner's initial claim (the petition) must be complete in that it clearly outlines the petitioner's full case. This petition must include all medical and potentially relevant records and affidavits. A complete petition is essential: it reduces delays that occur when additional information has to be requested; permits a detailed evaluation of the case by the respondent (DOJ) and the special master; and is necessary for the timely adjudication of the case.

B: DISMISSALS

The special master may dismiss a case at any time during the process. Dismissal can occur if the petitioner received an award in the tort system, if no evidence was offered for a doctor to form an opinion, or if the Claims Court does not have jurisdiction over the case.

C: OUTSIDE EXPERT

Whenever the PHS staff physician decides a case is not compensable, it is sent to an outside medical expert who is not on the PHS staff. The expert may request additional information, especially medical tests, just as the staff physician does in order to form an opinion on the case. This opinion becomes the official PHS decision, referred to as the "internal report."

D: RESPONDENT'S REPORT

Prepared by DOJ attorneys, this document serves as PHS's answer to the petition. It incorporates the medical arguments made by the PHS physician or outside expert on whether or not PHS considers a case compensable and any relevant legal issues.

E: STATUS CONFERENCE

After reviewing the petition and respondent's report, the special master conducts an informal, "off-the-record," Rule 5 conference either by telephone or in person. The purpose of the conference is to speed and simplify the decision-making process. During the conference each party is given the opportunity to address the other's position. The special master offers his or her tentative view as to the merits of the case. Also, the petitioner, respondent, and special master establish which issues remain to be addressed. These conferences occasionally lead to settlement.

The special master often holds additional status conferences, usually by telephone, to expedite the processing of the case. Either party may request such a conference at any time. At these conferences, the parties may either suggest ways to process the case more efficiently, or make the special master aware of new case developments.

F: SPECIAL MASTER ORDERS CLERK TO ENTER JUDGEMENT

Within 240 days of the claim's filing date, the special master must issue a final decision determining whether or not an award of compensation shall be made and, if so, its amount. If neither party files a motion for review within 30 days of the special master's decision, the clerk enters judgement by day 270. Compensation, in awarded retrospective cases, is paid from this date of judgement.

NOTE:

In all cases the processes and time frames presented both in the flow chart and in the flow chart notes are those set forth in regulations and procedures; they may be different due to requested extensions or other unknown factors.

APPENDIX B

DESCRIPTION OF 90 CASES IN THE CASE FILE REVIEW

	number	*percent*
Case Status:		
Closed (case went through hearing)	25	28%
Dismissed early in process (no hearing)	20	22%
Open, awaiting PHS review	28	31%
Open, in or past PHS review	17	19%
Other Characteristics: (not mutually exclusive)		
Pro se	18	20%
Outside expert used	15	17%
DPT	66	73%
Injuries: (not mutually exclusive)		
Seizure disorder	53	59%
Encephalopathy	39	43%
Mental retardation/developmental delay	16	18%
Death	14	16%
Hypotonic/hyporesponsive collapse	11	12%
Anaphylactic shock	3	3%
Other	25	28%
Date Vaccine Administered: (closest approximation to date of injury)		
1972 and before	32	35.5%
1973 to 1982	32	35.5%
1983 to present	26	29%
Special Master Decision:		
Compensate	18	20%
Not Compensate	8	9%
Dismiss	20	22%
Other	1	1%
Information Not Available	2	2%
Not Applicable (case still open)	41	46%

APPENDIX C

DESCRIPTION OF THE ANALYSIS OF THE PHS DATABASE

To supplement the field work for this inspection, coded data were obtained that described a portion of the claims filed with the U.S. Public Health Service (PHS) Vaccine Injury Compensation Program (VICP). This data was analyzed to describe the program and delineate the effects on completion times of different characteristics ascribed to each case. This Appendix describes the results of that analysis.

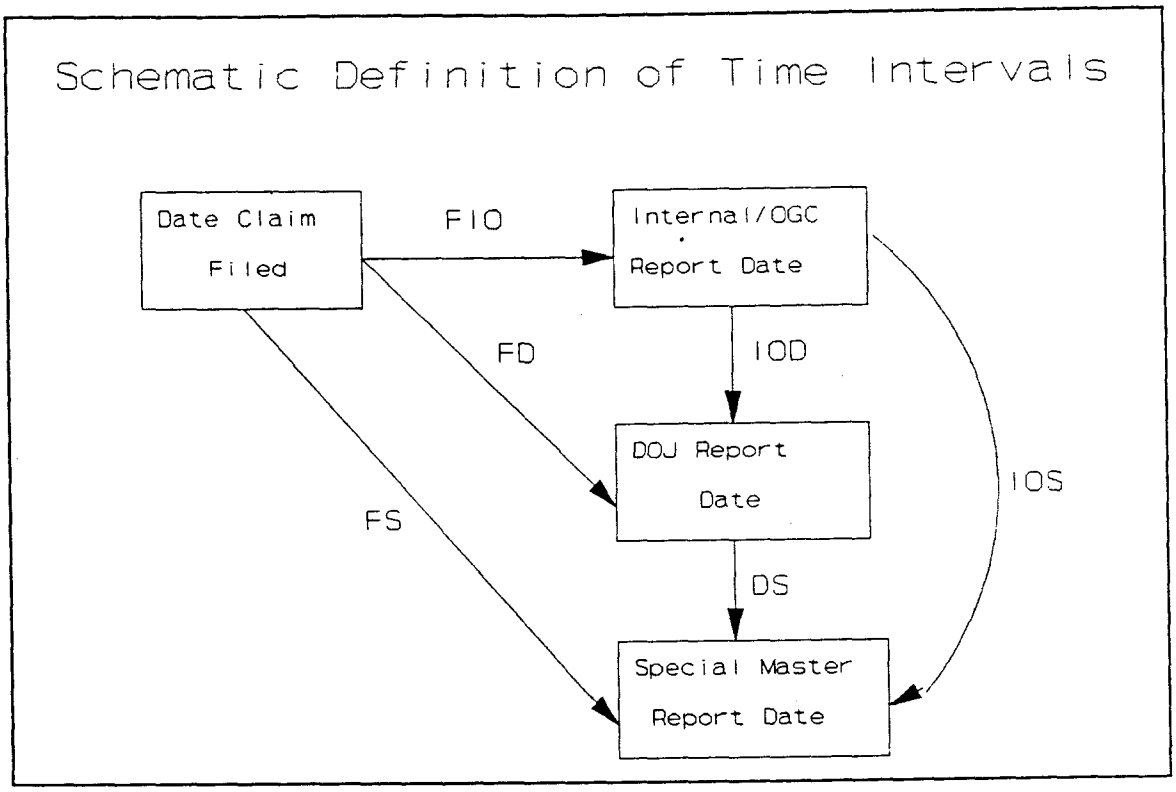
Description of Data Set

We received from the PHS a copy of their automated data that was current to August 26, 1991. A total of 2,478 cases were represented by the data in the file.

This analysis is structured on the presumed flow of cases filed with the VICP. Although up to 13 milestone dates are possible on the files provided, we have concerned ourselves with only four of these dates. These four dates include the date the claim was filed (Date Claim Filed), the later of the date of the internal report or the OGC (Office of General Counsel) report date (Internal/OGC Report Date), the DOJ (Department of Justice) report date (DOJ Report Date), and the Special Master (SM) report date (Special Master Report Date). This last date also served to define when a case was closed. We then defined intervals, measured in months, between each of these dates. These intervals are shown in the schematic drawing presented in Figure A. Cases were dropped that did not adhere to this sequence or were missing other important data. Of the original 2,478 cases, 60 were dropped because either the patients birth date was missing or the birth date followed a case's filing date. A further 71 cases were dropped because other dates in their file were out of sequence. Thus a total of 131 cases, 5.3 percent, were dropped due to bad dates. Except for unknown values in the individual variables that may lead to dropping a case from a specific analysis, the resulting 2,347 cases were included in the analysis presented here.

This analysis will show median times, in months, for each of the intervals illustrated in the figure. The most important is the interval labelled FS, the time from filing the claim until the Special Master report date. The analysis will concentrate on this interval. Results for the intervals labelled FD, the time from filing until the DOJ report date, and FIO, the time from filing until the internal or PHS report date, IOD, the time form internal or OGC report date until DOJ report date, DS, the time from DOJ report date until SM report date and IOS, the time from internal or PHS report data until SM report date, will be presented briefly in Table III.

Figure 1



For this analysis, one other variable, besides the intervals, was constructed to encode information not originally available on the file provided by PHS. During the period June 1, 1989 to December 31, 1989 the Department of Justice withdrew from the process. An indicator variable was created for cases completed during this period, whether they were dismissed, compensated or not compensated. Sixty-one completed cases fell into this group.

Eleven other indicator variables were created for this analysis, generally for use in the models applied to the data. These were constructed from data available in the files supplied by PHS. These additional variables define the type of vaccine given, the dates of filing for the cases, whether the patient died and whether the case was filed pro se or not.

For the cases represented in this data set, four outcomes can be defined as of Aug. 26, 1991. At this point in time the cases were either; (1) still open; (2) dismissed; (3) closed and compensated; or (4) closed and not compensated. Cases were designated as still open if no SM report date was recorded on the file. The other categories were determined by the coding found in the SM recommendation variable. Table I presents the status of the cases used in this analysis by these four categories. For the analysis presented here, two classes of completed cases were defined. One class included all completed cases, compensated, not compensated and dismissed. A second class

excluded the dismissed cases. This applied mostly to the analysis involving linear models, to be discussed below.

Table I

SM Recommendation	N	% of Tot.
Not Completed	1728	73.6
Compensated	246	10.5
Not Compensated	94	4.0
Dismissed	279	11.9
Total	2347	100.0

Methods

The main thrust of this analysis was to describe the time its takes to complete a case. We also wanted to know what factors associated with these cases might account for changes or differences in these completion times. To do this, methods associated with the analysis of survival times were employed. Ordinarily, these methods are concerned with the time elapsed to the failure of a study element from some selected starting time. For this analysis, we defined a failure as the closing of a case. Thus, the survival time is the interval from when the case is first filed until one of our endpoints is reached. For the most part, this will be the special master report date.

To determine median times to completion, we obtained Kaplan-Meier (KM) estimates[1]. This analysis provides estimates of the time it takes for 50 percent of the cases to reach the end of the defined time interval using censored data. Censored data occurs because, as of Aug. 26, 1991, cases were still open and at varying points in the process. We do not know when these cases will close. This approach is necessary because any estimate that relies solely on completed cases will give biased estimates. The results are expressed as the median time to completion, in months, for all cases. The KM estimates were obtained using PROC LIFETEST from the SAS statistics package for personal computers[2].

To test the effects of concomitant variables on the time it takes to complete a case, Cox regression techniques for life table data are used[3]. These techniques take the form of what is known as proportional hazards (PH) regression models. Using the interval from when the claim was filed until the Special Master report date (The interval labeled FS in Figure A.) as an example, once a claim is filed, it is at "risk" of being settled (receiving a SM recommendation) at any time following the filing date. This risk of settlement can be a function of certain characteristics of the cases in the data set. For example, are pro se cases settled sooner or later than non pro se cases?

Is there a similar difference for cases where the patient died? And how does the interaction of these two variables (pro se and death of the patient) effect the time to settlement? The PH regression model allows us to put all of these variables into a single equation and attempt to determine the independent affect of each of these characteristics. For each of the characteristics, we will be estimating the relative increase in risk of settlement for those with the characteristic as opposed to those without the characteristic. If the value of the relative risk is greater than one, then the presence of the variable increases the hazard rate; that is, decreases the length of time to complete a case. If the value is less than one, then the variable is likely to decrease the hazard rate, or increase the length of time to complete a case.

The SAS statistical program PROC PHREG for the personal computer was used to fit these models[4]. With this proportional hazards model, the exponential of the coefficients gives the relative risk described above. The model also assumes that the risk is constant over the follow up period. To test for the significance of each variable (and the ensuing relative risk), Wald chi-square statistics[5] with the appropriate degrees of freedom are calculated. Given p values of less than 0.05 would indicate that the relative risk is significantly different from 1.0.

Results

The results presented in Table II indicate that 50 percent of the cases are completed within 15 months of the filing date. This is true whether or not dismissed cases are included. The data also indicate that most of this time appears to be absorbed in the early stages of the process, from the time the case is filed until the Internal or PHS report date.

Overall, the characteristics of the cases analyzed here do not seem to change the total time it takes to complete a case except in two areas. Table IV provides the KM estimates of the median time to completion for each of the characteristics separately, using the interval from the date filed to the SM report date. Where no data is indicated in the table, less than 50 percent of the cases were completed as of Aug. 26, 1991. The first from this generalization involves the pro se cases. When the dismissed cases are included, half the cases handled pro se are completed within 13 months. When the dismissed cases are excluded, this median time to completion increases to 18 months. These results would indicate that the pro se cases are handled differently. It is possible that they are dismissed sooner and when not dismissed, take longer to complete.

The second area of difference stems from the type of vaccine used. Those cases involving the intravenous polio vaccine (IPV) vaccine look to take longer to complete. The median time to completion is 20 months, with or without the dismissed cases.

Looking at Figure B, approximately 80 percent of the dismissed cases close within 10 months. This compares to about 39 percent of the closed cases. Ninety-nine percent of the open cases are younger than 21 months. This data would indicate that for the

cases found in the data set, the vast majority are being handled within the statutory limits of 32 months.

The results of the proportional hazards regression analysis (Table IV.) show that cases filed before 7/90 (variable B790) are more likely to be completed earlier (approximately 5 times more likely) than cases filed during the third quarter of 1990 (the referent category.) Conversely, cases involving the IPV vaccine are less likely to be settled earlier that cases involving the DTP vaccine (approximately a quarter as likely.) Both of these variables are statistically significant.

Including dismissed cases, all of the variables indicating when the case was filed are significantly related to the time it take to close a case. This is also true for type of vaccine (IVP compared to DPT) and pro se status. These results are essentially consistent with the univariate results presented in Table III. However, the multivariate model indicates that death is significantly related to the time to close a case. When the dismissed cases are excluded, death remains significant. When dismissed cases are excluded, only cases filed before July, 1990 take significantly shorter lengths of time to complete. Those cases associated with the IVP vaccine take significantly longer. The effect of pro se cases also becomes non-significant. Again an indication that pro se cases are probably more likely to be dismissed.

Table II

Median Time Between Intervals

From Date	To Date: Internal OGC Report	DOJ Report	Special Master Report
Date Filed	12	13	15
Internal OGC Report		3	11
DOJ Report			no data

(Dismissed cases included.)

From Date	To Date: Internal OGC Report	DOJ Report	Special Master Report
Date Filed	13	13	15
Internal OGC Report		3	11
DOJ Report			no data

(Dismissed cases excluded.)

Table III

Median Number of Months to Completion

	Dismissed Cases	
	Included	Excluded
All Cases	15	15
Period Filed		
Before 7/90	13	13
7/90-9/90	no data	no data
10/90-12/90	no data	no data
1991	no data	no data
Date Vaccine Administered		
Prior to 10/88	15	15
After 10/88	14	14
Patient Died		
Yes	14	14
No	15	15
Case is pro se		
Yes	13	18
No	15	15
Vaccination Type		
DPT	14	15
IPV	20	20
Measles	16	16
Other, Unkn.	37	no data

Figure A

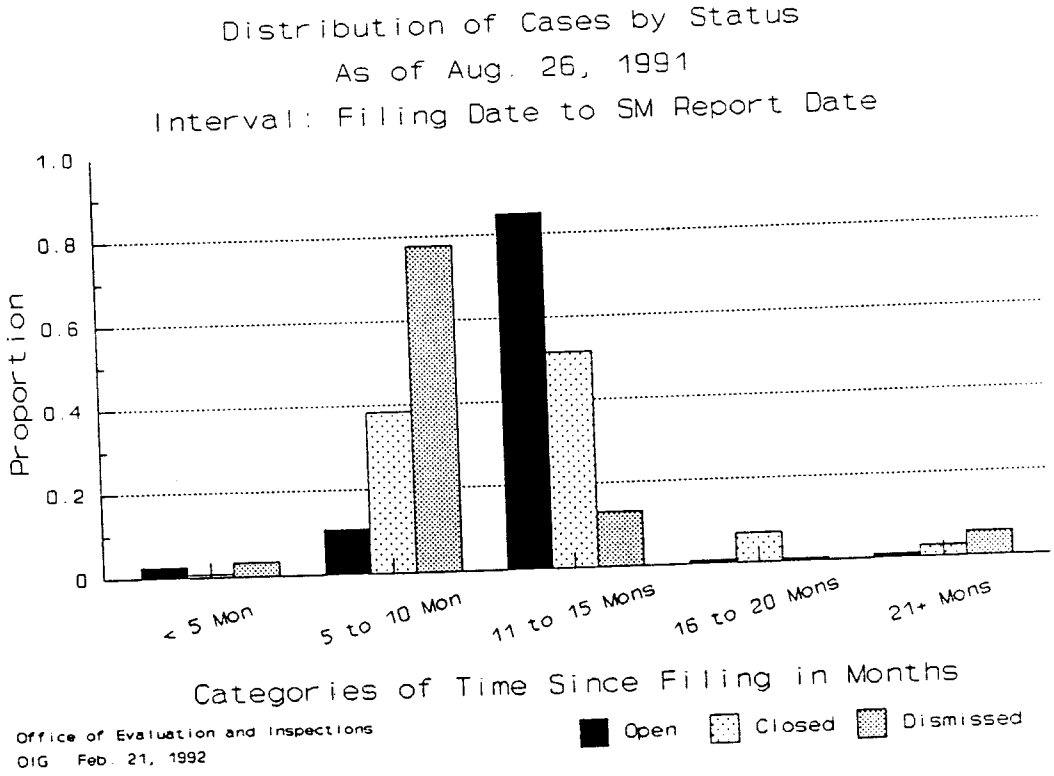

Distribution of Cases by Status
As of Aug. 26, 1991
Interval: Filing Date to SM Report Date
1.0
0.8
0.6
0.4
0.2
0
Proportion
< 5 Mon
5 to 10 Mon
11 to 15 Mons
16 to 20 Mons
21+ Mons
Categories of Time Since Filing in Months
Open
Closed
Dismissed
Office of Evaluation and Inspections
OIG Feb. 21, 1992

Table IV
Proportional Hazards Regression
Date Filed to Special Master Report Date
Dismissed Cases Included

Variable	Relative Risk	95% conf. int. Lower	Upper	p Value
Prospective Case	1.10	0.60	1.99	0.641
Case Filed before 7/90	5.17	4.03	6.62	<0.001
Case Filed 4th Qrt.,FY1990	4.79	3.70	6.20	<0.001
Case Filed During FY1991	14.40	6.79	30.53	<0.001
Patient Died	1.31	1.06	1.63	0.013
IPV Vaccine Given	0.25	0.17	0.35	<0.001
MMP Vaccine Given	0.76	0.58	0.99	0.045
Other Vaccine Given	0.98	0.59	1.64	0.949
PRO SE Case	3.05	2.44	3.81	<0.001
Claim Filed after 1/31/91	0.13	0.02	1.05	0.055

Dismissed Cases Excluded

Variable	Relative Risk	95% conf. int. Lower	Upper	p Value
Prospective Case	1.55	1.04	2.33	0.031
Case Filed before 7/90	5.26	4.02	6.87	<0.001
Case Filed 4th Qrt.,FY1990	1.26	0.80	1.98	0.319
Case Filed During FY1991	2.45	0.57	10.47	0.228
Patient Died	1.43	1.13	1.81	0.003
PV Vaccine Given	0.47	0.29	0.75	0.002
MMP Vaccine Given	0.75	0.52	1.08	0.125
Other Vaccine Given	1.47	0.46	4.71	0.514
PRO SE Case	1.47	0.95	2.28	0.084
Claim Filed after 1/31/91	0.89	0.08	9.93	0.924

Literature Cited

1. Kaplan, E.L. and Meier, P. 1958. Nonparametric estimation from incomplete observations. Journal of the American Statistical Association. 53:457-481.

2. SAS Institute Inc. 1988. SAS Technical Report: P-179 Additional SAS/STAT Procedures, Release 6.03. Cary, NC.

3. Cox, D.R. 1972. Regression models and life tables (with discussion). Journal of the Royal Statistical Society B. 34:187-220.

4. SAS Institute Inc. 1991. SAS Technical Report P-217, SAS/STAT Software: The PHREG Procedure, Version 6. Cary, NC.

5. Kalbfleisch, J.D. and Prentice, R.L. 1980. The Statistical Analysis of Failure Time Data, New York, John Wiley & Sons, Inc.

APPENDIX D

COMMENTS TO THE DRAFT REPORT

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date OCT 9 1992

RECEIVED 10/16/92

From Assistant Secretary for Health

Subject Office of Inspector General (OIG) Draft Report "The National Vaccine Injury Compensation Program: A Review"

To Acting Inspector General, OS

Attached are the Public Health Service comments on the subject OIG report. We agree that the changes recommended in this report would improve the management and increase the efficiency of the Vaccine Injury Compensation Program. Our comments describe the actions underway or planned to address these changes. In addition, we offer a series of technical comments for your consideration.

James O. Mason

James O. Mason, M.D., Dr.P.H.

Attachment

IG	
PDIG	
DIG-AS	
DIG-EI	V
DIG-OI	
AIG-MP	
OGC/IG	
EX SEC	V
DATE SENT	10/13

PUBLIC HEALTH SERVICE (PHS) COMMENTS ON THE OFFICE OF INSPECTOR GENERAL (OIG) DRAFT REPORT "THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM: A REVIEW," OEI-02-91-01460

OIG Recommendation:

The PHS, Department of Justice, and Claims Court should:

- o inventory the backlog (of petitions for compensation submitted to the U.S. Court of Claims) to set priorities and better estimate future resource needs,
- o further streamline the process,
- o use latest scientific evidence,
- o improve contacts with petitioners and their attorneys, and
- o emphasize use of annuities.

PHS Comments

While this recommendation is not directed specifically to PHS, we nevertheless concur that the recommended changes would improve the management and increase the efficiency of the Vaccine Injury Compensation Program (VICP). The PHS components involved in the VICP will continue to work with the Department of Justice and the Claims Court to resolve the retrospective cases as quickly as the availability of resources will permit and, concurrently, apply improved skills and techniques to maintaining the efficient processing of prospective cases.

The program has been working with a PHS Task Force on the VICP to change the Vaccine Injury Table and the Qualifications and Aids to Interpretation to reflect current science. The Task Force finalized its recommendations for changes to the Table and Aids after intensive review by several scientific and policy groups. The Office of Management and Budget recently approved these proposed revisions both as part of a Notice of Proposed Rulemaking and a legislative package.

We agree with the objective of the recommendation to improve contact with petitioners and their attorneys. However, PHS is limited by its role in the process. The Claims Court has the sole authority to assign cases for adjudication. As such, they should provide information to petitioners and their attorneys on the status of unassigned cases. PHS' Division of Vaccine Injury Compensation (DVIC) regularly receives calls from claimants or their attorneys on active cases and responds as information allows.

The DVIC has been working with the Advisory Committee on Childhood Vaccines' (ACCV) newly formed Subcommittee on Process.

This Subcommittee is responsible for seeking, receiving, and analyzing systematic feedback from interested parents' groups, petitioners' attorneys, and others on implementation of the VICP. The ACCV has also offered petitioners and their attorneys the opportunity to communicate concerns and suggestions for improving the process.

In addition to our comments on the recommendation, we suggest that two subjects be clarified in the final report. First, on pages 10 and C-4, the report indicates that the longest period of time for processing cases is the time from the date a claim is filed to the date of the Office of the General Counsel/PHS report. This incorrectly suggests that PHS is delaying the processing of claims. It would be more appropriate to track from the time the claim is filed to the date the Special Master assigns the case and schedules the respondent report date. OIG may not be able to determine this interval since this information is not in the program's database. Therefore, we suggest that the report simply indicate that the program does not begin to process cases until they are scheduled by the Court, and that is the reason for the delay.

The second clarification recommended would be to delete the sentence on page 19 regarding the need to better publicize the HHS Hotline telephone number. A lawsuit was filed, and subsequently withdrawn, charging that there was insufficient publicity for this special number. Even though this suit was withdrawn, the program has recently distributed a new poster along with a set of questions and answers regarding the program. These materials, which were developed to further inform vaccine administrators throughout the country about programmatic issues, include the 800-Hotline number.

Technical Comments

Page 2, first paragraph, first sentence. The words "Section 2110" should be replaced with "Subtitle 2 of Title XXI."

Page 2, first paragraph, second sentence. The following changes should be made:

- "Section 2110" should be replace by "Subtitle 2,"
- the phrase "by the 1988 and 1989 amendments," should be inserted after "1987," and

- the words "Health Information, Health Promotion, and" should be inserted before "Vaccine Injury Compensation Amendments of 1991."

Page 2, second paragraph, first sentence. The phrase "(in Subtitle 1 of Title XXI of the PHS Act)" should be inserted after "Act."

Page 2, second paragraph, second sentence. The phrase "(Section 2105 of the PHS Act)" should be inserted after "(NVAC)."

Page 2, second paragraph, last sentence. This sentence should be deleted from the final report.

Page 2, third paragraph, first sentence. The phrase "(Section 2119 of the PHS Act)" should be inserted after "Vaccines."

Page 3, Table I. Cells in the table should be revised as follows:

- for both the "retrospective" and "prospective" cells under "basis of awards," the words "of rehabilitative, and related" should be inserted between "medical expenses,"
- the "prospective" cell under "basis of awards" should be revised by adding "up to $250,000" after "pain and suffering," and
- the word "and loss of earnings" should be added at the end of footnote "***."

Page 5, second paragraph, first sentence. The word "entire" should be inserted before the phrase "...program if funding is insufficient."

Page 5, second paragraph, last sentence. The end of this sentence should be rewritten as follows: "...and the petitioner could then seek recourse only in the tort system."

Page 5, third paragraph, last sentence. A comma should be inserted after the word "million."

Page 5, fourth paragraph, first sentence. The beginning of this sentence should be revised as follows: "A Boston University professor recently completed...."

Page 9, second paragraph from bottom of page, first sentence. The words "and petitioner's counsel" should be inserted after "from DOJ and PHS."

Page 10, second paragraph from bottom of page, second sentence. This sentence should be rewritten as follows: "Once scheduled for review, the medium time for both retrospective and prospective cases to reach a special master decision is 15 months."

Page 10, second paragraph from bottom of page, third sentence. The words "date the case is scheduled by the Court" should be inserted in place of "PHS OGC report date."

Page 14, last paragraph, last sentence. Insert "PHS" in place of "VICP."

Page 15, second paragraph, last sentence. The sentence beginning "Representatives from HHS, DOJ and the Claims Court..." should be deleted since this is an inaccurate statement.

Page 17, first paragraph, first sentence. The words "the PHS Task Force has" should be replaced with "HHS and the Advisory Commission have."

Page 17, first paragraph, second sentence. The word "encephalopathy" and the comma after "seizure disorder" should be deleted.

Page 17, last paragraph. In the three places it is shown, "VICP" should be replaced with "PHS."

Page C-1, third paragraph, second sentence. In the two places it is shown, "OGC" should be replaced with "PHS."

Page C-4, third paragraph, last sentence. "OGC" should be replaced with "PHS."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

AUG 11 1992

TO: Bryan B. Mitchell
Principal Deputy Inspector General

FROM: Assistant Secretary
for Planning and Evaluation

SUBJECT: OIG Draft Report: "The National Vaccine Injury Compensation Program: A Program Review," OEI-02-91-01460 -- *COMMENTS*

Thank you for submitting for my review and comment the draft report on "The National Vaccine Injury Compensation Program: A Program Review." As you know, we and the Public Health Service (PHS) have been very interested in examining the Vaccine Injury Compensation Program (VICP) and looking for improvements in its operation. Your report was informative on these issues and will help as we proceed to propose changes. We suggest that upon completion of this report that it be made available to the Advisory Commission on Childhood Vaccines as its charge is to advise Secretary Sullivan on issues facing the VICP.

We do, however, have a technical comment. On page 16, the sentence discussing the Department of Justice (DOJ) proposal to provide for stronger corroboration of evidence should be modified to "HHS and DOJ support stronger corroboration of evidence requirements."

If you have any questions, please call Elise Smith on 690-6870.

Martin H. Gerry

cc: Michael Mangano

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington D.C. 20201

AUG 14 1992

TO: Bryan Mitchell
Acting Inspector General

FROM: Arnold R. Tompkins
Assistant Secretary for Management and Budget

SUBJECT: Comments on "The National Vaccine Injury Compensation Program: A Program Review"

We read with interest the above referenced draft report. As you know, there has been a good deal of interest in this program and its operations since its inception. There are several comments we believe would strengthen the report.

Executive Summary

- Both page i of the Executive Summary and page 9 of the report contain a section headed by "Cases are delayed due to a front-end backlog resulting from scheduling constraints and lack of resources." The primary cause of the backlog is the large unanticipated influx of cases filed around the statutory deadline. While admittedly, administrative resources did not match well with this influx, these resources *per se* were not the primary issue. Even if additional resources of this type were available and all cases had been processed immediately, the resources to pay this level of claims is neither authorized by law nor appropriated. This then, is the true limiting step.

- On page ii of the Executive Summary, the report states that "Respondents identify specific resources which they consider insufficient to handle the backlog." This is not a completely accurate statement. The program can and is handling the backlog, albeit at a rate slower than some of the respondents would prefer.

- On page i of the Executive Summary, the number of cases referred to in the last paragraph of the "Background" section is not consistent with the number of cases cited only two paragraphs later. Apparently the difference is attributable to the fact that the HHS data base does not include all cases. If so, are the cases not in the data base significantly different from the ones in the data base? This should be clarified.

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Updating For Most Current Information

- On page 8 of the findings section, the OIG raises the concern that "the program will only be able to complete one-third of the retrospective cases by the new deadline." This statement seems to fail to recognize the enactment of the Vaccine Injury Compensation Amendments of 1991. These amendments gave the petitioner the option of remaining in the program beyond the statutory deadline if that is the preference of the petitioner.

Recommendations

- We would suggest modifying the first recommendation regarding the need to set priorities to better estimate future resource needs. Given the fact that, without a change in law, resources are available only to compensate a portion of the retrospective cases annually, it is conceivable that it may take as long as seven or eight years to pay all retrospective claims. With this in mind, we believe the recommendation should be amended to ask that PHS, DoJ and the Claims Court to develop a methodology to compensate parties in an equitable manner. Those considering this recommendation might ask: Should the last claim filed be adjudicated and paid prior to one that was filed months before the filing deadline? How can claims be arranged to assure that a basic rule of fairness is applied to the timing of payments?

- Discussion about reasons why Special Masters overturn the recommendations of the government's medical and legal staff could be strengthened. In only one instance is an interview with a Special Master cited. To understand as clearly as possible why decisions are overturned, OIG should interview all Special Masters and attempt to quantify the reasons for disagreement. Understanding the reasons why government expert staff is successful in only fifty percent of the cases may suggest additional reforms.

- On page 18, some of the recommendations appear to be resolving non-existent problems or seem incompatible with each other. For example, recommendations include action to streamline the process. The first streamlining idea is to assure more complete filing of the petitions at the front end in order to avoid the backlog. However, the only backlog which has been experienced in the program is for the pre-1988 claims, not for the post-1988 claims. All pre-1988 claims have already been filed and it is expected that no additional pre-1988 claims will be accepted. Another streamlining recommendation is to "use past damages decisions as a basis for future ones." This appears to be incompatible with the recommendation to "use latest scientific information" to determine compensation. The OIG report recommends revisions to the vaccine injury table as

well as stronger "Aids to Interpretation" which are not consistent with how previous claims were determined.

RECOMMENDATIONS

The PHS, DOJ and Claims Court should:

Inventory the Backlog to Set Priorities and Better Estimate Future Resource Needs

The Claims Court, in consultation with PHS and DOJ, should evaluate the existing workload to determine which cases it should handle first, what mix of resources will be needed to handle them, and how best to handle more complicated cases. In particular, Claims Court staff attorneys could be added to identify priority cases and those likely to be dismissed. A medical review contract may be an option if more medical review expertise is required.

Our analysis of case characteristics and handling times (See Appendix C) indicates that some aspect of cases, such as whether the patient died, the type of vaccine used, when the case was filed, and whether it was handled pro se, affect the length of time to process the case. Perhaps these and other factors can be used to schedule the cases more efficiently or to help determine the expertise required.

Further Streamline the Process

To help make the process more expeditious and non-adversarial, the agencies should review the following ideas:

* Assure more complete filing of petitions, particularly medical evidence by giving more guidance to petitioners and their attorneys.
* Due to the scarcity of expert witnesses, have one objective expert witness per case appointed by the special master, as opposed to one for the petitioner and one for the government.
* Use past damages decisions as a basis for future ones.
* Process damages determinations more quickly.

Use Latest Scientific Information

The Department of Health and Human Services should support its Task Force's proposed legislation to revise the Vaccine Injury Table to reflect the latest scientific information available, such as the IOM study. The Aids to Interpretation should include sufficient detail so the table can be interpreted more consistently.

Improve Contact with Petitioners and their Attorneys

The program should designate a contact person in the Claims Court to respond to the questions and concerns of petitioners and their attorneys, especially those questions about cases not yet assigned.

Emphasize Use of Annuities

The special masters should continue using annuities as the primary settlement option in injury cases.

COMMENTS

Comments on the draft report received from PHS; the Assistant Secretary for Policy and Evaluation and the Assistant Secretary for Management and Budget (ASMB) generally concur with the recommendations of this report. However, PHS pointed out that its role in the process is a limited one. We agree. We have directed our recommendations to the DOJ and the Claims Court as well as PHS. Suggestions for changes in the wording, clarifications of the text and any technical changes have for the most part been incorporated into the final report. The actual comments received are in Appendix D.

The PHS stated that the report incorrectly suggests that PHS is delaying the processing of claims because we did not track the date the claim is filed to the date the special master assigns and schedules the case. We are aware that delays were experienced from the time of the case filing to scheduling. However, those dates are not included in the program's database. We thus were unable to include it in our analysis.

Lastly, ASMB stated that the true limiting step of the program is that the resources to pay the level of claims submitted are neither authorized by law nor appropriated. We understand their point. We nevertheless believe that a more effective process can shed light on the extent of the problem and the true extent of the resources needed. In response to ASMB's recommendation to develop a methodology to compensate parties in an equitable manner, we note that this was not within the scope of the inspection. The ASMB also observed that since all retrospective cases have been filed at this time, the recommendation to assure more complete filing of petitions at the front end, and to give more guidance to petitioners and their attorneys is not necessary. However, many retrospective cases require additional information after the initial filing. To clarify matters we have eliminated the phrase "at the front end" from the recommendation.