

December 1999

# VACCINE INJURY COMPENSATION

## Program Challenged to Settle Claims Quickly and Easily



G A O

Accountability \* Integrity \* Reliability

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**Health, Education, and  
Human Services Division**

B-281968

December 22, 1999

The Honorable James M. Jeffords  
Chairman, Committee on Health,  
Education, Labor and Pensions  
United States Senate

Dear Mr. Chairman:

Infectious diseases are responsible for nearly half of all deaths worldwide of people under the age of 44. In the United States, vaccinating children against such diseases is considered to be one of the most effective public health initiatives ever undertaken. Since vaccination programs began, the number of people contracting vaccine-preventable diseases in the United States has been reduced by more than 95 percent. In some instances, however, a vaccine can have severe side effects, including death or disabling conditions requiring lifetime medical care. In the 1980s, lawsuits stemming from such incidents threatened to affect the availability and cost of vaccines as well as the development of new ones.

To address this issue, the Congress, beginning in 1986, created a different approach for compensating people injured by certain vaccines routinely provided in childhood. Instead of suing vaccine manufacturers and vaccine administrators, people—including adults—who believe they have been injured by these vaccines must first file a claim under the Vaccine Injury Compensation Program (VICP).<sup>1</sup> VICP contains a vaccine injury table, which is designed to minimize difficulties petitioners have in proving that their injury resulted from a vaccine. The injuries listed on this table are presumed to have been caused by certain vaccines, unless the government can prove otherwise. By contrast, in a lawsuit filed under the civil tort system, the injured party bears the burden of proving that the vaccine caused injury.

Administered by the Department of Health and Human Services (HHS), the program pays claims from a trust fund supported by an excise tax on each dose of vaccine that is covered by the program.<sup>2</sup> As of February 1999, 5,355

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<sup>1</sup>When VICP became effective in October 1988, it covered vaccines required for immunizing children against seven infectious childhood diseases: diphtheria, pertussis (whooping cough), tetanus, polio, measles, mumps, and rubella (German measles). Vaccines against hepatitis B, hemophilus influenzae type b (Hib), and varicella (chicken pox) were added to the program in August 1997; and a vaccine against rotavirus was added, effective October 1998.

<sup>2</sup>Claims arising from vaccinations administered prior to October 1, 1988, are paid from general fund appropriations.

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claims had been filed under VICP and close to \$1 billion had been awarded since October 1988, when the program became effective. The majority of claims filed and compensation paid have been for neurological injuries associated with the DTP (diphtheria, tetanus, and pertussis) vaccine.

Although VICP was created to provide compensation “quickly, easily, with certainty and generosity,”<sup>3</sup> there is debate surrounding how well the program meets this purpose. Some contend that the claims process takes too long and that recent changes to the program’s vaccine injury table make compensation too difficult to obtain. Another concern is the VICP trust fund, which had a balance of \$1.3 billion at the end of fiscal year 1998 and has been collecting much more than it pays out in claims. To help with congressional oversight of the management and financing of the program, you asked us to determine

- how long it takes to process a claim through VICP;
- the extent that recent changes to the program’s injury table have made it easier or more difficult for petitioners to obtain compensation for vaccine-related injuries; and
- why the trust fund continues to grow, and what budgetary effect proposed options for addressing the growing trust fund balance would have.

Our work included analyses of claims data from HHS’ VICP database from the inception of the program to February 1999. We supplemented our analyses with interviews and information from the federal agencies responsible for the VICP claims process and financial accounting of the VICP trust fund, petitioner advocates, members of the scientific community, and a pediatric physician professional organization. (See app. I for more on our scope and methodology.) We conducted our work from January through November 1999 in accordance with generally accepted government auditing standards.

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## Results in Brief

Overall, while the program appears to provide an easier process for obtaining compensation than the traditional civil tort system, the process has not been as quick or as easy as expected. Processing most VICP claims takes more than 2 years. The Congress expected the program to process claims in 1 year or less, but only about 14 percent of claims met this expectation. In 1988 and 1989, the program received about 200 claims and processed nearly all of them within 2 years. But in 1990, when a filing

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<sup>3</sup>Report of the House Committee on Energy and Commerce accompanying the legislation establishing VICP, H.R. Rep. No. 99-908, p. 3 (1986).

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deadline neared for injury claims relating to vaccinations received before October 1988, the number of claims filed jumped to over 3,200. This influx created an immediate and large backlog of claims, which HHS is still working to resolve. Another factor significantly increasing processing times is that as the program received additional funding for staff and experts to defend claims, the government increasingly challenged claims in which the cause of injury was in doubt. As a result, petitioners needed more information and time to prepare cases, which resulted in processing times that were much longer than envisioned when the program began.

HHS' recent changes to the vaccine injury table will make the process easier for some people to obtain compensation, but will make it more difficult for a larger number to do so. This is because far more claims have historically been associated with injuries HHS removed from the table than with injuries HHS added to it. For example, about half of the awards made since the program's inception have been for neurological injuries that HHS later removed from the table in 1995 and 1997. Removing these injuries shifts the burden of proof to the petitioner, making it more difficult to qualify for compensation under VICP. HHS based its decisions to add or remove table injuries on various factors but did not have a clear and transparent methodology to demonstrate that these factors were consistently applied for each injury table change. Without such transparency, changes that make compensation more difficult for petitioners may continue to be questioned by some, regardless of their merit. We are making a recommendation to HHS to develop and apply a consistent methodology for its decisionmaking process for making changes to the vaccine injury table.

The VICP trust fund has grown to \$1.3 billion, primarily because the income from vaccine excise taxes has been higher than payments for claims and associated administrative costs and interest has been accruing on the fund balance. The excess tax revenue—\$948 million, as of 1998—has been loaned to the Treasury and used for other federal programs and activities. Vaccine manufacturers, federal agencies, and petitioner advocates have expressed concerns about the rising balance and have proposed options to decrease the vaccine excise tax or increase trust fund spending. Exercising these options, however, would have implications for the overall federal budget, possibly requiring new or higher taxes elsewhere or a decrease in spending for other programs and activities.

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## Background

All 50 states require that virtually all children be vaccinated against common childhood diseases before they enter school,<sup>4</sup> and HHS reports that over 12 million vaccinations are given to children each year. These laws have dramatically reduced many infectious diseases in the United States. For example, the number of reported cases of measles, which can lead to brain damage and death, has dropped from about half a million in 1960 to about 100 in 1998. For most children, freedom from the effects of measles, diphtheria, polio, tetanus, pertussis, and other diseases is a decided benefit. But immunization programs also carry a human cost. A small number of children who receive immunizations have serious and unexpected reactions to them. These reactions can be devastating—paralysis, permanent disability, and even death. Affected families without adequate insurance coverage may face significant expenses, because the costs for residential or home care, therapy, medical equipment, and drugs needed to care for an injured child over a lifetime can exceed several million dollars. Prior to VICP, families could seek compensation for damages only through the civil tort system or through a settlement agreement with the vaccine manufacturer or health care provider.

Filing a lawsuit in the civil tort system was considered to be unsatisfactory for those claiming to have suffered an adverse reaction to a vaccine. Petitioners had difficulty proving vaccine-related injuries because studies and medical evidence needed to definitively link vaccines with various medical conditions were often insufficient to establish the level of proof required for compensation in the legal system.<sup>5</sup> Establishing this link can be difficult because most injuries that can be caused by vaccines can be caused by other things as well. For example, symptoms of neurological disorders often show up in the first year of life, which is the same time that most vaccines are administered.

Petitioners are not the only ones who found the legal system difficult. As the number of lawsuits increased, particularly for the DTP vaccine, vaccine manufacturers became concerned not only with problems of time and expense but also with the availability and affordability of product liability insurance. The federal government, in turn, became concerned that if

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<sup>4</sup>States generally require vaccination against each of the original seven childhood diseases covered by the program, but there is some variation. Six states, for example, do not require the pertussis vaccine and six others do not require the mumps vaccine.

<sup>5</sup>For example, the Institute of Medicine studied 75 specific relationships between vaccines and adverse events and concluded that medical evidence was insufficient to prove or disprove a relationship in two-thirds of the cases. See a discussion of Institute of Medicine studies in *Research Strategies for Assessing Adverse Events Associated With Vaccines: A Workshop Summary* (National Academy Press, 1994).

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manufacturers withdrew from the market, vaccine shortages would result and infectious diseases would reemerge as serious health threats.

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### VICP Represented a New Approach to Injury Compensation

VICP established a new system for vaccine injury compensation that was expected to be fair, simple, and easy to administer. Rather than filing a lawsuit against the vaccine manufacturer or vaccine administrator in the civil tort system, an individual claiming injury from vaccines covered by the program must first file a petition for “no-fault” compensation with the U.S. Court of Federal Claims.<sup>6</sup> Special masters of the court—attorneys appointed by the judges of the court—conduct informal hearings as necessary to determine whether the petitioner is entitled to compensation from VICP, and if so, how much. HHS, as overall administrator of VICP, is represented by Department of Justice (DOJ) attorneys, while the petitioner may be represented by a private attorney.<sup>7</sup> (See app. II for a description of the claims process.)

To ensure access to the program, VICP pays attorney fees and costs for the petitioner, regardless of whether the petitioner is awarded compensation.<sup>8</sup> VICP features designed to expedite the process include a relaxation of the rules of evidence, discovery, and other legal procedures that can prolong cases in the legal system. Features designed to control costs include a legislated \$250,000 payment for compensable deaths. For compensable injuries, the program purchases annuities covering the lifetime costs of care not covered by insurance and compensates for pain and suffering and lost wages. VICP does not pay punitive damages. Compensation is available for reasonable attorney fees and costs, which generally reflect the actual time and expense devoted to the case.

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### Program’s Injury Table Is Its Most Important Feature

There are two ways a petitioner can qualify for compensation under VICP. Similar to the civil tort system, petitioners must be able to prove that a vaccine caused an injury or, unique to VICP, the petitioner must have an injury listed on the program’s injury table. The number of vaccines and injuries listed on the table have changed over time. Legislation establishing

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<sup>6</sup>Lawsuits may be filed against manufacturers or health care providers if a petition is dismissed or judged noncompensable under VICP and the judgment is rejected by the petitioner, if the award granted by VICP is rejected by the petitioner, or if the vaccine is not covered under VICP.

<sup>7</sup>The vaccine manufacturer and whoever administered the vaccine are not involved as parties to the proceedings.

<sup>8</sup>Attorney fees and costs are paid if the court determines there is a reasonable basis for the petition and the petition was filed in good faith.

the original injury table included five different medical conditions related to vaccines against seven diseases (see table 1).

**Table 1: Original Vaccine Injury Table**

| <b>Vaccine and injury<sup>a</sup></b>                                  | <b>Time period<sup>b</sup></b> |
|--|--------------------------------|
| <b>Vaccines against diphtheria,<sup>c</sup> tetanus, and pertussis</b> |                                |
| Anaphylaxis  | 24 hours                       |
| Residual seizure disorder  | 3 days                         |
| Shock-collapse <sup>d</sup>  | 3 days                         |
| Encephalopathy   | 3 days                         |
| <b>Vaccines against measles, mumps, and rubella</b>                    |                                |
| Anaphylaxis  | 24 hours                       |
| Residual seizure disorder  | 15 days                        |
| Encephalopathy   | 15 days                        |
| <b>Vaccines against polio</b>  |                                |
| Paralytic polio <sup>e</sup>   | 30 days/6 months <sup>f</sup>  |
| Anaphylaxis <sup>g</sup>   | 24 hours                       |

Note: For current vaccine injury table, see app. III.

<sup>a</sup>Injuries are defined in "Qualifications and Aids to Interpretation," reprinted in app. III.

<sup>b</sup>For first symptom, onset, or aggravation of injury after vaccination.

<sup>c</sup>Administered with tetanus and/or pertussis vaccines.

<sup>d</sup>For vaccines against pertussis.

<sup>e</sup>Injury related to oral polio vaccine.

<sup>f</sup>Time intervals are for immunocompetent/immunodeficient individuals who receive oral poliovirus. Contact cases have no limit.

<sup>g</sup>Injury related to inactivated polio vaccine.

**Filing a claim using the injury table relieves petitioners from some of the uncertainty caused by gaps in medical knowledge. Under VICP, vaccines on the injury table are presumed to have caused the listed injury if incurred within specific time periods. For example, under the original table, someone suffering neurological damage from seizures within 3 days after receiving a vaccine against pertussis would receive compensation if HHS could not prove that the condition was due to factors unrelated to the administration of the vaccine. Thus, for the petitioner, VICP's injury table may provide a benefit over the civil tort system.**

## Funding for Compensation Has Come From Two Sources

VICP finances awards and attorney payments differently, depending on when the vaccine causing the alleged injury was administered. For vaccines administered prior to October 1, 1988, payments are made from general revenues appropriated by the Congress each year. For vaccines administered on or after this date, payments are made from the VICP trust fund, which is supported by a \$.75 excise tax on each dose of vaccine sold<sup>9</sup> and interest accumulating on the trust fund balance. As of February 1999, VICP had paid close to \$1 billion for awards and attorney payments—75 percent from appropriated general funds rather than from the trust fund (see table 2).

**Table 2: Financing for VICP Claim Payments**

| VICP claims                                    | Filing deadline  | Funding source        | Number of claims filed as of Feb. 1999 | Awards/ attorney payments <sup>a</sup> as of Feb. 1999 |
|--|--|-----------------------|--|--|
| Vaccines administered prior to Oct. 1, 1988    | Jan. 31, 1991  | Annual appropriations | 4,245                                  | \$742,244,679  |
| Vaccines administered on or after Oct. 1, 1988 | Within 24 months from date of death or 36 months from date of injury | Vaccine excise tax    | 1,110 <sup>b</sup>                     | 250,296,568  |

<sup>a</sup>The maximum award paid was close to \$8 million while the median paid was \$318,943.

<sup>b</sup>Includes five cases where the data field for date of vaccination was blank.

## Processing VICP Claims Takes Longer Than Expected

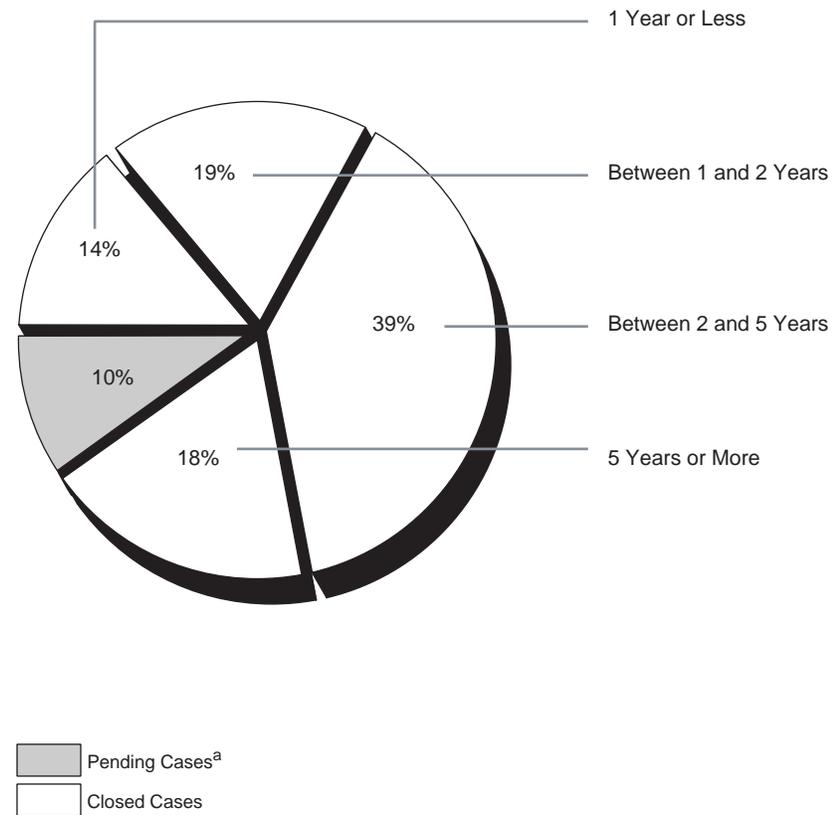
Processing VICP claims continues to take longer than expected. When the Congress established VICP, the expectation was that the court would take 1 year or less<sup>10</sup> to judge whether a claim was entitled to compensation and, if so, how much that compensation would be. The program became effective on October 1, 1988, and as of February 1999, 5,355 claims had been filed. Of this number, about 14 percent received judgment within 1 year (see fig. 1). Most did not receive judgment within 2 years. Of the total

<sup>9</sup>This uniform rate of taxation became effective Aug. 6, 1997 (P.L. 105-34). Prior to this date, the excise tax rate varied by vaccine in accordance with the expected compensation payments associated with each covered vaccine.

<sup>10</sup>The original legislation required a judgment on claims no later than 365 days after the claim was filed. This was subsequently amended to require a judgment by the special master within 240 days exclusive of suspended time. Either party may appeal the decision to a judge of the court, which would add time to the process. (See app. II.) If the special master fails to make a decision within 240 days or if appealed and a judgment is not rendered within 420 days, petitioners are allowed to withdraw from VICP and sue the manufacturer or health care provider directly.

claims filed during this period, 10 percent had not received a judgment as of February 1999 and remained open.

Figure 1: Status of VICP Claims



Note: Data are for cases filed as of February 1999.

<sup>a</sup>The length of time pending cases had been in process ranged from less than 1 month to more than 8 years.

Two interrelated reasons are central to explaining these longer than expected processing times. The first was a large influx of claims filed a few years after the program began. The second was that as more funding became available to defend claims, HHS increasingly challenged the ones it regarded as not clearly meeting the statutory criteria.

## Delays Due to Volume

When VICP took effect on October 1, 1988, it gave claimants 2 years and 4 months (until January 31, 1991) to file claims on injuries for vaccines administered prior to October 1988. As people began responding to the deadline, the number of claims filed under VICP jumped from 125 claims in 1989 to 3,263 claims in 1990. Nearly 800 more claims were filed in the month before the deadline. As table 3 shows, this large influx of claims created an immediate backlog. The number of pending claims rose to as high as 3,548 at the end of 1991 and remained above 1,000 until the end of 1995.

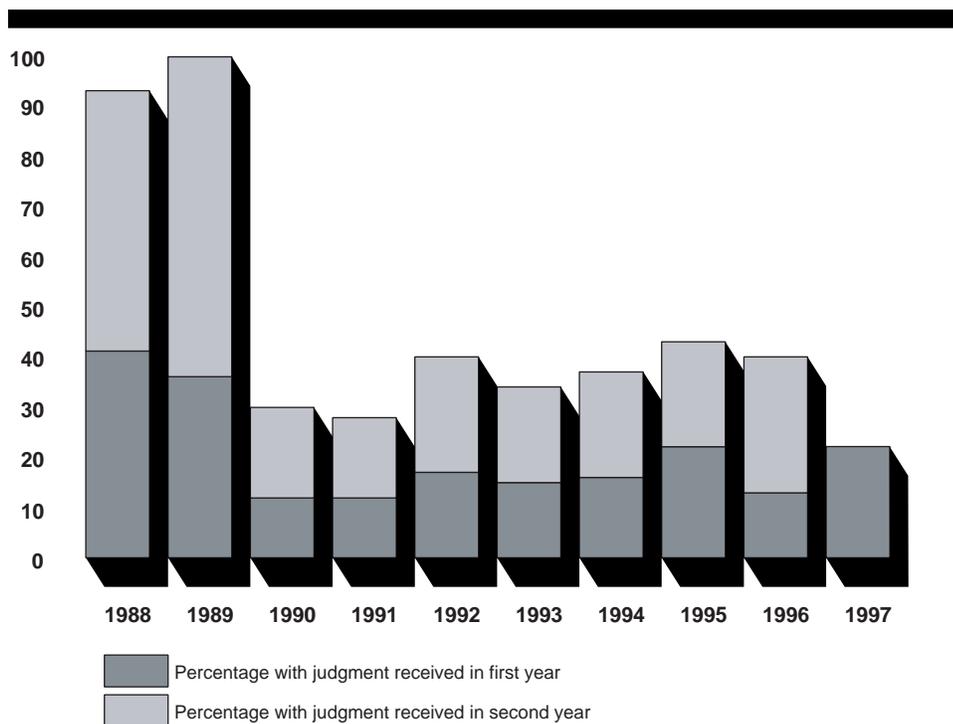
**Table 3: VICP Claims Filed, Adjudicated, and Pending, by Calendar Year**

| Year              | Claims filed | Claims adjudicated | Claims pending |
|-------------------|--------------|--------------------|----------------|
| 1988              | 79           | 0                  | 79             |
| 1989              | 125          | 61                 | 143            |
| 1990              | 3,263        | 153                | 3,253          |
| 1991              | 968          | 673                | 3,548          |
| 1992              | 174          | 735                | 2,987          |
| 1993              | 119          | 637                | 2,469          |
| 1994              | 121          | 612                | 1,978          |
| 1995              | 164          | 707                | 1,435          |
| 1996              | 92           | 573                | 954            |
| 1997              | 107          | 332                | 729            |
| 1998              | 131          | 309                | 551            |
| 1999 <sup>a</sup> | 12           | 25                 | 538            |
| <b>Total</b>      | <b>5,355</b> | <b>4,817</b>       |                |

<sup>a</sup>Data as of February 1999.

As might be expected, processing times began to increase as HHS worked to respond to the influx of claims. Before 1990, nearly all claims were processed within 2 years. Starting in 1990, however, only about 30 to 40 percent of claims filed each year have been processed this quickly (see fig. 2).

**Figure 2: Percentage of Claims Filed in Calendar Years 1988 to 1997 With Judgment Received Within 2 Years**



Note: Second-year data for 1997 are incomplete. In addition, only data for 1988 through 1991 include claims for vaccinations given prior to October 1988 because the filing deadline for such claims was January 31, 1991. Data for 1992 through 1997 include claims for vaccinations on or after October 1988.

### Delays Due to Change in Program Implementation

As figure 2 shows, the percentage of claims processed within 1 or 2 years changed somewhat from year to year but has not increased much since 1992. Although table 3 shows that the number of claims filed since the 1991 deadline dramatically decreased, the number of claims adjudicated generally declined in following years. A key reason is because in 1990, HHS and DOJ began to increasingly scrutinize claims of vaccine injury as funding to fully implement their legislated authority under the program became available. DOJ established a cadre of attorneys specializing in vaccine injury to represent HHS in hearings, and HHS established an expert witness program to help assess whether alleged vaccine injuries such as seizure disorders may have been present from birth or were due to other causes.

Full implementation of HHS' statutory authority to defend claims had implications for claims processing times, making it more difficult for

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claims to be processed within the 1-year period originally envisioned or even a 2-year period. For example, HHS data show that more than half of all petitioners were requested to provide supplementary medical records or other information, and most took at least a year to do so. Both sides often made use of expert witnesses to review the evidence and report on their findings. After all the information was received, in most cases, it took the court over another year to reach its decision.

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## Steps Taken to Expedite Claims Processing

HHS, DOJ, and the U.S. Court of Federal Claims have taken some steps to expedite the claims process, including the following:

- Since 1990, HHS has cut its average time for completing its medical review and submitting its recommendation to the court from nearly 6 months<sup>11</sup> to about 3 months.
- In 1990, the court produced a guide for petitioners and their attorneys explaining how to process claims through VICP, and in 1994, DOJ published steps to expedite the resolution and payment of compensation and attorney fees.
- Starting in the fall of 1997, the court initiated a practice of holding conference calls between the special masters and attorneys within 30 to 45 days after the filing of a petition to discuss any deficiencies in the petition, such as absence of pertinent medical records, and ways to remedy them.<sup>12</sup>

The chief special master said that while the court could process claims more quickly, delays are granted primarily to benefit petitioners who need more time to gather information, have medical tests performed, or identify costs related to an injured child's developmental needs. If a judgment is not received within 240 days, petitioners can withdraw their claim from VICP and file a lawsuit in the civil tort system. Yet HHS, DOJ, and court officials stated that none have done so.

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<sup>11</sup>Data for 1990 are for claims relating to vaccines administered after Sept. 30, 1988. The 1990 average for all claims is over 2 years.

<sup>12</sup>For example, DOJ states that where appropriate, it will subpoena medical records on behalf of the petitioner.

## Injury Table Changes May Increase Difficulty Petitioners Face in Obtaining Compensation for Vaccine-Related Injuries

Of the 4,817 petitioners receiving judgment under the program as of February 1999, close to 30 percent received compensation for a family member’s injury or death. Most compensated claims alleged injuries listed on the program’s vaccine injury table. Since the program began, HHS has made two sets of changes to the table, removing some injuries and adding other injuries and vaccines. However, far more claims are associated with injuries removed from the table than with injuries that were added. As a result, more petitioners now must prove that a vaccine caused the injury, rather than HHS having to prove that the injury was due to factors unrelated to the vaccine.

## Number of Petitioners Potentially Covered by the Vaccine Injury Table Has Decreased

Most of the petitioners who filed claims and received awards under VICP alleged injuries listed on the program’s vaccine injury table. Petitioners who did not claim injuries listed on the injury table—about 28 percent—had the burden of proving that a vaccine caused the injury; of these petitioners, only 13 percent were able to obtain compensation. The remaining 72 percent claiming injuries on the table had compensation rates nearly three times higher.

**Table 4: VICP Petitions Claiming Table/Off-Table Injuries**

| Vaccine   | Percent table claims |              | Percent off-table claims |              |
|---|----------------------|--------------|--------------------------|--------------|
|   | Filed                | Compensated  | Filed                    | Compensated  |
| Vaccines against diphtheria, tetanus, and pertussis | 83                   | 32           | 17                       | 15           |
| Vaccines against measles, mumps, and rubella        | 53                   | 43           | 47                       | 25           |
| Vaccines against polio                              | 39                   | 60           | 61                       | 3            |
| Vaccines against hepatitis B                        | 7                    | <sup>a</sup> | 93                       | <sup>a</sup> |
| Vaccines against varicella                          | 0                    | <sup>b</sup> | 100                      | <sup>a</sup> |
| Unspecified/nonqualifying                           | 0                    | <sup>b</sup> | 100                      | 0            |
| <b>Total</b>  | <b>72</b>            | <b>35</b>    | <b>28</b>                | <b>13</b>    |

<sup>a</sup>Judgment pending.

<sup>b</sup>Not applicable.

Under the act that created VICP, HHS has rulemaking authority to change the injury table and has done so on two occasions. The act established the first injury table, with HHS to make future changes as more information became available. The act further called for the Institute of Medicine, of the National Academy of Sciences, to assist HHS in this regard by reviewing existing medical studies and literature related to a set of specific

conditions that might be related to vaccines covered by the program. After the reviews were completed in 1991 and 1994, the Institute of Medicine identified certain conditions that were consistent or inconsistent with a causal relationship, those that favored or did not favor a causal relationship, and those where evidence was insufficient to indicate the presence or absence of a causal relationship.<sup>13</sup> HHS used these findings—in conjunction with public policy considerations provided by the Advisory Commission on Childhood Vaccines, scientific issues raised by its National Vaccine Advisory Committee, and input from the public—to add seven injuries and remove three others from the table in 1995 and 1997 (see table 5).<sup>14</sup> In addition, HHS refined the supporting guidance to the table, “Qualifications and Aids to Interpretation.” This document provides definitions for injuries and the specific circumstances under which the table injuries must occur (see app. III for the current injury table and interpretation aids).

**Table 5: Injuries Added to and Removed From the VICP Vaccine Injury Table**

| Vaccine   | Injury added   | Injury removed            |
|---|--|---------------------------|
| <b>Effective Mar. 10, 1995</b>                      |  |                           |
| Vaccines against pertussis                          |  | Shock-collapse            |
| Vaccines against pertussis and tetanus              |  | Residual seizure disorder |
| Vaccines against rubella                            | Chronic arthritis                                      |                           |
| <b>Effective Mar. 24, 1997</b>                      |  |                           |
| Vaccines against measles, mumps, and rubella        |  | Residual seizure disorder |
| Vaccines against measles                            | — Thrombocytopenic purpura<br>— Vaccine-strain measles |                           |
| Vaccines against polio <sup>a</sup>                 | Vaccine-strain polio                                   |                           |
| Vaccines against hepatitis B                        | Anaphylaxis  |                           |
| Vaccines against hemophilus influenzae type b (Hib) | Early-onset Hib  |                           |
| Vaccines against tetanus                            | Brachial neuritis                                      | Encephalopathy            |

<sup>a</sup>Applies to oral polio vaccine.

<sup>13</sup>Most conditions fell in the third category, as the Institute of Medicine concluded that there was insufficient medical evidence to prove or disprove a relationship between vaccines and two-thirds of the 75 medical conditions studied.

<sup>14</sup>HHS publishes the proposed and final rules of injury table changes in the Federal Register. HHS must allow 180 days for public comment on a proposed rule. HHS must also provide 90 days for review of proposed rule by the Advisory Commission on Childhood Vaccines, comprised of parents of injured children, health professionals, and attorneys appointed by HHS. The National Vaccine Advisory Committee is comprised of representatives from state and local health departments, vaccine companies, academia, and consumer groups.

Although HHS added more injuries than it removed from the original injury table, fewer petitioners now have the potential to use it. Where 74 percent of petitioners filed claims alleging injuries on the injury table prior to the 1995 and 1997 changes, only 55 percent filed such claims after the table was revised.<sup>15</sup> To some extent, this decrease is because more claims were associated with the injuries removed from the table than were associated with the injuries that were added. Significantly, as shown in table 6, about 45 percent (611) of the 1,368 claims awarded compensation under VICP were for injuries subsequently removed from the table. These claims accounted for about half of the \$974 million awarded thus far under the program. These numbers are significant because petitioners with injuries not listed on the injury table historically have had a lower probability of being compensated than those with injuries that were listed.

**Table 6: Claims Associated With Injuries Added to and Removed From the VICP Vaccine Injury Table**

| Vaccine   | Injury                    | Claims for injuries added to injury table |               | Claims for injuries removed from injury table |               |
|---|---------------------------|---|---------------|---|---------------|
|   |                           | Number compensated                        | Total awarded | Number compensated                            | Total awarded |
| Vaccines against rubella  | Chronic arthritis         | 9   | \$622,101     | a   | a             |
| Vaccines against tetanus  | Brachial neuritis         | 0   | 0             | a   | a             |
| Vaccines against measles  | Thrombocytopenic purpura  | 0   | 0             | a   | a             |
| Vaccines against measles  | Vaccine-strain measles    | 0   | 0             | a   | a             |
| Vaccines against polio  | Vaccine-strain polio      | 0   | 0             | a   | a             |
| Vaccines against hepatitis B  | Anaphylaxis               | 0   | 0             | a   | a             |
| Vaccines against hemophilus influenzae type b (Hib)                                       | Early-onset Hib           | 0   | 0             | a   | a             |
| Vaccines against pertussis  | Shock-collapse            | a   | a             | 61  | \$27,228,905  |
| Vaccines against measles, mumps, pertussis, rubella, and tetanus                          | Residual seizure disorder | a   | a             | 547   | 452,141,726   |
| Vaccines against tetanus  | Encephalopathy            | a   | a             | 3   | 529,074       |
| <b>Total claims compensated/amounts awarded for injuries added/removed from the table</b> |                           | 9   | \$622,101     | 611   | \$479,899,705 |
| <b>Percent of all claims compensated/amounts awarded</b>                                  |                           | 0.7                                       | 0.0           | 44.7  | 49.3          |

<sup>a</sup>Not applicable.

<sup>15</sup>The actual percentages of claims qualifying as table injuries are lower due to restrictions in the definition of an injury or time of onset listed in "Qualifications and Aids to Interpretation." (See app. III.)

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## Lack of Clear Methodology for Table Changes Raises Questions of Consistency

HHS has published its rationale for each revision to the injury table in the Federal Register but has not published an overall method of applying the criteria it uses in conjunction with the Institute of Medicine findings. Because HHS' modifications of the table determine whether the government or petitioner has the burden of proof for affected claims, table changes that make compensation more difficult for petitioners have been questioned by some. Defining the criteria related to the level of program and financial risk that the government will bear is controversial and there is disagreement about what the Congress intended in this regard. For example, HHS interprets the legislative history as directing it to recognize table injuries where there is definitive information linking vaccines to injuries, while others cite the same legislative history as directing that, until definitive information is available, the benefit of doubt should remain with the petitioner.

Particularly because of these differences, establishing a clearly defined, transparent decisionmaking process is important to help advance the appearance of fairness. HHS has not produced such a methodology, and its actions do not always convey a sense of consistency, as illustrated in the following examples:

- The Institute of Medicine found that existing scientific evidence favored acceptance of a causal relationship between tetanus vaccines and brachial neuritis, and HHS added that condition to the injury table. On the other hand, the Institute also found evidence of a causal relationship between the tetanus and oral polio vaccines and Guillain-Barre syndrome, but HHS did not add this condition to the injury table.
- The Institute of Medicine found the evidence inadequate to accept or reject a causal relation between vaccines and residual seizure disorder, and HHS removed this condition from the injury table. The Institute also found evidence inadequate to accept or reject a causal relation between the measles and mumps vaccines and encephalopathy, yet HHS left this condition on the injury table.<sup>16</sup>

HHS stated in the Federal Register that decisions not to add injuries, such as Guillain-Barre syndrome, or to remove injuries, such as residual seizure disorder, were based to some extent on the level of risk in compensating an inordinate number of non-vaccine-related cases for the extremely rare vaccine-related case. In applying this criterion, however, HHS' assumptions about the number of potential claims and thresholds for deciding the

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<sup>16</sup>HHS narrowed the definition of encephalopathy in the "Qualifications and Aids to Interpretation," which would preclude use of the table for some petitioners.

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reasonable level of financial risk for compensating non-vaccine-related injuries were not defined.

---

## Trust Fund Income Exceeds Need for Claims Payments

The VICP trust fund has grown to \$1.3 billion primarily because the income from vaccine excise taxes is higher than claims payments and because the government pays interest on the trust fund balance. Program participants have expressed concerns about the rising balance and have proposed options to address them. Exercising these options, however, would have implications for the overall federal budget, possibly requiring new or higher taxes elsewhere or a decrease in spending for other federal programs and activities.

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## VICP Trust Fund Continues to Grow

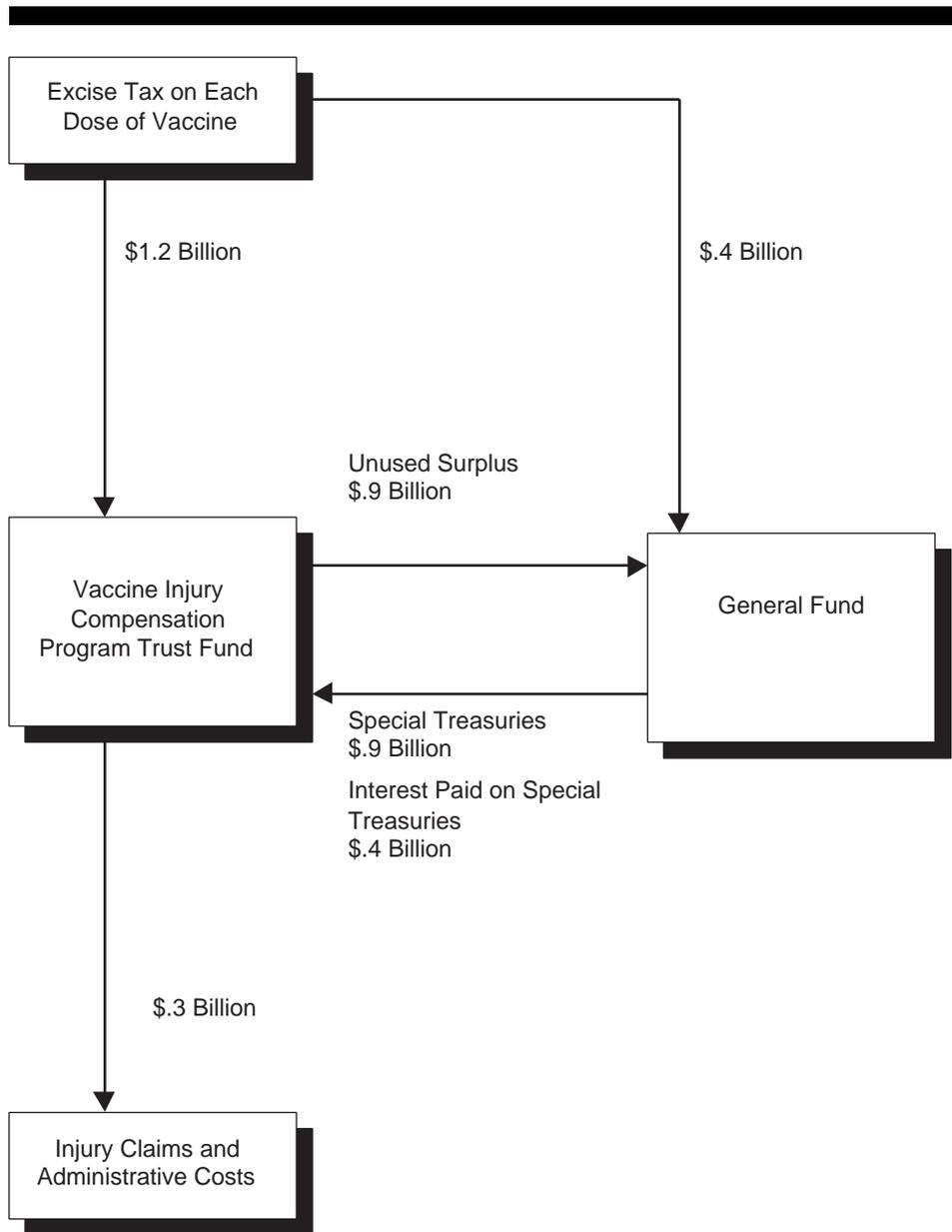
The VICP trust fund has historically received more in vaccine excise taxes than it has paid out for claims and related administrative costs. Since the program began, the Treasury reported it has collected over \$1.6 billion in vaccine excise taxes: \$4 billion of this amount went directly to the general fund to offset income and payroll taxes lost to the general fund as a result of the excise tax.<sup>17</sup> The remaining \$1.2 billion went to the VICP trust fund for claims payments and related administrative costs. Because the trust fund has spent only about \$290 million of the \$1.2 billion received, the remaining \$948 million was loaned to the Treasury and used for other federal programs and activities. In exchange, the trust fund received Treasury securities to be redeemed if needed to pay future claims.<sup>18</sup> Interest on these Treasuries held by the trust fund totaled about \$374 million by the end of fiscal year 1998. This \$374 million in interest and the \$948 million loaned to the Treasury comprise the \$1.3 billion trust fund balance existing as of the end of fiscal year 1998.

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<sup>17</sup>The 25-percent factor is the standard offset used when excise tax provisions are scored for budget purposes during the legislative process. Budget estimating conventions are that gross domestic product and the price level are fixed. Therefore, any increase in excise taxes must reduce payments to labor and capital (such as wages and rents) and, therefore, reduce income and payroll taxes deposited to the general fund.

<sup>18</sup>As provided in section 9602(b) of the Internal Revenue Code for management of trust funds in general.

**Figure 3: Money Flows Attributable to Vaccine Excise Taxes Collected From Fiscal Year 1989 Through Fiscal Year 1998**



At current rates, the Congressional Budget Office (CBO) estimates that the VICP trust fund balance will reach \$2.6 billion within the next decade and

the program will generate almost three times more revenue than will be used to pay annual claims and administrative costs. However, the vaccine excise tax rate is not based on an empirical risk assessment set to fund future benefits, and HHS officials do not believe that there is an outstanding liability requiring a large trust fund balance to meet future claims payments.<sup>19</sup> If this expectation holds true, the trust fund balance reflects the amount of vaccine excise taxes and interest on Treasury securities that is not expected to be needed for VICP purposes.

### Options to Address Concerns About the Growing Trust Fund Balance

Vaccine manufacturers, parent groups, and others involved with VICP have expressed concerns about the large trust fund balance and have proposed options to address them. These options generally involve cutting the excise tax supporting the trust fund or spending more of the money received on designated vaccine-related activities. Views and options include the following:

- Some vaccine manufacturers view the trust fund balance as an indicator that the vaccine excise tax rate is too high. They support legislative proposals to reduce the tax rates.
- Parent groups view the trust fund balance as an indicator of the government's unwillingness to recognize vaccine injuries and compensate people fairly for these injuries. They advocate a less restrictive injury table that would increase the number of petitioners compensated from the trust fund.
- HHS officials from the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) responsible for monitoring vaccine safety view the trust fund balance as a source of potential revenue if the Congress decides to expand trust fund spending to vaccine-related activities. Although the Administration has not submitted formal proposals to increase support of these activities or taken a position on the potential use of the trust fund, FDA and CDC officials we contacted supported dedicating a portion of the trust fund revenue not needed for claims payment to provide funding for vaccine injury surveillance systems and for research examining links between vaccines and delayed onset or chronic diseases.

### Budgetary Implication of Options to Reduce the Trust Fund Balance

Because excise tax revenue received by the VICP trust fund and not spent on the program is invested in Treasury securities and these proceeds are used by the general fund, implementing options to control the growth of

<sup>19</sup>See Budget Issues: Budgeting for Federal Insurance Programs (GAO/AIMD-97-16, Sept. 30, 1997) for further information on budget issues for federal insurance programs.

the trust fund balance not only affect the trust fund but also affect revenue and spending for the overall federal budget. Options requiring a change in legislation are also affected by requirements of the Budget Enforcement Act (BEA).<sup>20</sup> Under BEA, the Congress has to offset the cost of legislation that reduces revenue or increases spending by establishing new or higher taxes elsewhere or by decreasing spending for other programs.<sup>21</sup> For example, if the Congress had passed a law in 1998 that either lowered the vaccine excise tax rate to match claims payments or allowed the trust fund to spend the annual excess for new activities, funding for other federal programs and activities would have to have been reduced by \$59 million.<sup>22</sup> Had legislation been enacted in 1998 allowing new spending beyond the annual income received by the trust fund, the trust fund would have had to draw upon the \$1.3 billion trust fund balance by redeeming its Treasury securities. In this case, BEA would have required a reduction in spending for other federal programs—or an increase in other taxes—to offset the new spending by the trust fund.

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## Conclusions

While VICP was expected to provide compensation for vaccine-related injuries quickly and easily, these expectations have often not been met. In establishing the vaccine injury table as a desirable alternative for petitioners over the civil tort system, the Congress was initially willing to accept the risk that some compensation would be provided for injuries where the role of vaccines is uncertain. But in administering and refining the injury table, HHS is in the position of determining how much of this uncertainty the program will continue to bear. When HHS removes or does not add injuries to the vaccine injury table, the petitioner bears the burden of proof rather than the government. Where science is insufficient to determine causal relationships between a vaccine and injuries, it is not clear that HHS' criteria and approach to making injury table changes are consistent. Establishing a standard method with criteria that will be used consistently for all table changes may help eliminate questions regarding HHS' programmatic decisions.

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<sup>20</sup>The Budget Enforcement Act of 1990 and subsequent amendments (the Omnibus Budget Reconciliation Act of 1993 and the Budget Enforcement Act of 1997) are collectively referred to as the Budget Enforcement Act. These acts amended the Balanced Budget and Emergency Deficit Control Act of 1985, sometimes called Gramm-Rudmann-Hollings.

<sup>21</sup>The act requires that all legislation that increases mandatory spending or decreases receipts be fully offset—or paid for—so that it is deficit neutral. The Balanced Budget Act of 1997 requires that the impact of spending and receipts legislation be offset in the current year, the budget year, and the following 4 fiscal years. A point of order may be raised in the Senate if the change is not deficit neutral in the second 5 years. This provision is enforced through sequestration, which is done annually.

<sup>22</sup>This result assumes that if vaccine excise taxes were reduced, the manufacturer would not decrease vaccine prices to pass on the tax savings to purchasers. If the tax savings were passed on to the vaccine purchaser, funding for other federal programs would need to have been reduced by \$30 million.

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## Recommendation to the Secretary of HHS

We recommend that the Secretary of HHS develop and apply a consistent methodology for evaluating and reporting on the various factors used to add injuries to or remove injuries from VICP's injury table. This methodology should include specific scientific and public policy considerations and their relative weight in the decisionmaking process and should be applied to any future table changes.

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## Agency Comments and Our Evaluation

Both HHS and DOJ provided written comments on our draft report. Their comments are reprinted as appendix IV and appendix V, respectively. We summarized their comments and provide our response below.

Both HHS and DOJ raised issues with our analysis of claims processing times. In addition, HHS did not concur with our recommendation regarding the need to establish a clear methodology for revising the vaccine injury table and said that the Administration has not taken a position on potential uses of the VICP trust fund surplus.

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## Claims Processing Times

HHS commented on what it considered an inappropriate use of the original legislated criteria of 1 year to measure VICP performance. HHS pointed out that subsequent legislation allows petitioners additional time, as needed, to obtain medical records and bolster the sufficiency of their cases. We made several modifications to the final report to reduce the perceived focus on historical expectations. Nevertheless, while the legislation was amended to provide petitioners with the flexibility to keep the case open longer, there is no indication that the Congress changed its expectation that claims would be processed quickly. In fact, the law was amended to require a special master decision within 240 days, exclusive of suspended time.<sup>23</sup>

HHS also commented that our analysis should more clearly differentiate adjudication times between claims related to vaccinations administered prior to October 1988 (pre-1988 claims) and claims related to vaccinations on or after this date (post-1988 claims). HHS stated that pre-1988 claims are not representative of current and future processing times and should be reported on separately. HHS said the average processing time for post-1988 claims was 2 years. To clarify that our analysis did differentiate between pre- and post-1988 claims, we added a note to figure 2 to indicate that the years 1992 through 1997 include only post-1988 claims. We also note that

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<sup>23</sup>Either party may file an appeal of the special master decision, which would add time to the process (see app. II).

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HHS' 2-year number is the average time for only those cases that have been closed. However, after 2 years, a majority of the cases filed each year are still open.

HHS and DOJ said that the draft report implied that HHS' increased propensity to defend claims is a result of a significant change of position rather than the result of the Congress providing funding for DOJ attorneys to defend claims that HHS had defaulted on for the first 2 years of the program. We added language to clarify that HHS' increased level of defense in implementing its statutory authority was related to the availability of additional resources.

DOJ also commented that some statements in the draft may convey an incorrect understanding of why some cases have taken longer to resolve than originally anticipated. DOJ said a significant factor was that the court suspended claims processing in 1991 when an overwhelming number of claims were received. Legislation does allow the court to suspend proceedings when the volume of claims is onerous, and our report does state that the large volume of cases was a primary factor in delayed processing times. However, we also point out that volume is not the only factor. For example, we report that even though caseloads declined between 1992 and 1997, the percentage of new claims processed within 2 years has remained relatively the same. We have added wording to the report text to help clarify this point.

HHS also pointed out that our draft report did not discuss recent legislative proposals to improve VICP. In our view, the legislative proposals advanced by HHS in June 1999 do not directly address the findings related to our report objectives; therefore, we did not include them. The proposals primarily cover technical aspects of the program, such as expanding the statute of limitations for filing claims and clarifying statutory terms that define entitlement to compensation.

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## Vaccine Injury Table

HHS did not concur with our recommendation that in considering future changes to the vaccine injury table, HHS formalize and apply a set of standard criteria for making decisions to add or remove injuries. HHS stated that it is inappropriate to reduce the scientific basis for decisions to the application of weighted criteria and that a standard approach in making such decisions is not possible because the scientific and public policy considerations vary on a case-by-case basis. Further, HHS stated that the Institute of Medicine had cautioned against using a "formula"

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approach, and HHS had gone to great lengths to explain its rationale for each table decision when it published the proposed and final rules in the Federal Register.

We recognize that HHS has a difficult task of applying judgment when scientific uncertainties exist about the causal links between vaccines and injuries, and we did not question the table changes that were made. However, using a variety of criteria on a case-by-case approach does not, in our view, clearly communicate to the public that HHS is acting consistently in applying its judgment. For example, in discussing its rationale for each change in the Federal Register, HHS generally cites some combination of four factors in controlling its decision. These factors include Institute of Medicine findings (and subsequent medical studies), biologic plausibility, recommendations from the Advisory Council on Childhood Vaccines and the National Vaccine Advisory Committee, and prevalence of the condition in the population attributable to vaccines. However, in communicating its decisions to the public, HHS does not uniformly discuss each of these factors, and the reasons why the relative importance of each factor varies among the decisions is not apparent in all cases. As HHS indicated in its comments, it is important to maintain public confidence in the fairness of the program. Our recommendation is being made with this objective in mind.

Further, we disagree that it is not practical for HHS to adopt a standard methodology to evaluate the available evidence and that doing so would constitute use of a formula. For example, the Institute of Medicine developed such a methodology to perform its review and evaluation of the available scientific evidence linking vaccines to adverse events. The Institute considered four types of scientific evidence (biologic plausibility, case reports, case series, and uncontrolled observational studies) and used qualitative and quantitative approaches to weight each type of evidence. The results were summarized in a matrix with narrative on how each factor was applied in the decisionmaking process. HHS could develop a similar decisionmaking methodology that includes the public policy considerations and other relevant criteria it uses in addition to the Institute's findings. We have reworded our recommendation to make it clearer that, in the future, HHS should apply a consistent methodology for evaluating and reporting on the factors used to make vaccine injury table changes.

HHS also commented that the reason compensation numbers significantly dropped for DTP after the vaccine injury table changes was not because of

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the table changes, as we reported, but because of a decrease in the use of this vaccine. HHS also stated that our report should reflect the fact that VICP's future workload will be primarily for vaccines other than DTP. Our point about the changes to the table does not relate to the use of the DTP vaccine or VICP's workload. Instead, our discussion concludes that, regardless of the vaccine in question, people have historically had a higher chance of being compensated for injuries that are on the table than for injuries that are not on the table. Since a higher percentage of people filed claims off-table after the table changes were implemented, the future percentage of claims compensated under the program may be lower.

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## Trust Fund Growth

HHS said the Administration has not submitted formal proposals to increase support of vaccine safety and research activities or taken a position on the potential use of the trust fund. We have added language to clarify that these options have not been formally endorsed by the Administration.

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As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this letter. At that time, we will send copies of this report to the Honorable Donna E. Shalala, Secretary of HHS; the Honorable Janet Reno, Attorney General; the Honorable Loren A. Smith, Chief Judge, U.S. Court of Federal Claims; and other interested parties. We will also make copies available to interested congressional committees and others upon request.

This report was prepared by Frank Pasquier, Assistant Director; Lacinda Baumgartner; and Linda Bade. Please call me at (202) 512-7118 if you or your staff have any questions.

Sincerely yours,



Kathryn G. Allen  
Associate Director, Health Financing  
and Public Health Issues

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**Abbreviations**

|      |  |
|------|--|
| BEA  | Budget Enforcement Act                     |
| CBO  | Congressional Budget Office                |
| CDC  | Centers for Disease Control and Prevention |
| DOJ  | Department of Justice                      |
| DTP  | diphtheria, tetanus, and pertussis         |
| FDA  | Food and Drug Administration               |
| HHS  | Department of Health and Human Services    |
| VICP | Vaccine Injury Compensation Program        |

# Scope and Methodology

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To obtain information on VICP, we interviewed (1) officials at HHS, DOJ, and the U.S. Court of Federal Claims involved in the VICP claims process; (2) a representative of the Institute of Medicine responsible for analyzing existing scientific evidence for HHS use in revising the VICP vaccine injury table; (3) officials at CDC and FDA responsible for the national immunization program and monitoring vaccine safety; (4) an attorney and a parent group representing the interests of people injured by vaccines; (5) a representative of a professional association representing pediatric physician interests; (6) Treasury officials responsible for the financial accounting and reporting for the VICP trust fund; and (7) the CBO official responsible for budgeting aspects of the trust fund and presentation in the federal budget.

We also reviewed relevant legislation, financial reports, budget documents, and reports evaluating various aspects of VICP operation. We obtained and analyzed data from HHS on claims filed under VICP from 1988 to February 1999. In addition, we obtained the Federal Register notices discussing HHS changes to the VICP injury table and reviewed the Institute of Medicine's analysis of information available to link vaccines to various medical conditions.

We conducted our work from January through September 1999 in accordance with generally accepted government auditing standards.

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## Claims Processing

To determine how long it took to process claims through VICP, we analyzed HHS' VICP claims database. This database included data fields on when the claim was filed and a history of processing steps through when the claim was settled. We did not perform a reliability assessment of the data system.

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## The Effect of Table Changes on Compensation Rates

We used HHS' VICP claims database to identify compensation rates for claims that did and did not allege injuries on the vaccine injury table. We identified such claims by comparing injuries on the injury table with those listed in the HHS claims database for each claim. We provided a list of the injuries in the database to HHS officials, and they confirmed those injuries that they would consider as potentially being on or off each of the three injury tables. Because three different injury tables were in effect over the life of the program, we first grouped the claims according to the injury table that was applicable at the time the claims were filed. We then computed the number and proportion of claims in each group that did or

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did not allege injuries on the injury table. Compensation rates and associated awards for alleged table and non-table claims were then identified using the data fields for the U.S. Court of Federal Claims' judgment and award amounts in the HHS database.

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### Budgetary Effect of Options to Address Growing Trust Fund Balance

To determine the budgetary effect of options proposed to reduce the trust fund balance, we first obtained financial statements for the VICP trust fund from the Treasury. These financial statements identified the revenue that flowed into the trust fund from vaccine excise taxes and interest accrued on Treasury securities, as well as expenditures that flowed out of the trust fund for claims and associated administrative expenses. We did not audit the trust fund financial statements.

Because of the interrelationship between the trust fund and the general fund in the federal budget, we used the trust fund financial information to identify the amounts that flowed directly and indirectly through the Treasury to the general fund as a result of the program. Direct general fund revenue includes 25 percent of all vaccine excise taxes collected by the Treasury. As discussed with Treasury and CBO officials, we backed into the total tax collected by the Treasury by dividing the vaccine excise tax provided to the VICP trust fund by 75 percent. We then subtracted the trust fund share of the tax from the total tax collected to get the amount of tax available to finance general fund programs and activities. Indirect general fund revenue includes amounts derived from Treasury securities issued to the trust fund. The Treasury securities balances were listed on the trust fund financial statements.

To demonstrate how proposed legislative changes to reduce the excise tax rate or increase trust fund spending would affect the overall budget, we used a rolling average of trust fund revenue and expenses in 1997 and 1998 (hereafter referred to as 1998). We used a rolling average to minimize timing differences in accounting for revenue and expenses. We assumed that if new legislation had resulted in a match between trust fund revenues and expenditures in 1998, the amount of offset required by the Budget Enforcement Act for 1998 would have been the difference between the total excise tax actually received and expended by the trust fund in that year.<sup>24</sup> Our computation reflects the assumption that vaccine manufacturers would not decrease vaccine prices to pass on the tax savings to vaccine purchasers because HHS officials said that they did not

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<sup>24</sup>This excludes loss of the 25 percent in vaccine excise taxes provided directly to the general fund because budget scoring convention assumes these taxes will be recouped through commensurate increases in income and payroll tax revenue.

reduce prices when VICP took on the burden of liability. However, we also computed the somewhat lesser effect on the general fund if the manufacturer had passed on the savings. The effect is less because CDC information on federal vaccine purchases shows that nearly half of all vaccine purchases are made by the federal government. Therefore, lower vaccine prices to federal agencies purchasing vaccines would offset the decrease in excise tax. We computed the government's loss as the percentage of excess in the trust fund that was related to state and private vaccine purchases.

# VICP Claims Process

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Three federal agencies are involved in the VICP claims process: HHS, DOJ, and the U.S. Court of Federal Claims. The process consists of several steps. (See table II.1.)

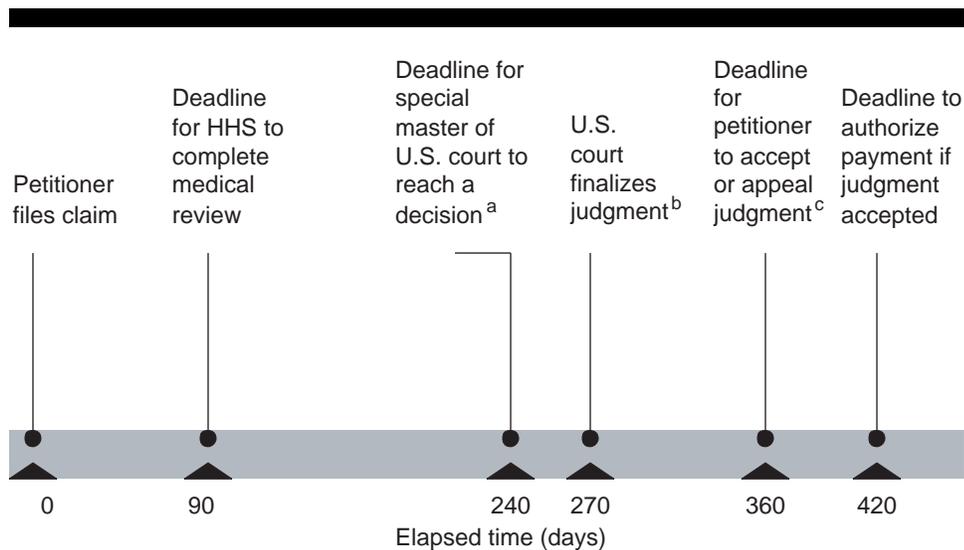
**Appendix II  
VICP Claims Process**

**Table II.1: Claims Process Steps and Time Frames**

| <b>Step</b>   | <b>Time frame</b>  |
|---|--|
| <b>Petition filed</b>   |  |
| An individual or representative claiming injury or death from a vaccine files a petition for compensation with the court.   | <ul style="list-style-type: none"> <li>— In the case of an injury, the claim must be filed within 36 months after the first symptoms appeared, and the effects must have continued at least 6 months after vaccination.</li> <li>— In the case of a death, the claim must be filed within 24 months of the death and within 48 months after the onset of the vaccine-related injury causing the death.</li> </ul>  |
| <b>Physician review</b>   |  |
| A physician at the Division of Vaccine Injury Compensation, HHS, reviews each petition to determine whether it meets the medical criteria for compensation. This recommendation is provided to the court through a report filed by DOJ, although it is not binding.   | <ul style="list-style-type: none"> <li>— Court rules require the report to be sent to the court within 90 days from the date the claim was filed. This deadline is subject to change depending on a petitioner’s ability to obtain all relevant medical records and file a complete petition.</li> </ul>   |
| <b>Special master decision</b>  |  |
| A “special master” of the court is required to make the initial decision for compensation under the program. A special master is an attorney appointed by the judges of the court. At hearings before the special master, HHS is represented by a DOJ attorney and the petitioner is represented by a private attorney. | The special master is required to issue a judgment within 240 days (exclusive of suspended time) from the date a claim is filed, or petitioners are allowed to withdraw their claim from VICP and file a lawsuit against the vaccine manufacturer or vaccine administrator in the civil tort system.   |
| <b>Acceptance or rejection of special master decision</b>   |  |
| The petitioner and HHS accept or reject the special master’s decision.  | <ul style="list-style-type: none"> <li>— Either party has 30 days to file a motion for review by the court. If a motion is filed, an additional 30 days is provided to the other party to respond.</li> <li>— Instead of filing a motion for review, if a petitioner files an election to reject a special master’s judgment within 90 days after entry of judgment, the petitioner may proceed to file a lawsuit in the civil tort system.</li> </ul>   |
| <b>Court judgment</b>   |  |
| The court issues a judgment on the special master’s decision.   | <ul style="list-style-type: none"> <li>— The court is required to enter a judgment within 420 days from the date the claim was filed (exclusive of the time spent on remand to the special master).</li> <li>— Within 60 days, either party may file a petition for review of the judgment with the U.S. Court of Appeals for the Federal Circuit. Final appeal from the Federal Circuit is to the U.S. Supreme Court through a petition seeking a writ of certiorari. Within 90 days of the conclusion of the appeals process, if a petitioner files with the court an election to reject the judgment, the petitioner may proceed to file a lawsuit in the civil tort system. If the petitioner takes no action within 90 days, the judgment is deemed “accepted” by law.</li> </ul> |
| <b>Payment of award</b>   |  |
| Petitioners accepting the judgment and awarded compensation are paid from the VICP trust fund if the vaccine was administered on or after October 1, 1988, or from annual appropriations if administered before this date.  | Agency criteria requires HHS to pay petitioners within 60 days after payment is authorized by the court and DOJ.   |

**Appendix II**  
**VICP Claims Process**

**Figure II.1: Time Line of VICP Claims Processed in U.S. Court of Federal Claims Without an Appeal**



<sup>a</sup>Parties can request suspensions adding up to 180 days to the time before the special master reaches a decision. In addition, for claims related to vaccines administered before Oct. 1, 1988, the special master can suspend proceedings an additional 900 days.

<sup>b</sup>Parties may expedite this step by waiving their right to file a motion for review. If parties file a motion for review of the special master's decision, the deadline for the court to render judgment is extended by 150 days.

<sup>c</sup>The petitioner may expedite this step by immediately electing judgment.

# Current VICP Injury Table and “Qualifications and Aids to Interpretation”

**Table III.1: VICP Vaccine Injury Table**

| Vaccine  | Injury/adverse event <sup>a</sup>   | Time period <sup>b</sup>   |
|--|---|--|
| Tetanus-containing                               | Anaphylaxis or anaphylactic shock<br>Brachial neuritis  | 4 hours<br>2-28 days   |
| Pertussis-containing                             | Anaphylaxis or anaphylactic shock<br>Encephalopathy (or encephalitis)   | 4 hours<br>72 hours  |
| Measles, mumps, rubella in any combination       | Anaphylaxis or anaphylactic shock<br>Encephalopathy (or encephalitis)   | 4 hours<br>5-15 days   |
| Measles-containing                               | Thrombocytopenic purpura<br>Vaccine-strain measles in an immunodeficient recipient  | 7-30 days<br>6 months  |
| Rubella-containing                               | Chronic arthritis   | 7-42 days  |
| Polio live virus-containing                      | Paralytic polio<br>—In a nonimmunodeficient recipient<br>—In an immunodeficient recipient<br>—In a vaccine-associated community case<br>Vaccine-strain polio viral infection<br>—In a nonimmunodeficient recipient<br>—In an immunodeficient recipient<br>—In a vaccine-associated community case | 30 days<br>6 months<br>Not applicable<br>30 days<br>6 months<br>Not applicable |
| Polio inactivated virus-containing               | Anaphylaxis or anaphylactic shock   | 4 hours  |
| Hepatitis B                                      | Anaphylaxis or anaphylactic shock   | 4 hours  |
| Hemophilus influenzae type b (Hib), unconjugated | Early-onset Hib disease   | 7 days   |
| Hib, conjugated                                  | No condition specified  | Not applicable   |
| Varicella  | No condition specified  | Not applicable   |
| Rotavirus  | No condition specified  | Not applicable   |
| New vaccines recommended <sup>c</sup>            | No condition specified  | Not applicable   |

<sup>a</sup>Injuries also include any acute complication or sequela (including death) of the listed events (for all but the conjugated Hib, varicella, and new vaccines).

<sup>b</sup>For first symptom, onset, or aggravation of injury after vaccination.

<sup>c</sup>Any new vaccine recommended by CDC for routine administration to children, after publication by the Secretary of HHS of a notice of coverage.

**Appendix III  
Current VICP Injury Table and  
“Qualifications and Aids to Interpretation”**

**Figure III.1: “Qualifications and Aids to Interpretation”**

**Qualifications and Aids to Interpretation**

**(1) Anaphylaxis and anaphylactic shock**

Anaphylaxis and anaphylactic shock mean an acute, severe, and potentially lethal systemic allergic reaction. Most cases resolve without sequelae. Signs and symptoms begin minutes to a few hours after exposure. Death, if it occurs, usually results from airway obstruction caused by laryngeal edema or bronchospasm and may be associated with cardiovascular collapse. Other significant clinical signs and symptoms may include the following: Cyanosis, hypotension, bradycardia, tachycardia, arrhythmia, edema of the pharynx and/or trachea and/or larynx with stridor and dyspnea. Autopsy findings may include acute emphysema which results from lower respiratory tract obstruction, edema of the hypopharynx, epiglottis, larynx, or trachea and minimal findings of eosinophilia in the liver, spleen and lungs. When death occurs within minutes of exposure and without signs of respiratory distress, there may not be significant pathologic findings.

**(2) Encephalopathy**

For purposes of the Vaccine Injury Table, a vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period, an injury meeting the description below of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination.

(I) An acute encephalopathy is one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).

(A) For children less than 18 months of age who present without an associated seizure event, an acute encephalopathy is indicated by a "significantly decreased level of consciousness" (see "D" below) lasting for at least 24 hours. Those children less than 18 months of age who present following a seizure shall be viewed as having an acute encephalopathy if their significantly decreased level of consciousness persists beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication.

(B) For adults and children 18 months of age or older, an acute encephalopathy is one that persists for at least 24 hours and characterized by at least two of the following:

(1) A significant change in mental status that is not medication related; specifically a confusional state, or a delirium, or a psychosis;

(2) A significantly decreased level of consciousness, which is independent of a seizure and cannot be attributed to the effects of medication; and

(3) A seizure associated with loss of consciousness.

(C) Increased intracranial pressure may be a clinical feature of acute encephalopathy in any age group.

(D) A "significantly decreased level of consciousness" is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater (see paragraphs (2)(I)(A) and (2)(I)(B) of this section for applicable timeframes):

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**Appendix III  
Current VICP Injury Table and  
“Qualifications and Aids to Interpretation”**

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(1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);

(2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or

(3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

(E) The following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness as described above: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle. Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy.

(ii) Chronic encephalopathy occurs when a change in mental or neurologic status, first manifested during the applicable time period, persists for a period of at least 6 months from the date of vaccination. Individuals who return to a normal neurologic state after the acute encephalopathy shall not be presumed to have suffered residual neurologic damage from that event; any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy. If a preponderance of the evidence indicates that a child's chronic encephalopathy is secondary to genetic, prenatal or perinatal factors, that chronic encephalopathy shall not be considered to be a condition set forth in the Table.

(iii) An encephalopathy shall not be considered to be a condition set forth in the Table if in a proceeding on a petition, it is shown by a preponderance of the evidence that the encephalopathy was caused by an infection, a toxin, a metabolic disturbance, a structural lesion, a genetic disorder or trauma (without regard to whether the cause of the infection, toxin, trauma, metabolic disturbance, structural lesion or genetic disorder is known). If at the time a decision is made on a petition filed under section 2111(b) of the Act for a vaccine-related injury or death, it is not possible to determine the cause by a preponderance of the evidence of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the Table.

(iv) In determining whether or not an encephalopathy is a condition set forth in the Table, the Court shall consider the entire medical record.

**(3) Residual Seizure Disorder**

A petitioner may be considered to have suffered a residual seizure disorder for purposes of the Vaccine Injury Table, if the first seizure or convulsion occurred 5-15 days (not less than 5 days and not more than 15 days) after administration of the vaccine and 2 or more additional distinct seizure or convulsion episodes occurred within 1 year after the administration of the vaccine which were unaccompanied by fever (defined as a rectal temperature equal to or greater than 101.0 degrees Fahrenheit or an oral temperature equal to or greater than 100.0 degrees Fahrenheit). A distinct seizure or convulsion episode is ordinarily defined as including all seizure or convulsive activity occurring within a 24-hour period, unless competent and qualified expert neurological testimony is presented to the contrary in a particular case.

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**Appendix III  
Current VICP Injury Table and  
“Qualifications and Aids to Interpretation”**

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For purposes of the Vaccine Injury Table, a petitioner shall not be considered to have suffered a residual seizure disorder, if the petitioner suffered a seizure or convulsion unaccompanied by fever (as defined above) before the fifth day after the administration of the vaccine involved.

**(4) Seizure and convulsion**

For purposes of paragraphs (2) and (3) of this section, the terms, "seizure" and "convulsion" include myoclonic, generalized tonic-clonic (grand mal), and simple and complex partial seizures. Absence (petit mal) seizures shall not be considered to be a condition set forth in the Table. Jerking movements or staring episodes alone are not necessarily an indication of seizure activity.

**(5) Sequela**

The term "sequela" means a condition or event which was actually caused by a condition listed in the Vaccine Injury Table.

**(6) Chronic Arthritis**

For purposes of the Vaccine Injury Table, chronic arthritis may be found in a person with no history in the 3 years prior to vaccination of arthropathy (joint disease) on the basis of:

(A) Medical documentation, recorded within 30 days after the onset, of objective signs of acute arthritis (joint swelling) that occurred between 7 and 42 days after a rubella vaccination;

(B) Medical documentation (recorded within 3 years after the onset of acute arthritis) of the persistence of objective signs of intermittent or continuous arthritis for more than 6 months following vaccination:

(C) Medical documentation of an antibody response to the rubella virus.

For purposes of the Vaccine Injury Table, the following shall not be considered as chronic arthritis: Musculoskeletal disorders such as diffuse connective tissue diseases (including but not limited to rheumatoid arthritis, juvenile rheumatoid arthritis, systemic lupus erythematosus, systemic sclerosis, mixed connective tissue disease, polymyositis/dermatomyositis, fibromyalgia, necrotizing vasculitis and vasculopathies and Sjogren's Syndrome), degenerative joint disease, infectious agents other than rubella (whether by direct invasion or as an immune reaction), metabolic and endocrine diseases, trauma, neoplasms, neuropathic disorders, bone and cartilage disorders and arthritis associated with ankylosing spondylitis, psoriasis, inflammatory bowel disease, Reiter's syndrome, or blood disorders.

Arthralgia (joint pain) or stiffness without joint swelling shall not be viewed as chronic arthritis for purposes of the Vaccine Injury Table.

**(7) Brachial neuritis**

Brachial neuritis is defined as dysfunction limited to the upper extremity nerve plexus (i.e., its trunks, divisions, or cords) without involvement of other peripheral (e.g., nerve roots or a single peripheral nerve) or central (e.g., spinal cord) nervous system structures. A deep, steady, often severe aching pain in the shoulder and upper arm usually heralds onset of the condition. The pain is followed in days or weeks by

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**Appendix III  
Current VICP Injury Table and  
“Qualifications and Aids to Interpretation”**

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weakness and atrophy in upper extremity muscle groups. Sensory loss may accompany the motor deficits, but is generally a less notable clinical feature. The neuritis, or plexopathy, may be present on the same side as or the opposite side of the injection; it is sometimes bilateral, affecting both upper extremities. Weakness is required before the diagnosis can be made. Motor, sensory, and reflex findings on physical examination and the results of nerve conduction and electromyographic studies must be consistent in confirming that dysfunction is attributable to the brachial plexus. The condition should thereby be distinguishable from conditions that may give rise to dysfunction of nerve roots (i.e., radiculopathies) and peripheral nerves (i.e., including multiple mononeuropathies), as well as other peripheral and central nervous system structures (e.g., cranial neuropathies and myelopathies).

**(8) Thrombocytopenic purpura**

Thrombocytopenic purpura is defined by a serum platelet count less than 50,000/mm<sup>3</sup>. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with other causes such as hypersplenism, autoimmune disorders (including alloantibodies from previous transfusions) myelodysplasias, lymphoproliferative disorders, congenital thrombocytopenia or hemolytic uremic syndrome. This does not include cases of immune (formerly called idiopathic) thrombocytopenic purpura (ITP) that are mediated, for example, by viral or fungal infections, toxins or drugs. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with disseminated intravascular coagulation, as observed with bacterial and viral infections. Viral infections include, for example, those infections secondary to Epstein Barr virus, cytomegalovirus, hepatitis A and B, rhinovirus, human immunodeficiency virus (HIV), adenovirus, and dengue virus. An antecedent viral infection may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing. Bone marrow examination, if performed, must reveal a normal or an increased number of megakaryocytes in an otherwise normal marrow.

**(9) Vaccine-strain measles viral infection**

Vaccine-strain measles viral infection is defined as a disease caused by the vaccine-strain that should be determined by vaccine-specific monoclonal antibody or polymerase chain reaction tests.

**(10) Vaccine-strain polio viral infection**

Vaccine-strain polio viral infection is defined as a disease caused by poliovirus that is isolated from the affected tissue and should be determined to be the vaccine-strain by oligonucleotide or polymerase chain reaction. Isolation of poliovirus from the stool is not sufficient to establish a tissue specific infection or disease caused by vaccine-strain poliovirus.

**(11) Early-onset Hib disease**

Early-onset Hib disease is defined as invasive bacterial illness associated with the presence of Hib organism on culture of normally sterile body fluids or tissue, or clinical findings consistent with the diagnosis of epiglottitis. Hib pneumonia qualifies as invasive Hib disease when radiographic findings consistent with the diagnosis of pneumonitis are accompanied by a blood culture positive for the Hib organism. Otitis media, in the absence of the above findings, does not qualify as invasive bacterial disease. A child is considered to have suffered this injury only if the vaccine was the first Hib immunization received by the child.

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**Appendix III  
Current VICP Injury Table and  
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cases of thrombocytopenia associated with disseminated intravascular coagulation, as observed with bacterial and viral infections. Viral infections include, for example, those infections secondary to Epstein Barr virus, cytomegalovirus, hepatitis A and B, rhinovirus, human immunodeficiency virus (HIV), adenovirus, and dengue virus. An antecedent viral infection may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing. Bone marrow examination, if performed, must reveal a normal or an increased number of megakaryocytes in an otherwise normal marrow.

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# Comments From the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

NOV 18 1999

Ms. Kathryn G. Allen  
Associate Director  
Health Financing and Public Health Issues  
United States General  
Accounting Office  
Washington, D.C. 20548

Dear Ms. Allen:

Enclosed are the Department's comments on your draft report, "Vaccine Injury Compensation Program: Program Falls Short of Expectations to Quickly and Easily Settle Claims." The comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely,

A handwritten signature in cursive script that reads "June Gibbs Brown".

June Gibbs Brown  
Inspector General

Enclosure

The Office of Inspector General (OIG) is transmitting the Department's response to this draft report in our capacity as the Department's designated focal point and coordinator for General Accounting Office reports. The OIG has not conducted an independent assessment of these comments and therefore expresses no opinion on them.

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**Appendix IV  
Comments From the Department of Health  
and Human Services**

**Comments of the Department of Health and Human Services  
on the General Accounting Office Draft Report “Vaccine Injury  
Compensation Program: Program Falls Short of Expectations  
to Quickly and Easily Settle Claims” (GAO/HEHS-00-08)**

**General Comments**

The Department of Health and Human Services (the Department) thanks the General Accounting Office (GAO) for providing the opportunity to comment on the GAO draft report entitled, “Vaccine Injury Compensation Program: Program Falls Short of Expectations to Quickly and Easily Settle Claims.” To begin with, we believe the title of the draft report is misleading and, more important, not borne out by the substance of the draft report or by the facts presented. As stated on page 4 of the draft report, “...the program appears to provide an easier process for obtaining compensation than the traditional civil tort system,....” We therefore informally recommended revising the title to be more balanced and objective, and we understand that GAO agreed to do so. We applaud GAO for that decision.

While the draft report focuses on problems related to the adjudication of claims under the statute as enacted in 1986, it does not take into account the many improvements in the adjudication process implemented over the years both administratively and by the Administration working with Congress to enact numerous legislative improvements. Also, the draft report makes no mention of, nor offers any commentary on, the comprehensive set of legislative proposals to further improve the operation of the National Vaccine Injury Compensation Program (VICP) sent to the Congress by the Administration on June 14 of this year. This set of legislative proposals included doubling the statutory time limit for filing a claim, expanding compensation to families, and simplifying the process for adjudicating claims.

We disagree with GAO’s analysis of the operation of the VICP by combining data for the operation of what Congress and the Department have always considered to be two separate portions of the VICP. The “retrospective” portion of the VICP is for claims filed for alleged injuries occurring from vaccines administered prior to October 1, 1988, the effective date of the VICP. The pre-1988 portion has separate rules for determining amounts of compensation to claimants and is funded separately from the operation of the “prospective,” or post-1988 portion of the VICP. The GAO draft report, by deriving its conclusions on the processing of claims by combining data on these two separate portions, creates the potential to seriously undermine public confidence in what we consider to be a very well managed and highly successful program.

Rather than provide a detailed analysis of the entire draft report, we will address the three primary areas covered in the draft report: claims processing, changes to the Vaccine Injury Table and Trust Fund growth.

Now on p. 2.

**Appendix IV  
Comments From the Department of Health  
and Human Services**

Claims Processing

With respect to delays in the claims process, GAO provides various charts on adjudication time frames noting that Congress expected the process to take less time than has occurred. However, we believe assessing the VICP's performance based on the original statute is not proper. Congress initially set an adjudication deadline of 1 year, but changed this requirement in several sets of amendments to allow petitioners additional time to obtain supplemental medical records and otherwise bolster the sufficiency of their cases. We agree with the Chief Special Master's observation, as quoted on page 14 of the draft report, that "...while the Court could process claims more quickly, delays are granted primarily to benefit petitioners who need more time to gather information, have medical tests performed, or identify costs related to an injured child's developmental needs."

Now on p. 11.

Despite the fact that the draft report acknowledges the enormous influx of older claims, which put an incredible strain on the system (approximately 4,000 claims over a time span of only 5 months), the use of data from the retrospective portion of the VICP in determining average processing time greatly skews the results. We recommend that the analysis be limited to prospective claims as described in the RESULTS IN BRIEF section--page 4, or that GAO at least differentiate between the two portions and then explain why the prospective portion is the most relevant measure of claims processing time. The average processing time for all adjudicated post-1988 claims is 2 years. The prospective claims processing time is the most appropriate predictor of future claims processing times. Individual retrospective claims began the adjudication process only when the U.S. Court of Federal Claims (the Court) published an order for the Department's review. Clearly, the most important determinant of how quickly the retrospective claims were processed was the number of Special Masters available (maximum of eight), a number originally set by Congress and never modified.

Now on p. 2.

Based on the differences in adjudication time frames from the first 2 years of the VICP and in the intervening decade, the draft report implies that delays are also due to an increasing propensity for the Department to defend claims before the Court. However, the draft report does not cite the fact that in the initial 2-year period the Department was defaulting on cases adjudicated before the Court due to the lack of funding by Congress to allow for the Department of Justice to participate in the administration of the VICP. For GAO to imply that the Department significantly changed its position in choosing to defend claims does not recognize the basis for the change, as well as the inherent statutory responsibility of the Department to review claims for eligibility.

Finally, since GAO did not make specific recommendations to improve the claims process, we conclude that none were apparent from the review.

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**Appendix IV  
Comments From the Department of Health  
and Human Services**

Vaccine Injury Table

The draft report focuses extensively on changes to the Vaccine Injury Table (the Table) made by the Department in 1995 and 1997. It notes that the number of compensated claims for conditions removed have dropped significantly, that the changes have made it harder for petitioners to obtain compensation, and that there is a difference of opinion regarding the extent to which conditions that may be vaccine-related should be added to the Table. While not questioning the scientific basis of the changes, the draft report states there was no "...transparent methodology...." and calls for the Department to "...strengthen and formalize the criteria...." used in the decision-making process for changes.

First, the guiding principle in changing the Table was to carry out the statutory mandate that conditions listed in the Table be based on scientific evidence that there is a causal relationship between the vaccine and the condition. This is because the inclusion of an injury on the Table allows petitioners to benefit from a legal presumption of causation. Both sets of Table changes required nearly 4 years, utilizing rigorous scientific and policy analysis and input from several advisory committees and an overall public process including a public hearing, as required by the statute. The decision-making related to each proposed Table change was detailed extensively in the preambles to the proposed and final rules. The draft report's recommendation for a more clear methodology implies that the Department should publish a formula using the Institute of Medicine (IOM) findings. Indeed, the IOM in its 1991 presentation to the Advisory Commission on Childhood Vaccines cautioned against this very approach.

The draft report highlights a few examples of apparent inconsistencies in the decision-making, suggesting that IOM findings are the only considerations. If anything, these examples demonstrate the complexity of scientific review and how difficult it is to try and fit causation science into very narrow boxes. It is simply not practical. What is important is the scientific underpinning behind the final decisions regarding what should be listed as a Table condition, which is ascertained from information provided by not only the IOM, but others. The Department went to great lengths to be as clear and consistent as possible in the 1995 and 1997 proposed and final rules within the constraints of the scientific data available.

The GAO specifically raises an issue of consistency on page 18 related to Guillain-Barre Syndrome (GBS) and two vaccines covered under the VICP. Beyond the scientific and public policy aspects discussed above, is the statutory requirement of "preponderance of the evidence." The Department cannot create a presumption for conditions where in fact most cases are not vaccine-related. Requiring petitioners to prove causation is appropriate in these instances, and it is for this reason that GBS was not added to the Table.

Finally, and perhaps most important, great attention has been paid to DTwP (whole-cell) vaccine in the draft report, since it accounts for approximately 75 percent of retrospective claims. The fact that compensation numbers have dropped significantly for Diphtheria, Tetanus, and Pertussis

Now on p. 15.

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**Appendix IV  
Comments From the Department of Health  
and Human Services**

(DTP) since the Table changes, however, likely reflects a factor other than the Table change, one not mentioned in the draft report. Since 1991, DTaP (acellular) has been recommended for the fourth and fifth dose in the immunization schedule, and for **all** 5 doses since 1996. Use of DTwP has dropped dramatically, to the point where its use is only a very small percentage of pertussis-containing vaccines today and its use will soon be phased out entirely. Currently, the VICP has only 7 DTaP claims filed versus nearly 4,000 for DTwP. The future workload of the VICP will be primarily for vaccines other than DTP, and the report data, as well as future VICP changes, should reflect this reality.

Trust Fund Growth

With regard to the last paragraph on page 21 of the draft report we recommend that the references to the Food and Drug Administration and Centers for Disease Control and Prevention be deleted. The Administration has not submitted any formal proposals to increase support for activities related to vaccine safety or otherwise taken a position relative to potential use of the Trust Fund balance.

Recommendation

The GAO recommends that, "...the Secretary of HHS formalize and publish a set of standard criteria for making decisions to add or remove injuries from the VICP's Vaccine Injury Table. These criteria should cover the specific scientific and public policy considerations and their relative weight in the decision-making process, and should be applied to any future Table changes." As context for the recommendation, GAO states on page 17 of the draft report that, "HHS has published its rationale for each Table change in the Federal Register, but has not published an overall method of applying the criteria it uses in conjunction with the IOM findings."

We believe that the methodology GAO is seeking, given the reference to specific and weighted scientific and public policy considerations, would unnecessarily restrict a deliberative process that is dynamic and capable of integrating new or changing scientific information. The Department currently uses the process established in statute to obtain broad input regarding the Vaccine Injury Table and, after reaching decisions, the Department provides detailed descriptions in the rule-making notices of the basis for those decisions. The scientific and public policy considerations vary on a case-by-case basis. It would be inappropriate to adopt what might be perceived as a "one size fits all" approach, in which the scientific basis for decisions is reduced to the application of weighted criteria. The current process allows for a more complete consideration of many different and often complex variables. Therefore, the Department is unable to concur with the GAO recommendation.

Now on p. 18.

Now on p. 15.

# Comments From the Department of Justice



U. S. Department of Justice

Civil Division

Deputy Assistant Attorney General

Washington, D.C. 20530  
November 3, 1999

Kathryn G. Allen  
Associate Director  
U.S. General Accounting Office  
Health, Education and Human Services Division  
Washington, DC 20548

Dear Ms. Allen:

This letter responds to the GAO Draft Report entitled Vaccine Injury Compensation Program: Program Falls Short of Expectations to Quickly and Easily Settle Claims (GAO/HEHS-00-08) sent to the Department of Justice ("DOJ") for review. We appreciate the opportunity to provide comments.

In recognizing the importance of vaccines in preventing infectious disease, the GAO Draft Report appropriately credits immunizations as one of the most effective public health initiatives ever undertaken. The Vaccine Injury Compensation Program ("VICP") has played a key role in the overall success of the Nation's immunization program by encouraging childhood immunization, stabilizing the supply of vaccines and providing a feasible avenue for compensation in rare cases of vaccine injury. More than 1,450 families and individuals have received compensation for vaccine injuries since the inception of the Program eleven years ago. This statistic is evidence of success in the mission to provide relief to families of vaccine injured children who would have stood little, if any, chance of obtaining awards in the traditional tort system. Additionally, the combined total of awards paid under the VICP exceeds \$1 billion dollars. In our assessment, the title of the Draft Report unfortunately conveys an incorrect view that the Program is not operating effectively. In light of these statistics, we would suggest use of a more objective title in the final Report.

We recognize the GAO focus was narrow in scope, examining the length of time it takes to process cases, the effect of the revised Vaccine Injury Table, and the growth of the Trust Fund balance. Our comments are directed to the first inquiry — that of case processing time. While many cases are resolved promptly, a number of factors have impacted the speedy resolution of all vaccine injury cases. The Draft Report offers two main explanations for longer than expected case processing times — the high volume of cases filed and changes in Program implementation. The Draft Report also notes the Chief Special Master's assessment that cases could be adjudicated more promptly, but delays are granted primarily to benefit petitioners who often need more time to develop their cases. Certain statements in the Draft Report, however, may convey an incorrect understanding of why some cases have taken longer to resolve than originally anticipated.

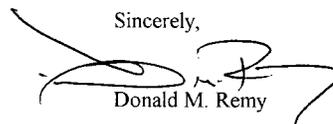
**Appendix V**  
**Comments From the Department of Justice**

The Draft Report correctly states that the number of claims filed under the VICP jumped from 125 claims in 1989, the year after the VICP took effect, to 3,263 claims in 1990. Another 968 claims were filed in 1991. The Draft Report notes that this large influx of cases "created an immediate backlog," and, "[a]s might be expected, processing times began to increase as HHS worked to respond to the influx of claims. Before 1990, nearly all claims were processed within 2 years. Starting in 1990, however, only about 30-40 percent of claims filed each year have been processed this quickly." These statements appear not to consider that due to the overwhelming number of cases filed, the Office of Special Masters at the U.S. Court of Federal Claims was unable to assign most cases to a special master for immediate adjudication. On November 1, 1991, the Chief Special Master issued an order in all pending cases explaining that cases could not proceed strictly in accordance with the time frames set forth in the Vaccine Act and Vaccine Rules. The court, making every effort to process the cases in the most efficient and effective manner possible, began to assign a small number of cases to each special master every month at which point a date was set for HHS review. Subsequent similar orders addressing the backlog of unassigned cases were issued over the next three years. Thus, due to the sheer volume of cases and limited resources, the court was forced to suspend proceedings on some cases for four or five years or more. Although the GAO data accurately reports that most cases were not processed within one to two years of filing, its discussion of this issue would be clearer and more accurate if it explained that many cases were suspended for at least several years and were not actively processed during that time period.

Finally, the GAO Draft Report states that "in 1990 when the number of claims dramatically increased, HHS significantly changed how the government would respond to vaccine injury claims," attributing delay in case processing to this "change in approach." This statement incorrectly suggests a causal relationship between the increase in case filings and the more thorough manner in which HHS reviewed each claim. Rather, by statutory design, DOJ was to represent HHS in VICP cases; however due to budgetary constraints, DOJ was unable to provide consistent representation until early 1990. Further, DOJ's involvement assisted in expedited case processing in many cases. DOJ was called upon to preliminarily review unassigned cases for completeness to assist petitioners and the court in efficiently resolving petitioners' claims.

The VICP is a worthwhile program that has stabilized the supply of vaccines, assisted in largely eliminating the specter of many deadly diseases and boosted the national health policy to the benefit of all Americans. The Draft Report includes some important data about the VICP. The above comments, however, provide a more complete view of the VICP with regard to its success in compensating more than 1,450 persons alleging injury from vaccinations through a streamlined system of recovery that is less adversarial, less expensive and less time-consuming than the traditional tort system.

Sincerely,



Donald M. Remy

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