

March 2000

VACCINE INJURY TRUST FUND

Revenue Exceeds Current Need for Paying Claims



G A O

Accountability * Integrity * Reliability

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Abbreviations

CDC	Centers for Disease Control and Prevention
DTP	diphtheria, tetanus, and whole-cell pertussis vaccine
DTaP	diphtheria, tetanus, and acellular pertussis vaccine
HHS	Department of Health and Human Services
Hib	hemophilus influenzae type b
IPV	inactivated polio vaccine
MMR	measles, mumps, and rubella vaccine
OPV	oral polio vaccine
VICP	Vaccine Injury Compensation Program



United States General Accounting Office
Washington, D.C. 20548

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

B-284440

March 31, 2000

The Honorable William V. Roth, Jr.
Chairman
The Honorable Daniel Patrick Moynihan
Ranking Minority Member
Committee on Finance
United States Senate

The Honorable Bill Archer
Chairman
The Honorable Charles B. Rangel
Ranking Minority Member
Committee on Ways and Means
House of Representatives

The Vaccine Injury Compensation Program (VICP) pays medical and other expenses for people injured through adverse reactions to vaccines against 11 specific diseases such as measles and polio. Such injuries, though rare, can be debilitating and require a lifetime of medical treatment. People seeking compensation for certain vaccine injuries must first file a claim under VICP, instead of suing vaccine manufacturers and vaccine administrators. The program uses a vaccine injury table that 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, petitioners with injuries not listed on the table bear the burden of proving that the vaccine caused injury.

From the program's inception in fiscal year 1988 through fiscal year 1999, the program's trust fund paid nearly \$350 million in compensation for vaccine injuries and attorney fees, as well as related administrative costs. The fund, which is supported by an excise tax of 75 cents on every dose of vaccine sold that is covered by the program, had a balance at the end of fiscal year 1999 of \$1.46 billion for paying claims.¹ If current trends hold, the Congressional Budget Office has projected that the balance will nearly

¹Any trust fund surplus is invested in Treasury securities. A more complete description of how the trust fund works is included in the Background section.

double in the next decade. This balance has raised questions such as whether the current excise tax rate exceeds the level necessary to meet the fund's stated purpose.

Public Law 106-170 directed us to review the operation of the trust fund and its adequacy to meet future claims. When the law was enacted in December 1999, we had completed a separate review of VICP in response to a request from the Chairman, Senate Committee on Health, Education, Labor and Pensions, which in part satisfied our requirement under the law to address these issues.² Therefore, as agreed with your offices, we are providing more specific information on the following questions related to the fund's adequacy for paying claims and administrative costs:

- Which vaccines have accounted for the majority of trust fund expenditures, and are these vaccines still being widely administered?
- How has the trust fund been affected by the addition of new vaccines?
- Have amounts appropriated for agency administrative costs and paid by the fund been sufficient to meet agency needs?
- Is the trust fund balance sufficient to meet future program demands?

Our responses to these questions are based in part on work completed for the previous report. We supplemented this work as needed with additional analysis of financial and claims information related to the fund. We conducted our work from December 1999 through February 2000 in accordance with generally accepted government auditing standards. (See app. I for more on our scope and methodology.)

Results in Brief

Two vaccines, accounting for about 88 percent of the trust fund payments for injury claims through 1999, are being phased out of use in the United States. One type of vaccine against pertussis (whooping cough) accounted for about 68 percent of trust fund payments, and one type of vaccine against polio accounted for another 20 percent. Trust fund payments for injuries and deaths associated with these two vaccines are expected to decline as the vaccines are replaced with others that to date have resulted in fewer reports of adverse reactions.

²*Vaccine Injury Compensation: Program Challenged to Settle Claims Quickly and Easily* (GAO/HEHS-00-8, Dec. 22, 1999).

Vaccines against four diseases have been added to VICP since 1997, but through December 1999, only 6 of the 285 claims filed related to these vaccines had been adjudicated, and only one \$600 payment for attorney fees had been made from the trust fund. For the remaining claims, program officials were either waiting for petitioners to submit missing information or were still processing them. Historically, claims experience for other vaccines has shown that payments are generally higher for claims with injuries listed on the vaccine injury table, but only five of the claims against new vaccines so far allege an injury listed on the table. For claims with nontable injuries, a lower percentage of petitioners obtain compensation, in part because available medical evidence often is insufficient to prove that the vaccine was responsible, and the amounts awarded often have been less. Through 1999, for example, claims with nontable injuries were awarded compensation about half as often as claims with table injuries, and the average amount of compensation paid was about 80 percent less than amounts paid for table injury claims.

Current annual appropriation levels to reimburse agencies from the trust fund for administrative expenses—about \$9.6 million—appear sufficient to meet agency needs. The Department of Health and Human Services (HHS) administers VICP, with involvement by the Department of Justice and the U.S. Court of Federal Claims to help adjudicate injury claims. In earlier years of the program, administrative expenses incurred by these agencies sometimes exceeded the amounts appropriated from the trust fund to reimburse them. Since fiscal year 1996, however, when the trust fund appropriation was increased from about \$7.8 million to \$9.4 million, appropriated amounts have exceeded actual expenditures by 3 to 11 percent each year.

The \$1.46 billion trust fund balance appears to provide a more than adequate reserve, given experience to date for claims payments and related administrative costs. If the Congress is concerned about the size of the balance and wants to reduce it or its rate of growth, various options are available to do so. These options include reconsidering the current excise tax rate, revising the criteria for compensating injuries, and considering other vaccine-related uses for fund revenues, such as vaccine injury surveillance systems and research examining potential links between vaccines and adverse events.

Background

Infectious diseases are responsible for nearly half of all deaths worldwide of people under the age of 44. By contrast, in the United States, vaccinating

children against infectious 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. However, in some instances a vaccine can have severe side effects, including death or disabling conditions requiring lifelong 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 enacted a different approach for compensating people injured by certain vaccines routinely provided in childhood with the passage of the National Childhood Vaccine Injury Act of 1986 (title III of P.L. 99-660). This law created VICP.

How the Program Works

Under VICP, rather than filing a lawsuit against the vaccine manufacturer or vaccine administrator in the civil tort system, individuals claiming injury from covered vaccines must first file a petition for “no-fault” compensation with the U.S. Court of Federal Claims.³ 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. As overall administrator of VICP, HHS is represented by Justice attorneys, while the petitioner may be represented by a private attorney.

To ensure access to the program, VICP pays reasonable attorney fees and costs for the petitioner, regardless of whether the petitioner is awarded compensation.⁴ There is 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.

³Lawsuits may be filed against manufacturers or health care providers directly for amounts up to \$1,000, or after a final judgment under VICP is rejected by the petitioner.

⁴Reasonable attorney fees and costs generally reflect the actual time and expense devoted to the case.

VICP originally covered vaccines against seven diseases—diphtheria, tetanus, pertussis, measles, mumps, rubella (German measles), and polio. Since 1997, vaccines against four more diseases have been added— hepatitis B, hemophilus influenzae type b (Hib), varicella (chicken pox), and rotavirus.⁵ There are two conditions for covering new vaccines under VICP. First, the Centers for Disease Control and Prevention (CDC) must recommend the vaccine for routine administration to children. Second, the excise tax for each dose of vaccine sold must be enacted into law.⁶

HHS is required by law to amend the table of vaccines covered by the program, including any injuries associated with such vaccines. In compliance with law, HHS has twice evaluated scientific information about links between injuries and vaccines and used this information to add and delete injuries from the table. The current vaccine injury table is shown in table 1.

⁵Manufacturers removed the vaccine against rotavirus from the United States market in October 1999 because of studies showing an increased risk of bowel obstruction after vaccination. However, it remains covered under the program.

⁶Other new vaccines are being considered but have not yet met the conditions for VICP coverage. For example, legislation was enacted establishing a tax for vaccines against streptococcus pneumoniae (pneumococcal disease) effective December 18, 1999; however, as of March 2000, CDC had not published recommendations for routine administration of this vaccine to children. Vaccines against hepatitis A are another example. CDC had not recommended routine administration of the hepatitis A vaccine to children in all states, but as of October 1999 had recommended routine use in 11 states and consideration of routine use in 6 others. HHS will make a determination of whether this recommendation merits coverage under VICP at the time the Congress enacts a tax on the hepatitis A vaccine, according to HHS officials.

Table 1: Vaccine Injury Table

Covered vaccines	Injury/adverse event ^a	Time period ^b
Included in the original table		
Tetanus-containing	Anaphylaxis or anaphylactic shock	4 hours
	Brachial neuritis	2-28 days
Pertussis-containing	Anaphylaxis or anaphylactic shock	4 hours
	Encephalopathy (or encephalitis)	72 hours
Measles, mumps, and rubella in any combination	Anaphylaxis or anaphylactic shock	4 hours
	Encephalopathy (or encephalitis)	5-15 days
Measles-containing	Thrombocytopenic purpura	7-30 days
	Vaccine-strain measles in an immuno-deficient recipient	6 months
Rubella-containing	Chronic arthritis	7-42 days
Polio live virus-containing	Paralytic polio or vaccine-strain polio viral infection	
	• In a nonimmunodeficient recipient	30 days
	• In an immunodeficient recipient	6 months
Polio inactivated virus-containing	• In a vaccine-associated community case	Not applicable
	Anaphylaxis or anaphylactic shock	4 hours
Added since 1997		
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	No condition specified	Not applicable

^aInjuries also include any acute complication or sequela (including death) of the listed events (for all but the conjugated Hib and varicella vaccines).

^bFor first symptom, onset, or aggravation of injury after vaccination.

The trust fund provides compensation for injuries related to vaccines administered after October 1, 1988.⁷ The excise tax supporting the trust fund is a flat tax, and the tax rate is not based on an empirical risk assessment to fund current or future benefits.⁸

Trust Fund Status and How the Trust Fund Works

The 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 Department of the Treasury reported it has collected over \$1.8 billion in vaccine excise taxes. Of this amount, \$456 million went directly to the general fund to offset income and payroll taxes lost to the general fund as a result of the excise tax.⁹ The remaining \$1.37 billion went to the VICP trust fund to be available for claims payments and related administrative costs. Because the trust fund has spent only about \$347 million of the \$1.37 billion received, the remaining \$1 billion 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.¹⁰ Interest on these securities held by the trust fund totaled about \$435 million by the end of fiscal year 1999. This \$435 million in interest and the \$1 billion loaned to the Treasury make up the \$1.46 billion trust fund balance existing as of the end of fiscal year 1999. Figure 1 summarizes the money flow.

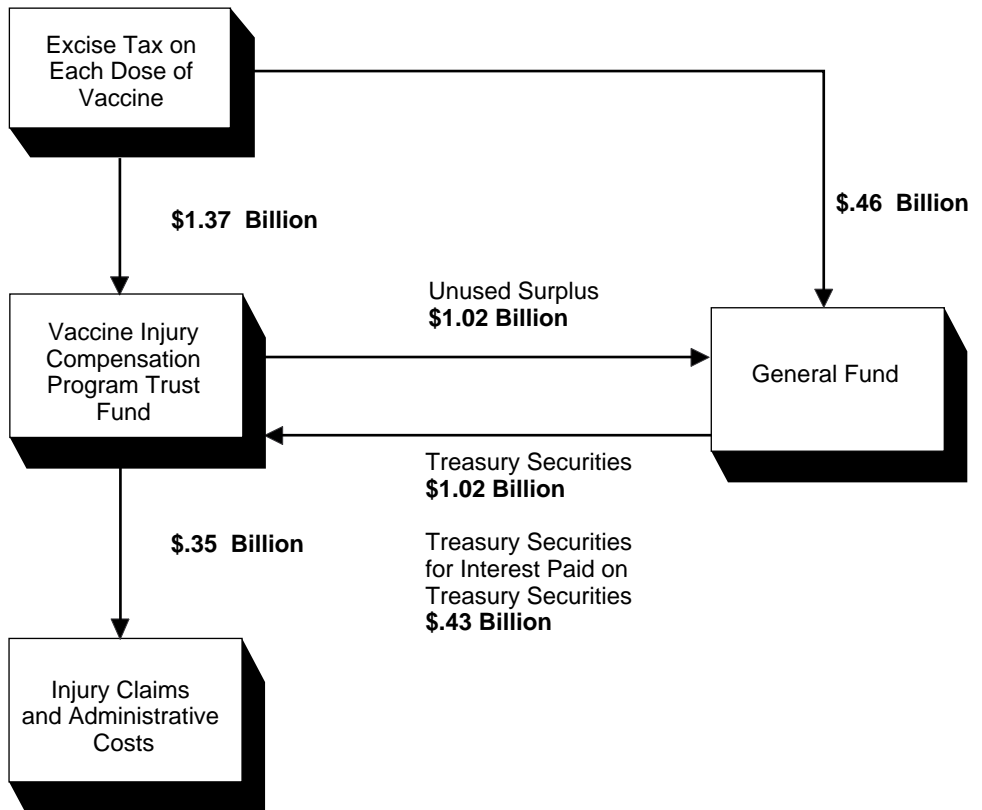
⁷Claims related to vaccines administered before October 1, 1988, are paid from general fund appropriations rather than the trust fund.

⁸We have reported on the need to establish a risk-based approach for federal insurance programs whenever possible; see *Budget Issues: Budgeting for Federal Insurance Programs* (GAO/AIMD-97-16, Sept. 30, 1997). According to HHS officials, using a risk-based approach to set the tax rate is not feasible within a reasonable degree of precision.

⁹A 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.

¹⁰Such arrangements are provided for under section 9602(b) of the Internal Revenue Code.

Figure 1: Money Flow Attributable to Vaccine Excise Taxes Collected, FY 1988-99



Vaccines Responsible for Most Trust Fund Expenditures Are Being Replaced

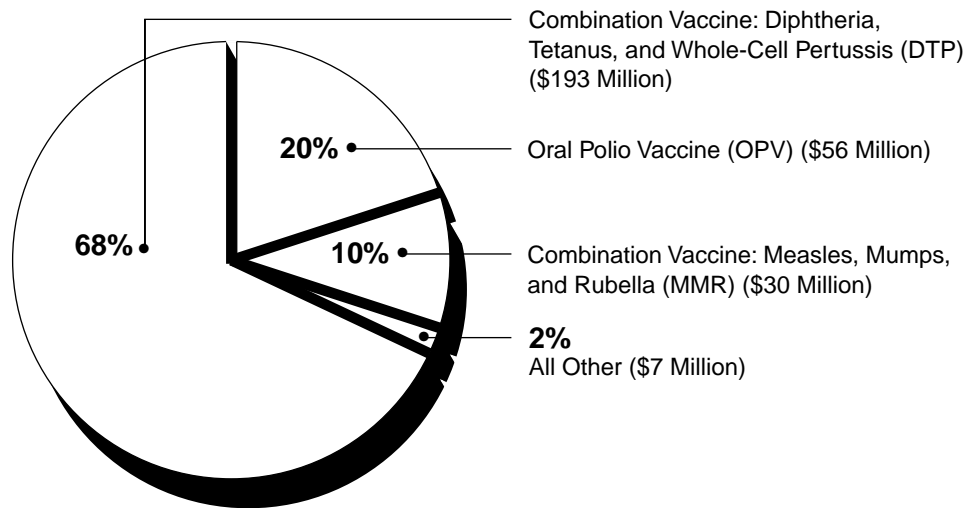
Two of the 13 vaccines for which individuals filed claims against the VICP trust fund accounted for 88 percent of the trust fund payments for injury claims. About 68 percent of total payments were for pertussis claims associated with the DTP (diphtheria, tetanus, and whole-cell pertussis) vaccine, and about 20 percent were for claims associated with OPV (oral polio vaccine). Trust fund payments for injuries and deaths associated with these vaccines are expected to decline as the vaccines are replaced with other vaccines reported to cause fewer or less frequent adverse reactions.

Pertussis and Polio Vaccines Accounted for Most Claim Payments

Through December 31, 1999, the VICP trust fund was authorized to pay over \$286 million in compensation and attorney fees for vaccine injury claims. Over \$193 million of this amount was associated with claims of

injury from the DTP vaccine. Most of the remainder was associated with OPV (see fig. 2).

Figure 2: VICP Trust Fund Payments by Type of Vaccine, CY 1989-99



Few Claims Have Been Associated With Replacement Vaccines

Future claims and compensation paid for DTP and OPV vaccine injuries are expected to decline as these vaccines are replaced with others that HHS considers to have less frequent or fewer adverse reactions. The replacement for DTP, called DTaP, includes an “acellular” pertussis vaccine instead of the “whole-cell” pertussis vaccine that was associated with many of the neurological injury claims against DTP.¹¹ The replacement for OPV, called IPV, includes an inactivated poliovirus rather than the live poliovirus associated with the polio injury claims against OPV.

The Food and Drug Administration licenses vaccines for sale in the United States, and both the public and the private sector sometimes issue recommendations on which of the licensed vaccines are preferable for use. In the federal sector, for example, CDC—which administers the National Immunization Program—has recommended DTaP over DTP since 1997

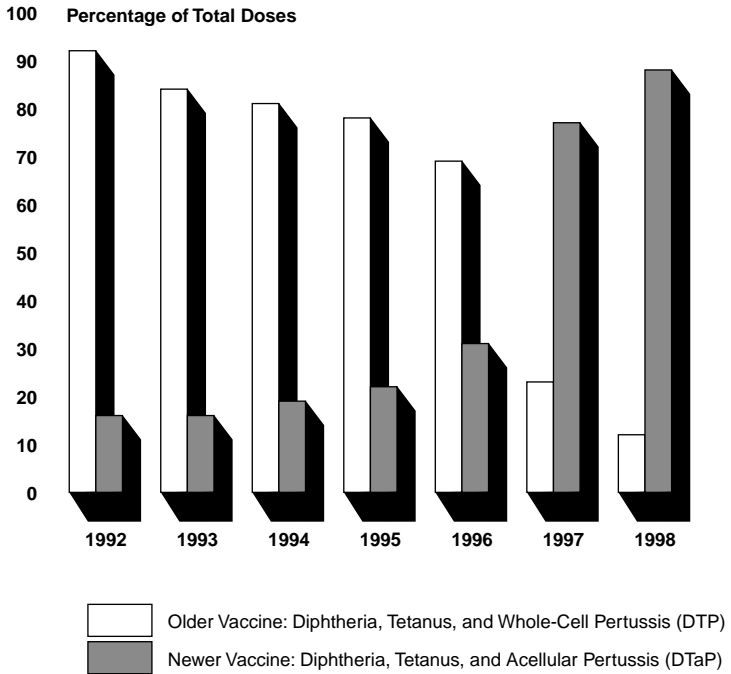
¹¹ Acellular pertussis vaccines contain inactivated pertussis toxin and may contain one or more other bacterial components, while whole-cell pertussis vaccines contain suspensions of inactivated *Bordetella pertussis* bacterial cells.

because DTaP is less likely than DTP to cause adverse reactions such as seizures or shock. Similarly, because OPV causes vaccine-strain polio in about 8 to 9 people each year, CDC recommended using IPV instead of OPV as of January 1, 2000. In the private sector, the American Academy of Pediatrics—which issues policy statements on immunization to pediatric physicians—makes similar recommendations.

These recommendations have had a significant effect on the types of vaccines distributed in the United States. CDC, for example, purchases about half of all vaccines sold in the United States under a consolidated contract for various immunization programs sponsored by federal and state agencies. CDC stopped purchasing DTP under these contracts in 1997, and most other purchasers followed suit.¹² By 1998, the percentage of DTP doses distributed in the United States had dropped to 12 percent from 92 percent in 1992 (see fig. 3). The purchase of DTP is now limited primarily to a combination DTP-Hib vaccine that CDC plans to stop purchasing after March 2000.

¹²While some doses of DTP continue to be sold outside of the CDC contracts, they composed less than 2 percent of all DTP/DTaP doses sold in 1998.

Figure 3: Distribution of Pertussis-Combination Vaccines in the United States, by Type, CY 1992-98



As the use of DTP in the United States has declined, the number of claims against it has also declined. By contrast, as the doses of DTaP in the United States have increased, VICP has received few injury claims associated with DTaP. From 1992 (just after DTaP was first licensed) through 1998, only 6 injury claims were filed against DTaP, compared with 311 injury claims against DTP during this same time period (see table 2).

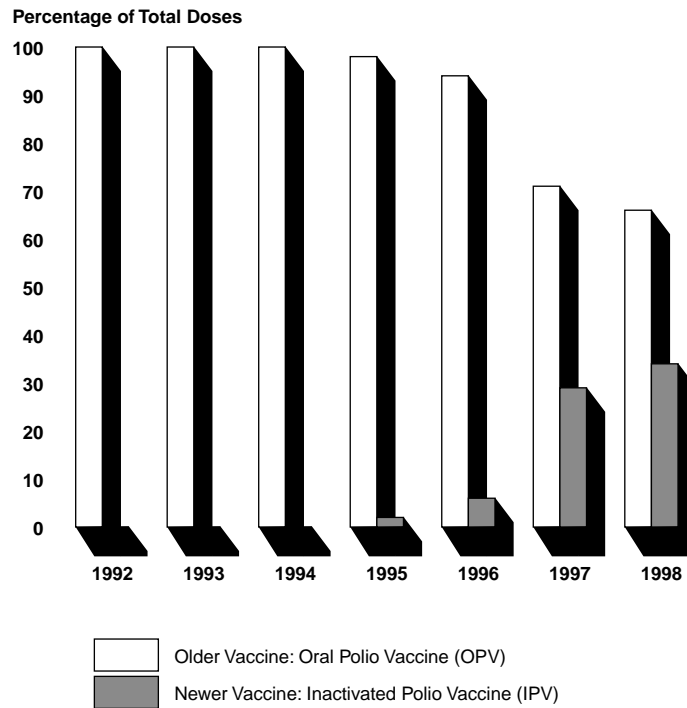
Table 2: Pertussis-Combination Injury Claims, by Calendar Year Vaccine Was Administered

Year vaccine administered	DTP ^a	DTaP
1988	41	Not applicable
1989	135	Not applicable
1990	94	Not applicable
1991	77	Not applicable
1992	73	0
1993	87	0
1994	77	2
1995	42	2
1996	27	0
1997	5	2
1998	0	0
Total	658	6

^aIncludes 10 claims against the DTP-Hib combination vaccine.

Similarly, since 1995 CDC has been decreasing the proportion of OPV purchased under contract in favor of IPV. Purchases outside the CDC contract have mirrored this change. In 1998, the percentage of OPV doses distributed in the United States had dropped to 66 percent from 98 percent in 1995 (see fig. 4). CDC did not renew the contract for OPV when it expired on December 31, 1999.

Figure 4: Distribution of Polio Vaccines in the United States, by Type, CY 1992-98



As the doses of OPV distributed in the United States decreased, injury claims filed against the vaccine also decreased. From 1988—about the time the current IPV was licensed—through 1998, 73 injury claims were filed against OPV. Thus far, there have been no claims of vaccine injury related to IPV (see table 3).¹³

¹³VICP received 264 claims alleging injuries sustained in the 1950s and 1960s from an IPV vaccine that was subsequently replaced with one of higher purity and effectiveness, according to HHS officials. The filing deadline for injury claims against this older IPV vaccine was January 31, 1991, and payments associated with claims filed against this IPV vaccine were paid from appropriated funds, not the VICP trust fund.

Table 3: Polio Vaccine Injury Claims, by Calendar Year Vaccine Was Administered

Year vaccine administered	OPV	IPV
1988	6	0
1989	16	0
1990	6	0
1991	7	0
1992	11	0
1993	8	0
1994	9	0
1995	4	0
1996	5	0
1997	1	0
1998	0	0
Total	73	0

Trust Fund Not Yet Affected by Claims Against New Vaccines

Vaccines against four diseases have been added to VICP since 1997, but as of December 31, 1999, only 6 of the 285 claims filed for these vaccines had been adjudicated and only one trust fund payment had been made. Program officials were either waiting for petitioners to submit missing information or were still processing the remaining claims. Historically, compensation has generally been higher for claims with injuries listed on the vaccine injury table, but only 5 of the 285 claims against the new vaccines allege a table injury. Claims experience for other vaccines shows that nontable injury claims are awarded compensation from the trust fund nearly 50 percent less often than claims with table injuries, and average amounts awarded for nontable injuries were generally 80 percent less.

No Claims Adjudicated for Vaccines Covered by VICP Since 1997

Vaccines against hepatitis B, Hib, varicella, and rotavirus were added to VICP since 1997, and as of December 31, 1999, 285 injury claims were filed. For three of the four vaccines, the number of claims filed was few or none (see table 4). Of the 285 claims filed, all but 10 were for injuries related to the hepatitis B vaccine. Most of the hepatitis B claims were filed shortly before an August 1999 filing deadline for vaccine injuries sustained in the previous 8 years.¹⁴

Table 4: VICP Claims Filed for New Vaccines Through Calendar Year 1999

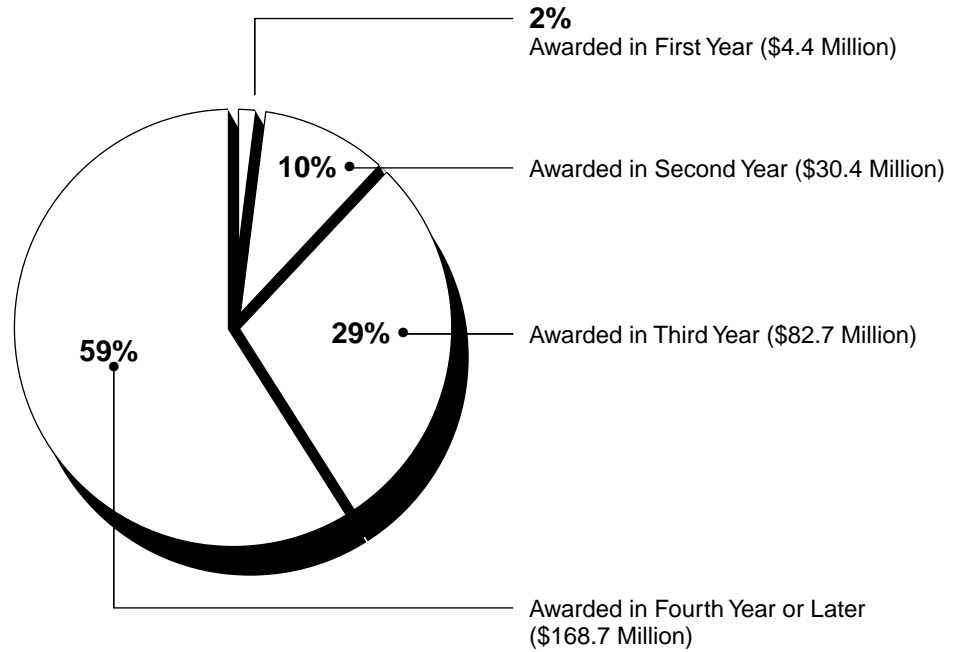
Vaccine	Injury claims filed
Hepatitis B	275
Hib ^a	3
Varicella	7
Rotavirus	0

^aHib may be administered in combination with other vaccines such as DTP. Fourteen injury claims were filed against the DTP-Hib combination vaccine.

Only 6 of the 285 claims had been adjudicated as of December 31, 1999, and for these 6 claims, only one payment for about \$600 in attorney fees had been made. Two main reasons explain why. First, most claims did not include the information necessary for VICP to process them, according to program officials. Officials said that in an attempt to file claims before the deadline, most petitioners did not submit medical records detailing information such as the date the vaccine was administered or the type of injury incurred. Of the 285 claims filed, for example, data show that 268 had not specified an injury. Second, the claims adjudication and payment process generally takes several years. Historically, less than 13 percent of the \$286 million in compensation and attorney payments awarded from the trust fund through 1999 was paid within 2 years of when the claims were filed. Close to 60 percent of all payments were made in the fourth year after the claim was filed or later. (See fig. 5.)

¹⁴After the August 1999 deadline, injury claims must be filed within 36 months after the first symptoms of injury appear, and death claims must be filed within 24 months of death. Six claims were filed against hepatitis B from September through December 1999.

Figure 5: Years Between Filing a VICP Claim and Receiving Payment, CY 1988-99



Data for Other Vaccines May Provide Some Perspective on Future Trust Fund Payments for New Vaccines

Because so few claims have been adjudicated, the effect of the new vaccines on trust fund payments is unknown. However, data available regarding compensation paid for other vaccines covered by VICP show that petitioners have been significantly more likely to obtain compensation if their injuries are listed on the injury table. While the injury table lists eight different medical conditions or injuries related to some vaccines, no injuries are listed on the table for varicella, Hib,¹⁵ or rotavirus. Only one injury, anaphylactic shock, is listed for hepatitis B. Of the 275 claims against hepatitis B, only 5 allege injury related to anaphylactic shock. See table 5 for a list of table and nontable injury claims for the new vaccines.

¹⁵The injury table lists early-onset Hib as an injury covered for an older type of Hib vaccine that is no longer administered. The type of Hib vaccine currently administered has no listed table injuries.

Table 5: New Vaccine Claims With and Without Table Injuries

Injuries alleged against new vaccines	Number of claims filed	Injury listed on table?	
		Yes	No
Anaphylactic shock	5	5	0
Arthritis	2	Not applicable	2
Encephalopathy	3	Not applicable	3
Guillain-Barre syndrome	3	Not applicable	3
Seizure disorder	4	Not applicable	4
Not specified	268	Not applicable	268 ^a
Total	285	5	280

^aIf anaphylactic shock in relation to hepatitis B vaccinations is eventually specified for any of these claims, the claims would become table injury claims.

Not having an injury listed on VICP's injury table is significant because compensation for claims with nontable injuries has historically differed from compensation for table injury claims in two ways: nontable injury claims tended to be approved for compensation less often, and the compensation amounts were lower. Because about one-third of all trust fund claims remain to be adjudicated, the full extent of the difference has yet to be determined. Through December 31, 1999, however,

- 50 percent of adjudicated table claims were compensated, compared with 27 percent for nontable claims,¹⁶ and
- when compensation was provided, the average amount awarded was \$942,859 for table claims, compared with \$184,244 for nontable claims.¹⁷

¹⁶If no remaining claims were adjudicated in the petitioner's favor, compensation rates would be 11 percent for nontable claims and 37 percent for table claims. If all remaining claims were adjudicated in the petitioner's favor, compensation rates would be 69 percent for nontable claims and 63 percent for table claims. Our earlier report on VICP stated that only 13 percent of petitioners filing claims for nontable injuries obtained compensation, while those with table injuries had compensation rates nearly three times higher. These results included all claims filed under VICP, either paid from general fund appropriations or from the trust fund, while those in this report include only claims paid by the VICP trust fund.

¹⁷The median amount awarded for table claims was \$306,852, and the median amount for nontable claims was \$75,027.

While this information may provide some perspective on what might happen with these new vaccine claims, such comparisons must be viewed with caution. Compensation rates might be higher or lower for the new vaccines if medical evidence becomes available to prove or disprove links between vaccines and injuries.¹⁸ For example, administration of the rotavirus vaccine was suspended in July 1999 because of a suspected causal link with bowel injury in infants.¹⁹ However, HHS officials are unaware of any current studies that would result in increased numbers of claims filed or compensated for the hepatitis B, Hib, or varicella vaccines.

**Trust Fund
Appropriations
Currently Are
Sufficient to Cover
Administrative
Expenses**

Appropriations from the trust fund for administrative expenses, \$9.5 million in fiscal year 1999, appear sufficient to cover current costs incurred by the agencies involved with the program. Although agencies had to absorb some administrative costs that exceeded appropriations during fiscal years 1988 through 1995, administrative costs have been lower than trust fund appropriations since fiscal year 1996.

¹⁸The Institute of Medicine studied 75 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 these studies in *Research Strategies for Assessing Adverse Events Associated With Vaccines: A Workshop Summary* (Washington, D.C.: National Academy Press, 1994).

¹⁹No claims have been filed with VICP for bowel injury resulting from the rotavirus vaccine. However, unless legislation is enacted to change eligibility requirements, compensation would not be provided because the program requires the adverse event to last 6 months or longer, and corrective surgery or other medical intervention generally occurs before this time frame, according to a program official.

Funds for Administrative Expenses Are Appropriated From the Trust Fund

Three agencies incur administrative expenses related to the program: HHS, the Department of Justice, and the U.S. Court of Federal Claims. Each year, the Congress appropriates a maximum amount that can be used from the trust fund to reimburse each agency for administrative expenses related to VICP (see table 6). If an agency spends more than the trust fund appropriation, it must absorb these administrative expenses elsewhere within its budget. On the other hand, if the amount appropriated from the trust fund exceeds agency spending for the program, the excess remains in the trust fund. Since fiscal year 1996, trust fund appropriations for administrative costs have amounted to about \$9.5 million per year.²⁰

Table 6: Trust Fund Appropriations for VICP Administration, FY 1988-2000

Fiscal year	HHS	Department of Justice	U.S. Court of Federal Claims	Total
1988 ^a				
1989 ^a				
1990	\$1,500,000	\$1,000,000	\$2,500,000	\$5,000,000
1991	1,500,000	2,000,000	1,500,000	5,000,000
1992	2,500,000	2,000,000	2,100,000	6,600,000
1993	2,500,000	2,000,000	2,075,000	6,575,000
1994	3,000,000	2,000,000	2,160,000	7,160,000
1995	3,000,000	2,500,000	2,250,000	7,750,000
1996	3,000,000	4,028,000	2,318,000	9,346,000
1997	3,000,000	4,028,000	2,390,000	9,418,000
1998	3,000,000	4,028,000	2,450,000	9,478,000
1999	3,000,000 ^b	4,028,000	2,515,000	9,543,000
2000	3,000,000	4,028,000	2,581,000	9,609,000

^aNo specific appropriations were made for VICP administration.

^bAn FY 99 rescission decreased the HHS appropriation to \$2,944,000.

²⁰In recent years, amounts appropriated for program administration have exceeded amounts authorized for that purpose in section 9510 of the Internal Revenue Code. HHS is proposing amendments to the Public Health Service Act that would, in part, increase the authorization level for reimbursed administrative expenses to \$10 million. HHS is not asking for additional appropriations beyond the fiscal year 2000 level of \$9.6 million.

Administrative expenses reimbursed by the trust fund can be divided into four main categories, as follows:

- *Salaries and benefits.* Those paid under the appropriation include employees of HHS, Justice, and the U.S. Court of Federal Claims who process the claims and represent the government's interests in legal proceedings.
- *Expert witnesses.* HHS has responsibility for obtaining and paying for medical experts to review petitioner claims and provide expert testimony during adjudication proceedings.
- *Advisory Commission on Childhood Vaccines.* The Commission is responsible for advising the Secretary of Health and Human Services on implementation of VICP, modifications to the vaccine injury table, and improvements in the safety of vaccines. The Commission, which meets at least four times a year, is composed of health professionals, attorneys, and members of the general public.
- *Other expenses, such as travel, training, rent, supplies, and equipment.* Each agency computes these costs in a different way. HHS computes rent on the basis of square-footage and charges the program for other indirect costs up to the limit of the appropriation. Justice uses set percentages to determine the amount of indirect costs to be charged to the program.

Administrative Expenses Are Now Fully Reimbursed by Trust Fund Appropriations

For the past 5 fiscal years, total administrative expenses claimed by the three agencies have been less than the amount appropriated from the trust fund for that purpose by the Congress (see table 7). In fiscal year 1995, for example, total reimbursed expenditures²¹ were \$7,520,000, or about 3 percent less than the appropriation of \$7,750,000. By fiscal year 1999, expenses claimed by the three agencies were 11 percent below the appropriated amount. Staffing costs accounted for the largest share of expenses—71 percent.

²¹For administrative expenses, agency expenditures—or outlays—are approximately the same as obligations.

Table 7: Comparison of Administrative Expenditures and Trust Fund Appropriations, FY 1995-99

Dollars in thousands

Expenditures	Fiscal year					Total	Percent
	1995	1996	1997	1998	1999		
Salaries and benefits	\$4,965	\$6,648	\$6,353	\$6,209	\$6,147	\$30,322	71
Expert witnesses	770	600	750	572	258	2,950	7
Advisory Commission on Childhood Vaccines	67	27	67	74	43	278	1
Other ^a	1,718	1,774	1,686	1,749	1,956	8,883	21
Total expenditures	\$7,520	\$9,049	\$8,856	\$8,604	\$8,404	\$42,433	100
Appropriation	\$7,750	\$9,346	\$9,418	\$9,478	\$9,487	\$45,479	
Difference	\$230	\$297	\$562	\$874	\$1,081		
Percentage difference	3%	3%	6%	9%	11%		

Note: HHS and Justice provided expenditures, while the U.S. Court of Federal Claims provided obligations. HHS and Justice data for fiscal year 1999 are preliminary. Financial data were not audited for accuracy.

^a"Other" includes expenses related to travel, training, supplies, equipment, rent, and overhead.

Agencies Absorbed Some Administrative Expenses in the Past

While current trust fund appropriations levels appear sufficient for all three agencies, this was not always the case. In the initial years of program implementation, agencies often absorbed a portion of the costs of program administration. At Justice, this continued until 1996.

Department of Justice

For several years in the early and mid-1990s, Justice absorbed about half of the administrative expenses related to the adjudication of petitioner claims. In fiscal year 1991, the backlog of cases had reached a high of 3,641, compared with 588 cases adjudicated that year. In fiscal years 1992 through 1994, Justice was reimbursed for about half the staff needed to operate the program from the trust fund appropriation and paid for the other half from its regular appropriation. In addition, in fiscal year 1995, Justice absorbed \$1.5 million in program administration costs to support the number of staff needed to process the caseloads. This, and the expectation of higher administrative expenses for fiscal year 1996, prompted Justice to request that its administrative appropriation from the trust fund be increased from \$2.5 million to slightly more than \$4 million. It received the increase, and, according to agency records, this amount was sufficient to cover the fiscal year 1996 expenditures.²²

Since fiscal year 1996, the number of full-time-equivalent positions (FTE) assigned to this effort has decreased. In fiscal year 1998, for example, the appropriation covered 40 FTEs, but Justice filled only 29 FTEs that year. Fewer FTEs has been the main reason that, since fiscal year 1997, Justice has spent less than the appropriated amount (see table 8). For fiscal year 2000, however, Justice anticipates an FTE level of 33 and has already begun staff expansion to deal with the hepatitis B claims filed in the past year. Justice intends to acquire alternative dispute resolution services in addition to those that had previously been obtained through the U.S. Court of Federal Claims. These services, while increasing overall costs of the program, are designed to resolve cases in a more expeditious manner. As a result, Justice plans to seek reimbursement for the total amount appropriated under VICP for its administrative costs in upcoming years.

²²Justice does incur expenses related to expert witnesses that are paid from its Fees and Expenses of Witnesses appropriation. This appropriation account is nonreimbursable, and therefore Justice does not bill the trust fund for these expenses, which have averaged about \$472,000 over fiscal years 1994-99.

Table 8: Department of Justice's Reimbursed Expenditures Compared With Trust Fund Appropriations, FY 1995-99

Dollars in thousands

Expenditures	Fiscal year				
	1995	1996	1997	1998	1999
Salaries and benefits	\$1,503	\$3,094	\$2,730	\$2,600	\$2,490
Other	997	934	1,007	852	852
Total	\$2,500	\$4,028	\$3,737	\$3,452	\$3,342
Appropriation	\$2,500	\$4,028	\$4,028	\$4,028	\$4,028
Difference	0	0	\$291	\$576	\$686

U.S. Court of Federal Claims

The federal judiciary budget also absorbed portions of the U.S. Court of Federal Claims' administrative expenses through 1992, when officials developed enough experience with the program to determine the appropriate amount of reimbursement that should be provided from the trust fund. For fiscal years 1995 through 1999, obligations were consistently below trust fund appropriations (see table 9). According to an Administrative Office of the Courts official, this appropriation has increased to account for pay raises and other cost increases.

While the U.S. Court of Federal Claims has authority for eight special master positions, the six filled positions have been adequate to address the current workload. However, with the addition of new vaccines, the future workload is unknown.²³ An official said that an increase in workload would prompt the U.S. Court of Federal Claims to hire additional special masters to handle claims filed. According to the Chief Special Master, the difference between current obligations and the appropriation would be adequate—albeit tight—to fill all eight authorized positions.

²³A U.S. Court of Federal Claims official said that the workload would be dependent on the number of new vaccines added to the program, the number of claims filed against these vaccines, and the extent that injuries were directly linked to the vaccines.

Table 9: U.S. Court of Federal Claims Obligations Compared With Trust Fund Appropriations, FY 1995-99

Dollars in thousands

Obligations	Fiscal year				
	1995	1996	1997	1998	1999
Salaries and benefits	\$1,631	\$1,644	\$1,652	\$1,687	\$1,707
Other	465	464	480	490	523
Total	\$2,096	\$2,108	\$2,132	\$2,177	\$2,230
Appropriation	\$2,250	\$2,318	\$2,390	\$2,450	\$2,515
Difference	\$154	\$210	\$258	\$273	\$285

Note: This table contains U.S. Court of Federal Claims obligations for VICP rather than expenditures. However, expenditures are approximately the same as obligations.

HHS

Except for the first 2 years of program implementation when there was no appropriation for administrative expenses (see table 6), HHS has operated within its trust fund appropriation (see table 10). According to budget personnel, HHS attempts to obligate the entire \$3 million administrative appropriation.²⁴

²⁴Administrative expenses and agency expenditures—or outlays—are approximately the same as obligations.

Table 10: HHS Expenditures Compared With Trust Fund Appropriations, FY 1995-99

Dollars in thousands

Expenditures	Fiscal year				
	1995	1996	1997	1998	1999
Salaries and benefits	\$1,831	\$1,910	\$1,971	\$1,922	\$1,950
Expert witnesses	770	600	750	572	258
Advisory Commission on Childhood Vaccines	67	27	67	74	43
Other	256	376	199	407	581
Total	\$2,924	\$2,913	\$2,987	\$2,975	\$2,832
Appropriation	\$3,000	\$3,000	\$3,000	\$3,000	\$2,944 ^a
Difference	\$76	\$87	\$13	\$25	\$112

^aIn fiscal year 1999, a \$56,000 rescission decreased HHS' appropriation.

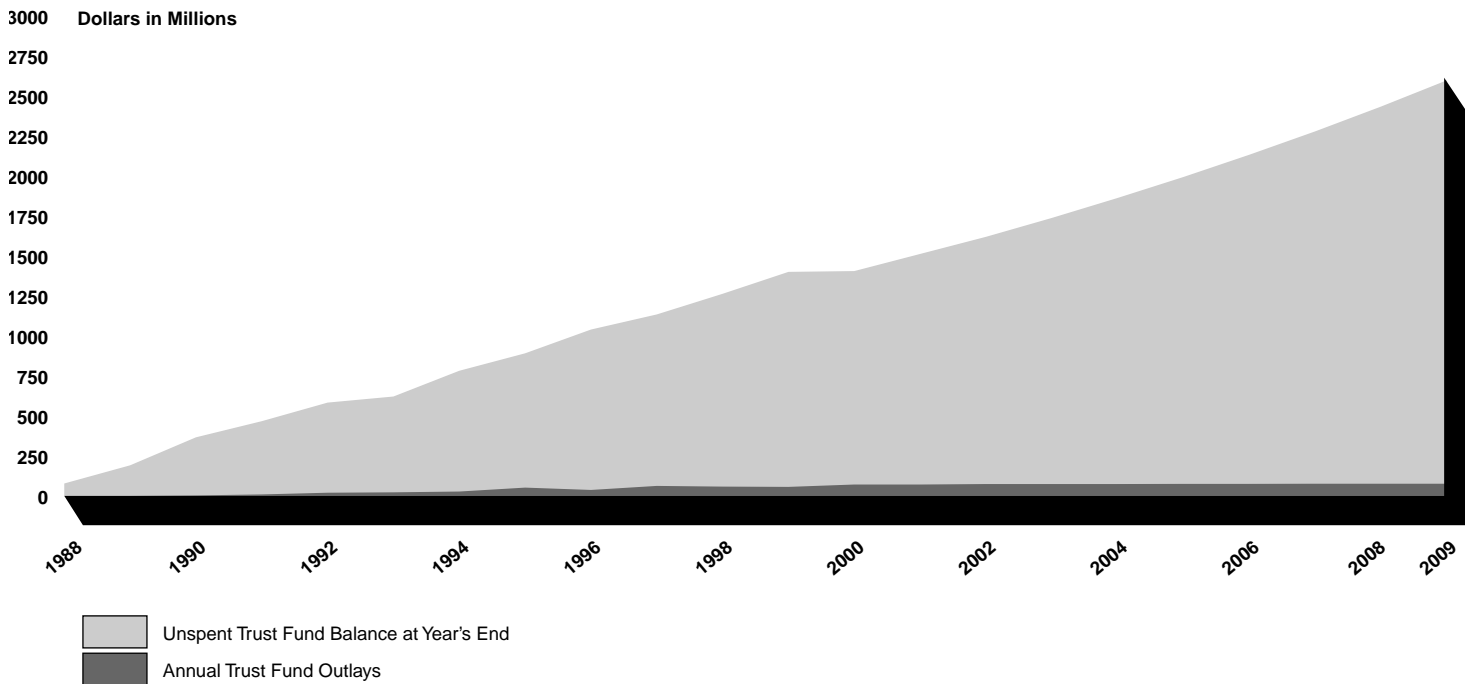
Trust Fund Balance Appears to Exceed Current Program Needs

If current VICP revenue and cost trends continue, the trust fund balance appears to be more than adequate to pay claims. While future circumstances are unknown, at current annual expenditures of about \$60 million, the current \$1.46 billion VICP trust fund balance would provide more than 23 years of spending (ignoring inflation) even if no additional revenue was received.

VICP Trust Fund Continues to Grow

The trust fund balance has continued to grow since the program's inception. The trust fund often has received twice as much in tax revenue in a year as it paid out for claims and administrative costs. In addition, the balance grows more because interest is paid on the balance. As safer vaccines are more widely administered, and unless new evidence linking injuries with vaccines becomes available, this trend of revenue exceeding expenditures is likely to continue. Using historical trend data, the Congressional Budget Office projects the trust fund will have a balance of at least \$2.7 billion by fiscal year 2009 (see fig. 6).

Figure 6: Actual and Projected Growth in VICP Trust Fund Balance, FY 1988-2009



Note: Amounts through 1999 are actual; amounts for 2000 through 2009 are based on projections by the Congressional Budget Office.

Options to Address the Growing Trust Fund Balance

The growing trust fund balance has been a matter of controversy for some vaccine manufacturers, parent groups, and others involved with VICP. Various options have been proposed to address the size of the balance. 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 rate.
- 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 compensation policy that would result in a less restrictive injury table,

which would in turn increase the number of petitioners compensated from the trust fund.

- HHS officials from the Food and Drug Administration and CDC responsible for monitoring vaccine safety suggested that if the Congress decided to authorize additional activities for trust fund spending, the balance could be used for 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, Food and Drug Administration and CDC officials we contacted supported dedicating a portion of the trust fund revenue to provide funding for vaccine injury surveillance systems and for research examining links between vaccines and delayed onset injuries or chronic diseases.

Implementing any of these options would affect not only the trust fund but also revenue and spending for the overall federal budget.²⁵ Annual excise tax revenue not used by the trust fund is loaned to the Treasury and used to fund other operations of the government or to reduce debt held by the public. Therefore, reducing the annual excise tax revenue or drawing down the trust fund balance would reduce the surplus and could require new or higher taxes elsewhere or a decrease in spending for other programs and activities.

Conclusions

While current trends are always subject to change, they suggest that attention to the VICP trust fund may be in order, not because the trust fund is in trouble, but because it is accumulating a sizeable balance. If current conditions continue in the future, the trust fund is likely to continue receiving more excise tax revenue than needed to cover costs. While proposals exist to reduce the trust fund tax receipts or increase trust fund spending, such actions can have consequences for the overall federal budget.

²⁵The Budget Enforcement 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. This provision is enforced through sequestration, which is done annually.

Agency Comments and Our Evaluation

HHS, the Department of Justice, and the U.S. Court of Federal Claims commented on our draft report. Officials of these agencies generally agreed with the report's findings. However, HHS cautioned that the VICP trust fund should not be considered "an impenetrable reserve of funds." HHS stated that certain factors could negatively affect the future trust fund balance, such as the increasing number and use of vaccines, accompanied by the potential for emerging knowledge that links adverse reactions to vaccines. Our report acknowledges that current trends are subject to change and discusses the uncertainty surrounding future claims payments, including those specifically cited in HHS' comments.

HHS, the Department of Justice, and the U.S. Court of Federal Claims also provided technical comments, which we incorporated where appropriate. HHS' comments are included as appendix II.

We are sending copies of this report to the Honorable Donna E. Shalala, Secretary of Health and Human Services; 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, Linda Bade, and Lacinda Baumgartner. Please call me at (202) 512-7118 if you or your staffs have any questions.



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

Scope and Methodology

For this report, we updated information gathered between January and September 1999 for our prior report on the Vaccine Injury Compensation Program (VICP).¹ We held discussions with officials responsible for program implementation at HHS, the Department of Justice, and the U.S. Court of Federal Claims. In addition, we talked with (1) Centers for Disease Control and Prevention (CDC) and Food and Drug Administration officials responsible for the national immunization program, licensing vaccines, and monitoring vaccine safety; (2) Department of the Treasury officials responsible for financial accounting and reporting for the VICP trust fund; and (3) the Congressional Budget Office official responsible for budgeting aspects of the trust fund and its presentation in the federal budget.

We also reviewed relevant legislation, financial reports, and budget documents. We obtained and analyzed data from HHS on claims filed under VICP from 1988 through 1999.

We conducted our work from December 1999 through February 2000 in accordance with generally accepted government auditing standards.

Administration of Vaccines Responsible for Most Trust Fund Expenditures

To determine which vaccines had been responsible for most trust fund expenditures, we analyzed HHS' VICP database. This database included data fields for each claim defining the vaccine alleged to have caused injury as well as amounts authorized for payment from the trust fund for compensation and attorney fees. We did not perform a reliability assessment of the data system. However, we did make adjustments to correct for a net \$2 million error in claims payments from the trust fund that should have been paid from appropriated funds.²

To determine the extent that vaccines were distributed in the United States, we used data provided by an official from CDC's National Immunization Program. This official tracks the number of vaccine doses purchased under CDC contract and obtains data from vaccine manufacturers on the total

¹*Vaccine Injury Compensation: Program Challenged to Settle Claims Quickly and Easily* (GAO/HEHS-00-08, Dec. 22, 1999).

²HHS paid 10 claims amounting to \$4,594,040 from the trust fund that should have been paid from appropriated funds. HHS paid 12 claims amounting to \$2,396,910 from appropriated funds that should have been paid from the trust fund. The VICP Director said that action was taken to correct these clerical errors.

number of vaccine doses sold in the United States each calendar year. Data provided by the manufacturers is self-reported and is not audited by CDC.

Effect of New Vaccines on Trust Fund Expenditures

We also used HHS' VICP database to provide some indication of the likely effect of new vaccines on the amount and timing of trust fund expenditures. We used the database to determine how many claims were filed for each of the new vaccines and whether these claims alleged injuries listed on the vaccine injury table. Claims history was insufficient to reliably project the amount of compensation that might be paid for claims attributable to the four new vaccines. Therefore, we looked at claims history data associated with other vaccines covered by VICP to get an idea of how long it takes to process claims and the resulting compensation rates.

- To determine how long it took to make payments for claims through VICP, we used data fields on when each trust fund claim was filed, when the claim was authorized for payment, and the amount of payment authorized.
- We had previously worked with HHS officials to identify which vaccine injuries they considered table injuries and which they did not. We computed compensation rates and associated awards for alleged table and nontable claims using the data fields for the U.S. Court of Federal Claims' judgment and award amounts in the HHS database.³

Sufficiency of Appropriations for Administrative Expenses

To determine sufficiency of appropriations for trust fund-reimbursed administrative expenses, we

- obtained and reviewed budgetary justification documents detailing the bases of Justice and HHS requests for VICP administrative costs,
- determined the appropriated amounts cited in relevant statutes for each of the three agencies—HHS, Justice, and U.S. Court of Federal Claims—and
- requested standardized expenditure reports from the three agencies responsible for program implementation for the previous 5 fiscal years (our scope did not include an audit or review of these data).

³We could not estimate compensation for specific injuries because most of the claims filed against new vaccines did not specify an injury.

Adequacy of Trust Fund to Meet Future Expenditures

To determine the adequacy of the trust fund balance to meet future expenditures, we obtained from the Treasury VICP financial data for fiscal years 1988 through 1999. These reports 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 financial reports. We obtained current Congressional Budget Office trust fund revenue and expenditure projections developed for the fiscal year 2001 budget.

Comments From the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

MAR 16 2000

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

Dear Ms. Allen:

The Department of Health and Human Services appreciates the opportunity to comment on the General Accounting Office's (GAO) draft report, "Vaccine Injury Trust Fund: Revenue Exceeds Current Need for Paying Claims" before its publication.

The Department has reviewed your draft report and commends GAO for their hard work in assessing the financial components of the national Vaccine Injury Compensation Program (VICP). Although GAO made no recommendations, they concluded that the \$1.46 billion trust fund balance appears to provide a more than adequate reserve given experience to date. The Department cautions against the impression provided within the report that the VICP trust fund is an impenetrable reserve of funds. With advancing technologies, the increasing utilization of vaccinations as a public health tool, and the limitations associated with identifying potential vaccine-associated adverse events in pre-licensure clinical trials that may later be identified during post-licensure surveillance (for example, the recent withdrawal of rotavirus vaccine by the manufacturer due to safety concerns), unanticipated events could potentially occur which could have serious implications with respect to the continuing adequacy of the VICP trust fund.

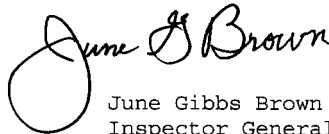
These comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

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

Page 2 - Ms. Kathryn G. Allen

The Department also provided a technical comment directly to your staff.

Sincerely,



June Gibbs Brown
Inspector General

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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