United States Government Accountability Office

Report to the Chairman, Committee on Oversight and Government Reform, House of Representatives

November 2014

VACCINE INJURY COMPENSATION

Most Claims Took Multiple Years and Many Were Settled through Negotiation

GAO-15-142

November 2014

VACCINE INJURY COMPENSATION

Most Claims Took Multiple Years and Many Were Settled through Negotiation

GAO Highlights

Highlights of GAO-15-142, a report to the Chairman, Committee on Oversight and Government Reform, House of Representatives

Why GAO Did This Study

Vaccines save lives by preventing disease in the people who receive them. In some instances, however, a vaccine can have severe side effects, including death or an injury requiring lifetime medical care. VICP provides compensation to people for injuries and deaths associated with certain vaccines for medical and other costs. The program includes an injury table that lists the injuries that are presumed to be caused by vaccines covered by the program. The program may also compensate individuals for injuries not on the table; however, in those cases causation is not presumed. In both cases, medical and other records are required. VICP pays claims from a trust fund. Since the program began in 1988, it has awarded more than $2.8 billion in compensation.

GAO was asked to review the program. GAO examined (1) how long it has taken to adjudicate claims and how claims have been adjudicated, (2) the changes to the vaccine injury table, and (3) how the balance of and spending from the Vaccine Injury Compensation Trust Fund have changed, among other objectives.

GAO examined data and interviewed officials from HHS, DOJ, and USCFC, including data on claims filed since fiscal year 1999 and their status as of March 31, 2014; reviewed laws and agency documents; and reviewed Treasury data and agency data on compensation and obligations for other VICP-related expenses for fiscal years 2009 through 2013.

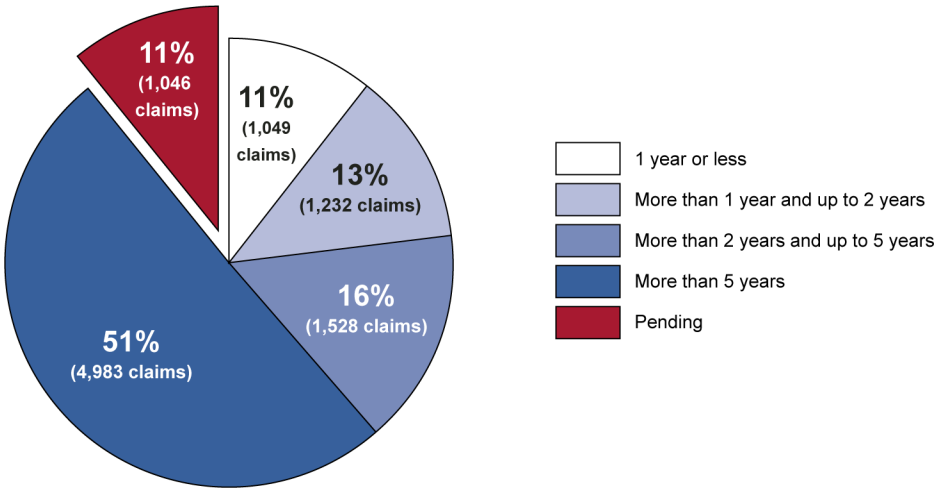
HHS and USCFC agreed with GAO's findings, and HHS, USCFC, DOJ, and Treasury provided technical comments that were incorporated as appropriate.

View GAO-15-142. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

What GAO Found

Most of more than 9,800 claims filed with the National Vaccine Injury Compensation Program (VICP) since fiscal year 1999 have taken multiple years to adjudicate (see fig.). More than 1,000 (11 percent) of claims filed since fiscal year 1999 were still in process (pending) as of March 31, 2014; most of these were pending for 2 years or less. A greater percentage of the claims filed since fiscal year 2009 were resolved within 1 or 2 years. In all but 1 year since fiscal year 2009, the program has met the target for the average time to adjudicate claims (about 3.5 years) tracked by the Department of Health and Human Services (HHS), which administers the program. Officials from the U.S. Court of Federal Claims (USCFC), where VICP claims are adjudicated, report that delays may occur while petitioners gather evidence for their claims. Since 2006, about 80 percent of compensated claims have been resolved through a negotiated settlement.

Time to Adjudicate National Vaccine Injury Compensation Program Claims Filed Fiscal Years 1999-2014, as of March 31, 2014



Source: GAO analysis of U.S. Court of Federal Claims data. | GAO-15-142

Since fiscal year 1999, HHS has added six vaccines to the vaccine injury table, but it has not added covered injuries associated with these vaccines to the table. This means that while individuals may file VICP claims for these vaccines, each petitioner must demonstrate that the vaccine that was administered caused the alleged injury. HHS is considering adding covered injuries associated with these vaccines; but as of September 2014, it had not published any final rules to do so.

The balance of the Vaccine Injury Compensation Trust Fund, managed by the Department of the Treasury (Treasury) increased from $2.9 billion in fiscal year 2009 to nearly $3.3 billion at the end of fiscal year 2013 as the trust fund's income (from net revenues from vaccine excise taxes and interest on investments) outpaced its disbursements to HHS, USCFC, and the Department of Justice (DOJ), which represents HHS in VICP proceedings. VICP compensation, funded by the trust fund, increased from less than $126 million in each of fiscal years 1999 to 2009 to over $254 million in fiscal year 2013.

Contents

Tables

Figures

Abbreviations

DOJ	Department of Justice
FTE	full-time equivalent
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
Treasury	Department of the Treasury
USCFC	U.S. Court of Federal Claims
VICP	National Vaccine Injury Compensation Program

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
Washington, DC 20548

November 21, 2014

The Honorable Darrell E. Issa
Chairman
Committee on Oversight and Government Reform
House of Representatives

Dear Mr. Chairman:

Vaccines save lives by preventing disease in the people who receive them. In some instances, however, a vaccine can have severe side effects, including death or an injury requiring lifetime medical care.[1] 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, Congress established the National Vaccine Injury Compensation Program (VICP), which is administered by the Department of Health and Human Services (HHS).[2] People who believe they or their child have been injured by vaccines covered by the program may file a petition making a claim with VICP for compensation for medical and other costs and for pain and suffering, as an alternative to civil court.[3] The program uses a vaccine injury table that lists the injuries and conditions that are presumed to be caused by vaccines covered by the program and thus may entitle a petitioner to compensation. The program may also compensate petitioners for injuries or conditions that are not on the vaccine injury table; however, in those cases causation is not presumed and the petitioner must demonstrate that the vaccine caused the injury or condition. The program pays claims from the Vaccine Injury Compensation Trust Fund, a trust fund supported by an excise tax on each dose of a vaccine covered by the program; since the program

[1]In this report, we use the term injury to refer to an illness, disability, or similar condition.

[2]VICP was established by the National Childhood Vaccine Injury Act of 1986. Pub. L. No. 99-660, title III, §§ 301 et seq., 100 Stat. 3743, 3755 (amending the Public Health Service Act by inserting a new title XXI; codified, as amended, at 42 U.S.C. 300aa-1 et seq.).

[3]Petitions may also be filed for compensation for deaths from vaccines covered by the program.

began in 1988, more than 15,000 claims had been filed and more than $2.8 billion has been awarded to petitioners.

In 1999, we reported that while the program appears to provide an easier process for obtaining compensation than through the civil court system, the claims process was not as quick or easy as expected.[4] Recently, concerns have been raised about the timeliness for adjudicating VICP claims and making changes to the vaccine injury table, how the funds in the Vaccine Injury Compensation Trust Fund have been spent, and petitioner experiences and awareness of the program. You asked that we examine these issues. Specifically, this report examines (1) how long it has taken to adjudicate VICP claims and how claims have been adjudicated, (2) the changes to the vaccine injury table and in the types of claims filed, (3) how the balance of and spending from the trust fund have changed, and (4) available information on petitioner experience with VICP and how HHS has informed the public of the availability of VICP.

To address these questions, we used data and information from the federal agencies involved in administering the program and managing the Vaccine Injury Compensation Trust Fund, and from stakeholders. Specifically, to examine how long it has taken to adjudicate VICP claims we examined VICP data and interviewed officials from HHS's Health Resources and Services Administration (HRSA), which administers VICP; the Department of Justice (DOJ), which represents HHS in VICP proceedings; and the U.S. Court of Federal Claims (USCFC) and the Office of Special Masters within USCFC that adjudicates, or decides, VICP claims.[5] We analyzed USCFC data to examine time frames for the adjudication of claims filed in fiscal years 1999-2014.[6] To examine changes to the vaccine injury table and in the types of claims filed, we reviewed relevant laws, and other documents, including Federal Register notices, studies conducted for HHS by the Institute of Medicine, and HRSA's proposals for revising the vaccine injury table since fiscal year

[4]GAO, *Vaccine Injury Compensation Program Challenged to Settle Claims Quickly and Easily*, GAO/HEHS-00-8 (Washington, D.C.: Dec. 22, 1999).

[5]For the purposes of this report, we use the term claim to refer to the petition and case filed under VICP. We refer to the individuals filing the claims as petitioners. HRSA administers the program in conjunction with DOJ and USCFC.

[6]We examined USCFC data showing when VICP petitions were filed and when each claim was adjudicated for petitions filed from fiscal year 1999 through March 31, 2014.

1999, and interviewed officials from HRSA and members of its Advisory Commission on Childhood Vaccines.[7] We also examined HRSA data on the numbers of claims filed, by vaccine, and USCFC data on the number of claims alleging injuries on the vaccine injury table. To examine the balance of and spending from the Vaccine Injury Compensation Trust Fund, we reviewed reports from the Department of the Treasury (Treasury), which manages the trust fund, to determine the income into and disbursements from the trust fund for fiscal years 2009-2013. We also analyzed HRSA data on the amounts the agency reported for petitioner compensation and attorneys' fees and costs, and data from HRSA, DOJ, and USCFC on the amounts they obligated for administrative and other expenses related to processing VICP claims for those fiscal years using appropriations from the trust fund.[8] Finally, to examine available information on petitioner experience with VICP and how HHS has informed the public of the availability of VICP, we reviewed documents, including the Public Health Service Act, agencies' congressional budget justifications, agency strategic plans, and studies prepared for HHS. We also reviewed statements and interviewed officials from HRSA, DOJ, and USCFC and stakeholders (from organizations representing providers, petitioners' attorneys, and parents) regarding available information on petitioner experiences with VICP and steps HHS has taken to inform the public about the availability of the program.[9] We determined that the data we used from HRSA, DOJ, and USCFC and from Treasury reports on the trust fund were sufficiently reliable for our purposes by discussing data collection processes and limitations of the data with agency officials, conducting electronic data checks, and comparing the data against other published sources.

[7]The Advisory Commission on Childhood Vaccines (ACCV) consists of nine members appointed by the Secretary of Health and Human Services and advises the Secretary on certain issues relating to VICP. See 42 U.S.C. § 300aa-19. Some individual members of the ACCV provided GAO with their personal views that do not necessarily reflect the official position of the ACCV, which is reflected in consensus recommendations made by the ACCV to the Secretary of HHS.

[8]The term obligation refers to a definite commitment by a federal agency that creates a legal liability to make payments immediately or in the future. We examined agency data on obligations for full-time equivalent (FTE) staff, and for other expenses.

[9]The stakeholders we contacted included the National Vaccine Information Center, Vaccine Injured Petitioners' Bar Association, American Academy of Family Physicians, and American Academy of Pediatrics. In addition, other individuals and organizations contacted GAO and provided comments, which we considered as we conducted our review.

We conducted this performance audit from February 2014 to November 2014 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

In general, individuals seeking compensation for a vaccine-related injury or death must first file a petition making a claim for compensation under VICP before suing in civil court.[10] Several federal agencies—HHS, DOJ, and USCFC, are involved in administering VICP, and Treasury manages the trust fund which funds compensation for successful claims.

Vaccines Covered by the Program and on the Vaccine Injury Table

VICP includes a vaccine injury table that lists the vaccines covered by the program and the injuries associated with each those vaccines. (See app. I for the table.) Vaccines are added to the list covered by the program after the Centers for Disease Control and Prevention recommends them for routine administration to children and they are made subject to an excise tax that funds the Vaccine Injury Compensation Trust Fund.[11] When individuals submit a claim for an injury listed on the table (called an on-table injury), they do not need to prove that the injury was caused by the vaccine. Instead, if they submit documentation showing that they received a particular vaccine and that they sustained the associated covered injury within the time interval specified on the table, they may receive compensation based on a presumption of causation (unless there is evidence that the injury is due to other factors).[12] Individuals seeking compensation may submit claims for injuries not listed on the table (called

[10]Petitioners must first file a VICP claim before suing in civil court unless the civil suit is for $1,000 or less. 42 U.S.C. § 300aa-11(a)(2)(A).

[11]The program may provide compensation for individuals who were injured or died after receiving the covered vaccines regardless of their age at the time of vaccination—that is, even though the vaccines are recommended for routine administration for children, adults who are vaccinated with a covered vaccine are also eligible for the program.

[12]42 U.S.C §§ 300aa-11(c)(1), 300aa-13(a)(1). A petitioner's claim of an on-table injury must also meet the Qualifications and Aids for Interpretation that define the injuries listed on the vaccine injury table.

off-table injuries) but they need to demonstrate by the preponderance of the evidence that the vaccine caused the alleged injury.[13]

HHS has authority to promulgate rules to modify the vaccine injury table when certain criteria are met.[14] HHS is also required to amend the table to include a vaccine within 2 years of the Centers for Disease Control and Prevention's recommending it for routine administration to children.[15] The Advisory Commission on Childhood Vaccines, which was established by the act creating the program, is required to make recommendations concerning changes to the table.[16] In 1999, GAO reported that HHS added seven injuries and removed three others from the table in 1995 and 1997, respectively, using findings from Institute of Medicine reviews conducted in 1991 and 1994—in conjunction with public policy considerations provided by the Advisory Commission on Childhood Vaccines, scientific issues raised by HHS's National Vaccine Advisory Committee, and input from the public.[17]

VICP Claims Process

Individuals who believe they or their child have been injured by or a death resulted from a vaccine covered by the program may file a petition

[13]The preponderance of evidence standard is generally interpreted to require that the party with the burden of persuasion—here, that party is the petitioner—must establish that a fact in question is more likely true than not. See 29 Am. Jur. 2d Evid. § 173. This standard is used for VICP claims in a manner similar to its use in civil court but without regard to fault.

[14]The agency must provide for notice and opportunity for a public hearing and at least 180 days of public comment, as well as provide the Advisory Commission on Childhood Vaccines at least 90 days to provide recommendations and comment on proposed rules to modify the table.

[15]42 U.S.C. § 300aa-14(e). The effective date for a vaccine added to the vaccine injury table is the effective date of an excise tax on the vaccine. The Omnibus Budget Reconciliation Act of 1993. Pub. L. No. 103-66 § 13632 (a)(3), 107 Stat. 312, 646 (codified at 42 U.S.C. § 300aa-14 note). When a new vaccine or a new injury is added to the vaccine injury table, claims that do not meet the general filing deadlines must be filed within 2 years from the date the vaccine or injury is added to the table for injuries or deaths that occurred up to 8 years before the table change.

[16]Pub. L. No. 99-660, § 311(a), 100 Stat. 3771 (codified as amended at 42 U.S.C. § 300aa-19).

[17]GAO/HEHS-00-8.

making a claim with the USCFC.[18] In general, to be eligible for compensation, a petition must be filed (1) for a vaccine-related injury within 3 years of the first symptom of the injury (or significant aggravation of an injury), or (2) for a death within 2 years of the death and within 4 years after the first symptom of the vaccine-related injury (or signification aggravation of an injury) from which the death resulted.[19]

HHS, as the respondent in the process, receives a copy of the petition, including medical records, and other documentation filed with the USCFC. HRSA sends a report of its medical review including HHS's recommendation regarding the claim to DOJ. DOJ lawyers, representing HHS in the proceedings, review the HRSA report and the legal aspects of the claim and produce a report that outlines the government's position as to why compensation should or should not be awarded, provides a summary and medical analysis of the petitioner's claims, and asserts applicable legal arguments.

After the claim is filed in USCFC, it is assigned to a special master, a judicial officer who examines the evidence and adjudicates the claim.[20] The special master reviews the petition and may order the petitioner to provide additional records if they are missing or if they are insufficient.[21] Additionally, petitioners and DOJ may file expert reports including additional medical evidence from scientific literature or studies. The

[18]Individuals eligible to file a VICP claim include the person who sustained the vaccine-related injury or that person's legal representative if that person is a child, disabled, or deceased. 42 U.S.C. § 300aa-11(b)(1)(A).

[19]See 42 U.S.C. § 300aa-16.

[20]The Office of Special Masters is an office within the USCFC, part of the judiciary, comprising up to eight court-appointed special masters who develop expertise in vaccine-injury claims. According to the Office of Special Masters, most claims are assigned to special masters on a random basis, but to the extent that a special master has acquired expertise in a specific injury or vaccine, claims may be directed to a particular special master.

[21]A special master may suspend activity on a claim while waiting for additional documentation.

special master then determines whether a claim should be compensated.[22]

For claims that are compensated, there are three adjudication categories:

- **Concession**. In a concession, HHS's review of medical records, scientific literature, and other documents finds that the petitioner is entitled to compensation, because the evidence meets the criteria of the vaccine injury table or because it is more likely than not that the vaccine caused the injury.
- **Negotiated settlement**. In a negotiated settlement, the petition is resolved via negotiation between HHS (represented by DOJ) and the petitioner.[23]
- **Contested decision in favor of the petitioner**. If HHS does not concede that a petition should be compensated or if both parties do not agree to settle, the special master issues a decision after weighing the evidence presented by both sides, which may involve conducting a hearing.[24]

If the petitioner is entitled to compensation as a result of a concession or contested decision in favor of the petitioner, the proceeding then moves to the damages phase, in which the amount of compensation is determined.[25] In a negotiated settlement, the amount of compensation is

[22]Even when HHS concedes a case or a case is settled, the USCFC issues a decision and judgment awarding compensation. A claim is not compensated if the court determines the petitioner is not entitled to compensation or in certain other circumstances, such as where the petitioner elects not to receive compensation or withdraws the petition.

[23]According to HRSA, such a settlement is not an admission by HHS that the vaccine caused the petitioner's alleged injuries, and in settlements, the court does not determine that the vaccine caused the injury. See Health Resources and Services Administration, Statistics Report-August 1, 2014, http://www.hrsa.gov/vaccinecompensation/statisticsreport.pdf, p. 9, accessed Sept. 8, 2014. Once a settlement is reached, it must be formally approved by the decision of the special master, provided the special master determines it is reasonable.

[24]If the special master rules that a petitioner is not entitled to compensation, the petitioner may request to have the decision reviewed by a judge of the USCFC who may issue a decision in favor of the petitioner. HHS may appeal the decision of the special master if the petitioner is awarded compensation.

[25]Damages may be agreed to by the parties, or the special master may hold another hearing or rule upon the record without conducting a hearing.

included in the settlement presented to the special master. VICP may also pay for attorneys' fees and costs deemed reasonable even for unsuccessful petitioners, and the amounts of these fees and costs may be part of a settlement between the parties or determined by the special masters.[26] After the claim has been adjudicated within VICP, the petitioner may choose to file a suit in civil court. Even if found to be entitled to compensation, the petitioner may elect to reject the compensation awarded and file a suit in civil court.[27]

The Vaccine Injury Compensation Trust Fund, managed by Treasury, is funded by an excise tax imposed on each dose of vaccine sold in the United States that is routinely recommended for administration to children.[28] Appropriations from the trust fund to HRSA pay compensation awarded under VICP for vaccine-related injury or death to the petitioner and may also pay for petitioner attorneys' fees and costs. Appropriations from the trust fund to HRSA, DOJ, and USCFC (for the Office of Special Masters) also pay for administrative and other expenses associated with processing VICP claims.[29]

USCFC has managed large influxes of similar vaccine injury claims through omnibus proceedings or groupings of claims. According to the Office of Special Masters, many of the claims alleging that a particular vaccine caused the same injury will rely on similar evidence, so by using omnibus proceedings or groupings to examine evidence for similar claims, the courts can more efficiently review the evidence.[30] In omnibus

[26]Attorney fees and costs may be paid if the court determines there is a reasonable basis for the petition and the petition was filed in good faith. These payments generally reflect the actual time and expense devoted to the case.

[27]See 42 U.S.C. § 300aa-21(a).

[28]The Vaccine Injury Compensation Trust Fund is funded by a $0.75 excise tax on each dose of vaccine recommended by HHS's Centers for Disease Control and Prevention for routine administration to children. The excise tax is imposed on each disease that is prevented in a vaccine. Influenza vaccine, for example, is taxed $0.75 because it prevents one disease; measles-mumps-rubella vaccine, which prevents three diseases, is taxed $2.25. The trust fund receives net revenues from the excise tax, plus interest on investments in government securities.

[29]Within USCFC, only the Office of Special Masters receives appropriations from the trust fund.

[30]The Chief Special Master is responsible to provide for the efficient, expeditious, and effective handling of petitions under VICP. 41 U.S.C. § 300aa-12(c)(6).

proceedings, petitioners select a lead claim in each category of injury, and develop these lead claims while the remaining petitioners choosing to participate in the omnibus elect for their remaining claims to be stayed, or put on hold, until the lead claim reaches a final disposition.

Requirements for Disseminating Information on the Program

HHS is required to include a statement of the availability of VICP in the vaccine information materials that health care providers are to distribute to the parent or legal representatives of a child or to any other individual to whom the provider intends to administer a covered vaccine.[31] These materials—referred to as vaccine information statements by HHS—are intended to explain both the benefits and risks of a vaccine covered by VICP. HHS is also required to undertake reasonable efforts to inform the public of the availability of the program.[32]

Most Claims Took Multiple Years to Adjudicate and Many Were Adjudicated by Settlement or Addressed by an Omnibus Proceeding

Most of the VICP claims filed since fiscal year 1999 have taken multiple years to adjudicate, but those filed since fiscal year 2009 have taken less time. For many claims, the parties have concluded the proceeding through a negotiated settlement, rather than a contested decision adjudicated by a special master or the courts. Additionally, certain claims were addressed along with similar claims as part of an omnibus proceeding or informal grouping.

Most Claims Filed Since Fiscal Year 1999 Have Taken Multiple Years to Adjudicate

VICP claims filed since fiscal year 1999 took an average of about 5 and a half years to adjudicate, according to USCFC data for the nearly 8,800 claims filed since fiscal year 1999 that were adjudicated as of March 31, 2014.[33] There was wide variation in the amount of time to adjudicate these claims. The claim that took the shortest time to adjudicate was filed in fiscal year 1999 and took 2 days, and the claim that took the longest time to adjudicate was filed in fiscal year 1999 and took 5,276 days (more

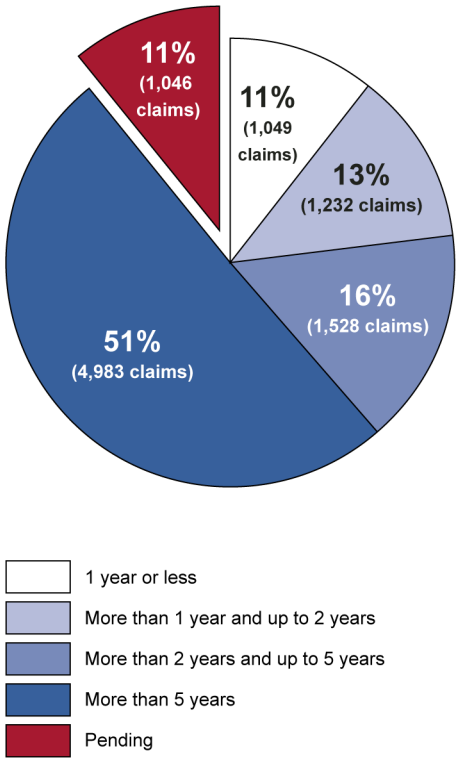
[31]See 42 U.S.C. § 300aa-26.

[32]42 U.S.C. § 300aa-10(c).

[33]USCFC data on processing times for claims runs from the time the petition was filed until judgment was entered.

than 14 years). More than 1,000 (11 percent) of the claims filed since fiscal year 1999 were still in process (pending) as of March 31, 2014; most of these had been pending for 2 years or less (see fig. 1.)

Figure 1: Time Taken to Adjudicate National Vaccine Injury Compensation Program Claims Filed Fiscal Years 1999-2014, as of March 31, 2014



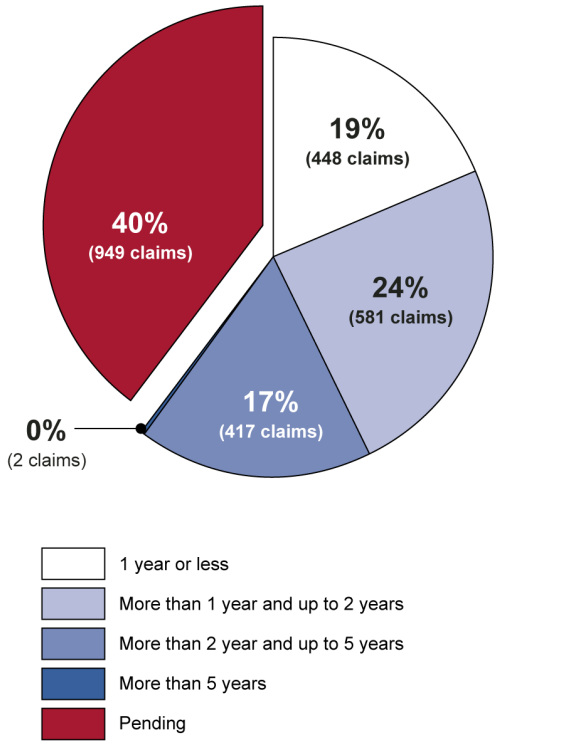
Source: GAO analysis of U.S. Court of Federal Claims data. | GAO-15-142

Note: This figure shows the time (as of March 31, 2014) to adjudicate claims for which petitions were filed in fiscal year 1999 through March 31, 2014, based on data from the U.S. Court of Federal Claims. Figures do not sum to 100 due to rounding.

For claims filed since fiscal year 2009, a greater percentage of claims were resolved within 1 or 2 years. One possible reason is that the vast majority of claims alleging autism as the injury were filed prior to fiscal year 2009. Autism claims may have taken longer because they were part of an omnibus proceeding, which suspended activity on most autism claims for a period of time. According to USCFC data, for the more than 1,400 claims filed since fiscal year 2009 that were adjudicated as of March 31, 2014, the average amount of time to adjudicate a claim was 587 days (about 1.6 years). More than 900 (40 percent) of the claims filed

since fiscal year 1999 were still pending, which could cause this average to increase over time as these pending claims are resolved (see fig. 2).[34] Of the pending claims, nearly half had been pending for 1 year or less as of March 31, 2014.

Figure 2: Status of National Vaccine Injury Compensation Program Claims Filed Fiscal Years 2009-2014, as of March 31, 2014



Source: GAO analysis of U.S. Court of Federal Claims data. | GAO-15-142

Note: This figure shows the status (as of March 31, 2014) of nearly 2,400 claims for which petitions were filed in fiscal year 2009 through March 31, 2014, based on data from the U.S. Court of Federal Claims.

HHS has reported the program has met its annual target of 1,300 days (about 3.5 years) for the average time to adjudicate non-autism claims in all but 1 year since fiscal year 2009. This target (1,300 days) has been in

[34]Of the claims filed since fiscal year 2009 that were adjudicated as of March 31, 2014, the claim that took the shortest time to adjudicate took 3 days, and the claim that took the longest time to adjudicate took 1,981 days (nearly 5 and a half years).

place since fiscal year 2009, and applies to claims concluded in a given fiscal year, regardless of the year they were filed, excluding claims that alleged autism as the vaccine-related injury.[35] HRSA has reported meeting this goal since fiscal year 2009, except in fiscal year 2012, when VICP claims concluded that year took an average of 1,309 days to complete.

Organizations representing petitioners have criticized the program for taking a long time to resolve claims. Petitioners report that long processing times delay receiving compensation to pay medical bills and other expenses related to the alleged injury. A HRSA-contracted survey of petitioners whose claims were adjudicated (regardless of whether or not they received compensation under VICP), found that nearly two-thirds of the 103 respondents indicated they were somewhat or very dissatisfied with the length of the process.[36] Petitioners may withdraw if a VICP decision is not made on their claim within specific time periods but according to the Office of Special Masters, petitioners rarely exercise this option.[37]

Officials cite certain delays within the process as factors that can increase average claims processing times. Officials at USCFC and DOJ told us

[35]Performance measures, including a measure for average claims processing time, were developed for VICP during the Program Assessment Rating Tool review conducted by the Office of Management and Budget for the fiscal year 2007 budget. HHS reports the targets and tracks the program's performance for average claims processing time in HRSA's annual congressional budget justifications.

[36]Altarum Institute, *Determining the Feasibility of Evaluating the National Vaccine Injury Compensation Program, Final Report*, a report prepared for the Health Resources and Services Administration, June 15, 2009. Of 716 petitioners the researchers identified as meeting their inclusion criteria,107 responded to their survey and 103 responded to this question on the length of the process. The results of this study cannot be generalized to the population of all petitioners who completed the VICP process; instead, they reflect only the VICP petitioners who responded to the survey. According to HRSA, petitioners were included in the sample if they (1) had filed a claim that had been compensated or dismissed in fiscal years 2004-2008 and (2) were represented by an attorney.

[37]If a special master fails to make a decision on a petition within 240 days (excluding any period of suspension), or if USCFC fails to enter a judgment on a petition within 420 days after the date on which the petition was filed (excluding any period of suspension), petitioners can withdraw their claim from VICP. 42 U.S.C. § 300aa-12(g). While USCFC officials report that most claims exceed both the 240-day and the 420-day limits when periods of suspension are not excluded, USCFC does not track suspensions so available data do not show how much time a case was suspended and how many cases met the statutory time frames.

that the time petitioners spend gathering supporting documentation or evidence can add significantly to the amount of time required to process a claim. These delays may occur at multiple points in the claims process, from petitioners needing to gather sufficient documentation for the court to begin an initial review, to the court needing documentation to determine the amount of compensation that a successful petitioner will receive.[38] According to HRSA, for claims adjudicated as of March 31, 2014, its medical review process averaged over 700 days for claims filed in fiscal year 2010. HRSA attributes the length of time for medical review primarily to time spent waiting for petitioners to submit requested documentation. During the medical review, HRSA may also consult with external experts, who require additional time to review the details of the case; HRSA's data indicate that over 1,200 outside reviews were conducted from fiscal years 2009 to 2014. Additionally, when special masters are reviewing the claim, a party may request that the special master delay a decision until additional documentation is available.[39] Special masters may also request additional information from petitioners—such as a specialist physician's opinion.

Many Claims Were Adjudicated through Settlement or Grouped in an Omnibus Autism Proceeding

According to HRSA data for claims filed since 2006, most compensated claims were adjudicated through negotiated settlement rather than a concession or a contested decision. HRSA's data indicated that about 80 percent of the more than 1,500 non-autism VICP claims filed since 2006 for which compensation was awarded were adjudicated through a negotiated settlement between the parties, compared to about 10 percent involving a contested decision in favor of the petitioner and about 10 percent conceded by HHS.[40] According to HRSA, claims which HHS does not concede may be resolved via a negotiated settlement for several reasons, including a desire by both parties to resolve a case quickly and efficiently. According to the Office of Special Masters, a special master

[38]Petitioners are required by statute to submit their supporting documentation or evidence at the time they file their petition. See 42 U.S.C. § 300aa-11(c)(2). According to DOJ, petitions are frequently filed without documentation, which delays adjudication.

[39]Special masters report allowing these delays in order to accumulate sufficient evidence to adjudicate a claim, but they could not provide a precise number.

[40]See Health Resources and Services Administration, Statistics Report-October 2, 2014, http://www.hrsa.gov/vaccinecompensation/statisticsreport.pdf, accessed October 8, 2014.

may recommend parties settle as an expeditious and efficient method of resolving certain claims.

The Office of Special Masters created an omnibus proceeding in order to address thousands of autism cases systematically and efficiently.[41] Beginning in 1999, parents began filing petitions for compensation under VICP alleging that autism or neurodevelopmental disorders similar to autism were caused by the measles-mumps-rubella vaccine or vaccines containing thimerosal, a mercury-containing preservative used in some vaccines, covered by the program, or both. In 2002, the Office of Special Masters held a series of meetings with an informal advisory committee, including attorneys who represented many potential petitioners and legal and medical representatives of HHS, to address the task of dealing with these claims. The Office of Special Masters decided to utilize a two-step procedure: first, looking into whether the vaccinations in question can cause autism and, if so, the circumstances under which this occurs, and second, applying the conclusions from the first step to the individual claims. The omnibus autism proceeding included test cases for two different theories by which vaccines were alleged to cause autism.[42] Some petitioners withdrew from the omnibus proceeding and elected to proceed within the vaccine program on other theories of causation. Some petitioners withdrew from the program entirely, as was their statutory right, which enabled them to pursue claims against vaccine manufacturers in civil court.[43]

[41]The omnibus autism proceeding was the largest of several instances in which the courts addressed groupings of similar claims. Since 1999, the USCFC has grouped similar claims to manage hepatitis B vaccine injury claims, claims alleging an injury of type 1 diabetes, and claims that certain childhood vaccinations have caused or contributed to autism. According to the Office of Special Masters, the omnibus autism proceeding was the largest of these groupings, involving over 5,000 claims, with the hepatitis B grouping involving several hundred and the type 1 diabetes grouping involving fewer than 50 claims.

[42]According to the Office of Special Masters, petitioners withdrew a third theory of causation.

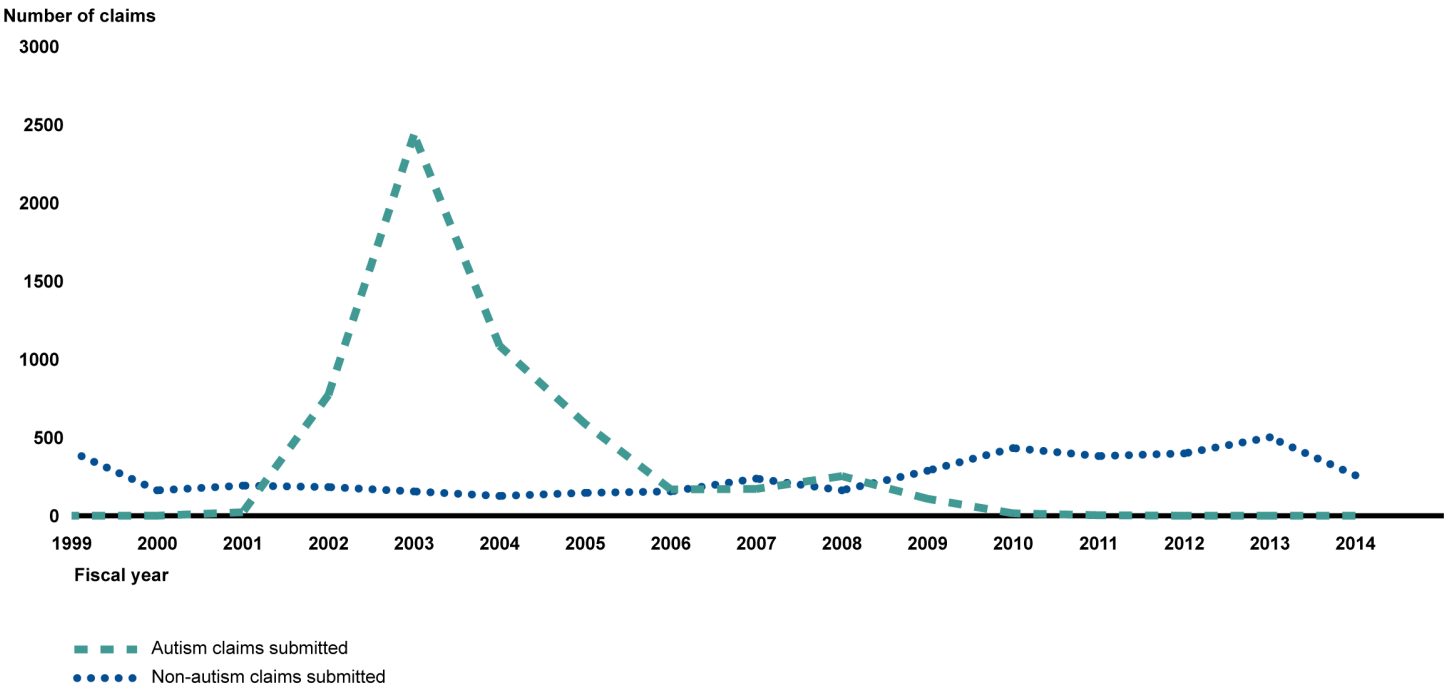
[43]See 42 U.S.C. § 300aa-21(b). By filing a "Short-Form Autism Petition for Vaccine Compensation," a petitioner could elect to be part of the Omnibus Autism Proceeding and simultaneously choose to stay his or her case-specific proceeding on his own petition until the conclusion of the Omnibus Autism Proceeding. See Office of Special Masters, Autism General Order #1, July 3, 2002 (http://www.uscfc.uscourts.gov/sites/default/files/autism/Autism+General+Order1.pdf), accessed October 14, 2014.

The influx of new VICP claims for autism continued in fiscal years 2002-2005, while the number of new non-autism claims remained relatively stable (see fig. 3). HRSA data show that during this period, nearly 90 percent of VICP claims filed alleged autism as the vaccine-related injury. Ultimately, the special masters did not award compensation in any of the test cases,[44] and most remaining omnibus autism proceeding claims were dismissed. However, according to the Office of Special Masters, some petitioners who had been part of the omnibus autism proceeding continued with claims separate from the omnibus proceeding.[45]

[44]See In Re: Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder, Fed. Cl. Spec. Mstr. Update, p. 3, Jan. 12, 2011 (indicating that proceedings in all test cases had concluded and that decisions in all such cases rejected petitioners' theories of causation).

[45]According to the Office of Special Masters, these petitioners proceeded on other theories of causation.

Figure 3: Number of National Vaccine Injury Compensation Program Claims Filed Alleging Autism, Fiscal Years 1999-2014, as of March 31, 2014



Source: GAO analysis of Health Resources and Services Administration data. | GAO-15-142

Note: Data for fiscal year 2014 are as of March 31, 2014.

Vaccines Have Been Added to the Vaccine Injury Table since Fiscal Year 1999 without Covered Injuries, Resulting in More Off-Table Claims

HHS has added vaccines to the vaccine injury table without adding covered injuries associated with those vaccines. Following their addition to the table, more claims were filed for off-table injuries.

Six Vaccines Have Been Added to the Vaccine Injury Table since Fiscal Year 1999 without Covered Injuries; HHS Is Considering Additional Changes

Since fiscal year 1999, HHS has added six vaccines to the vaccine injury table (but has not added covered injuries associated with these vaccines to the table).[46] This means that while individuals may file VICP claims for those vaccines, each petitioner must demonstrate that the vaccine that was administered caused the alleged injury. In general, each of the six vaccines was added within 2 years of the Centers for Disease Control and Prevention's recommending it for routine administration to children and having an excise tax imposed.[47] Since 1999, two vaccines, both of which had covered injuries associated with them, were removed from the vaccine injury table.[48] See appendix II for the vaccines and injuries added and removed from the vaccine injury table since 1999. At the end of the fiscal year 2014, 16 vaccines were covered by the program, 8 of which did not have associated covered injuries on the table.[49]

HHS has been considering adding injuries to the table in association with the eight vaccines that are listed without covered injuries.[50] Specifically, HRSA officials said they are working on a final rule to add an injury associated with one vaccine and a proposed rule that would add injuries associated with several other vaccines.

- In July 2013, HRSA published a proposed rule to add intussusception (obstruction of the bowels) as an injury associated with the rotavirus

[46]Although the rhesus-based rotavirus vaccine was added to the table with an associated injury in 2002, it was removed in 2008. See 67 Fed. Reg. 48558 (Jul. 25, 2002) (addition to table); 73 Fed. Reg. 59528 (Oct. 9, 2008) (removal from table).

[47]In October 1999, the Centers for Disease Control and Prevention recommended the hepatitis A vaccine be administered to children in states, counties, and communities with rates of hepatitis A that were twice the 1987-1997 national average or greater. However, the hepatitis A vaccine was not covered by VICP until 2004, when the American Jobs Creation Act of 2004 imposed an excise tax for all hepatitis A vaccines. Pub. L. No. 108-357, § 889(a), 118 Stat. 1418, 1643 (codified at 26 U.S.C. § 4132(a)(l)).

[48]In addition to the rhesus-based rotavirus vaccine, which was removed in 2008, unconjugated Hemophilus influenza type b (Hib) polysaccharide vaccine was removed from the vaccine injury table in 2002. See 67 Fed. Reg. 48558 (Jul. 25, 2002).

[49]There were two vaccines on the table prior to fiscal year 1999 that had no covered injuries listed: Hemophilus influenza type b (Hib) vaccine (which prevents meningitis and other serious infections) and varicella vaccine (which prevents chicken pox).

[50]HHS has also been considering adding injuries in association to covered vaccines that already have associated injuries on the vaccine injury table.

vaccine.[51] In proposing the addition, HRSA considered reviews and injury claims attributed to another vaccine that protected against rotavirus but had been removed from the table in fiscal year 2009. According to HRSA, the agency is working on a final rule to add this injury.

- HRSA officials said they are developing a proposed rule to add covered injuries for all seven of the remaining vaccines on the table without covered injuries. For example, HRSA is considering proposing to add Guillain-Barré Syndrome (a disorder in which the body's immune system attacks part of the nervous system and is characterized by muscle weakness and paralysis), as an injury associated with the influenza vaccine. The agency is also considering proposing to add other injuries associated with the influenza, hemophilus influenza type b conjugate, varicella, pneumococcal conjugate, hepatitis A, meningococcal, and human papillomavirus vaccines.

[51]78 Fed. Reg. 44512 (Jul. 24, 2013) (to be codified at 42 U.S.C. § 100.3).

According to HRSA officials, the factors informing the table changes that they are considering proposing include (1) an Institute of Medicine study of certain vaccines;[52] (2) HHS's independent review of vaccine causation and medical and scientific evidence; (3) the need to clarify injury definitions on the table[53]; and (4) recent studies related to injuries associated with the influenza vaccine.

As of September 30, 2014, HRSA had not promulgated regulations to make these changes to the vaccine injury table. According to HRSA officials, the agency plans

- to publish the final rule to add the injury associated with the rotavirus vaccine to the table by July 2015,[54] and
- to publish a proposed rule for the other injuries it is considering adding to the table by August 2015.

According to HRSA officials, the process to publish such a proposed rule can take about 9 months to 1.5 years. The officials also said that the process for publishing such a final rule can take about 1.5 years to 2.5 years after the proposed rule is published. In its justification accompanying its fiscal year 2013 budget request, HRSA acknowledged that many stakeholders, including Congress, have voiced interest and concern over keeping the injury table in line with current science. At that time, HRSA reported that other VICP activities, including medical reviews and court deadlines, have taken priority over updating the table.[55]

[52]In 2009, HHS commissioned the Institute of Medicine to review specific injuries in association with vaccines that are currently on the table. These vaccines include varicella; influenza, hepatitis B; human papillomavirus; measles, mumps, and rubella; hepatitis A; meningococcal; and vaccines containing tetanus. See Institute of Medicine, *Adverse Effects of Vaccines: Evidence and Causality* (Washington, D.C.: The National Academies Press: 2012).

[53]HRSA officials said they are also considering changes in the language defining injuries on the table.

[54]Public hearings on the proposed rule for adding intussusception as a covered injury associated with the rotavirus vaccine took place on January 13, 2014, and April 28, 2014.

[55]Health Resources and Services Administration, *Justification of Estimates to Appropriations Committees*, Fiscal Year 2013, accessed November 4, 2014 http://www.hrsa.gov/about/budget/budgetjustification2013.pdf.

While the injuries HRSA is considering have not yet been added to the table, HRSA and DOJ officials report that many claims alleging these injuries that HRSA is considering adding to the table have been conceded or settled. For example, according to DOJ officials, there have been numerous settlements for cases alleging Guillain-Barré Syndrome as an injury associated with the influenza vaccine.

Changes in the Vaccine Injury Table Contributed to More Claims for Off-Table Injuries and for Injuries in Adults

The addition of the six vaccines to the vaccine injury table without associated injuries has contributed to an increase in off-table claims. When we reported on this program in 1999, 2 of the 12 vaccines on the injury table were without associated injuries listed on the table. We reported that about one-quarter (28 percent) of claims filed as of February 1999 were for off-table injuries.[56] In contrast, of the 3,007 claims filed since fiscal year 2005 (the year that trivalent influenza vaccine was added to the table) for which the covered vaccine associated with the alleged injury was specified, at least 59 percent were associated with one of five vaccines added to the table without associated table injuries, according to HRSA data.[57] To receive compensation, the petitioners in these claims would not have the presumption of causation associated with an on-table claim. Overall, since 2009, more than 98 percent of the new claims filed alleged off-table injuries that required the petitioner to prove their injury was caused by the vaccine they received, according to the Office of Special Masters.

Claims alleging injuries to adults also increased as a result of the addition of vaccines that are recommended for administration in adults (as well as children) to the vaccine injury table. Several of the vaccines added to the injury table—in particular, the vaccine to prevent influenza—are

[56]GAO/HEHS-00-8.

[57]The five vaccines included hepatitis A, human pappilomavirus, influenza, meningococcal, and pneumococcal conjugate vaccines. According to HRSA data, 1,245 claims filed since fiscal year 2005, including claims filed as part of the Omnibus Autism Proceeding, did not specify a vaccine and 30 claims specified a nonqualified vaccine—that is, a vaccine not covered under VICP.

recommended for routine administration to adults as well as children.[58] As a result, although the vaccines were added to the table because they were recommended for children, adults who are vaccinated with them are also eligible for compensation under VICP. More than half (51 percent) of the 4,402 VICP claims filed since fiscal year 1999 (for which the covered vaccine associated with the alleged injury was specified) were for injuries to adults and 1,287 (29 percent) were for adults alleging injuries in association with influenza vaccine, according to HRSA data.[59]

Trust Fund Balance Has Increased since 2009, As Has Petitioner and Attorney Compensation and Other VICP-Related Spending

The Vaccine Injury Compensation Trust Fund balance increased to more than $3 billion in fiscal year 2013 despite increased spending by HRSA, DOJ, and USCFC on petitioner compensation, attorneys' fees and costs, and other VICP-related expenses.

[58]Vaccines generally recommended for adults (as well as children) and currently covered by VICP include vaccines to protect against influenza, tetanus, diphtheria, pertussis, varicella, human papillomavirus, pneumococcal disease (pneumococcal conjugate vaccine), measles, mumps, and rubella. See http://www.cdc.gov/vaccines/schedules/downloads/adult/adult-schedule-easy-read-bw.pdf, accessed Oct. 9, 2014.

[59]According to HRSA data, 5,377 claims filed since fiscal year 1999 (as of March 31, 2014) did not specify which covered vaccine caused an alleged injury and 57 claims specified a vaccine not covered by the program.

From Fiscal Year 2009 to 2013 the Trust Fund Balance Gradually Increased to More than $3 Billion

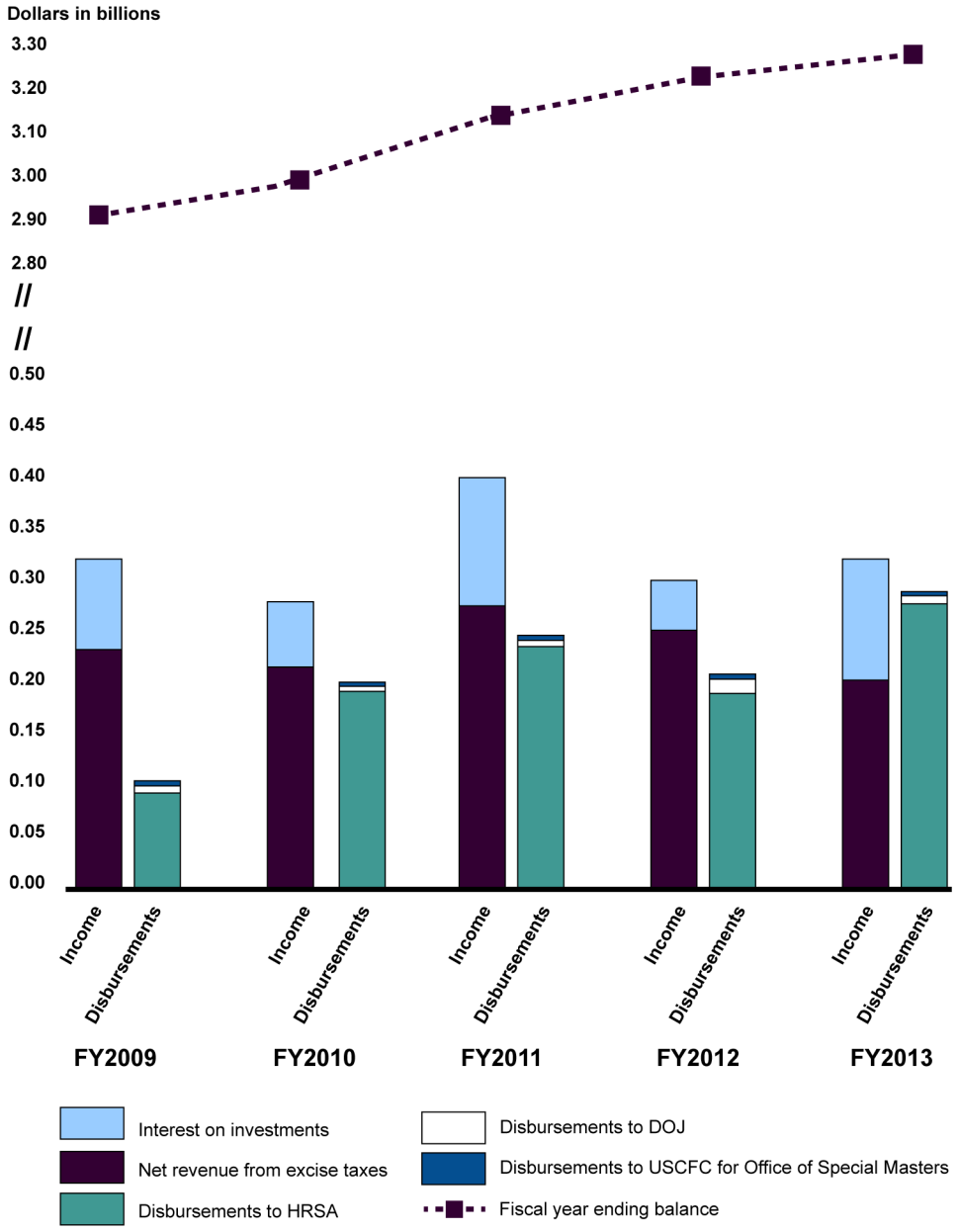
The balance in the trust fund increased from $2.9 billion at the end of fiscal year 2009 to nearly $3.3 billion at the end of fiscal year 2013.[60] The balance increased because the trust fund's income outpaced its disbursements to HRSA, DOJ, and USCFC, although disbursements also increased during this period (see fig. 4).[61] Treasury reported over $200 million in net revenues from the vaccine excise tax in each of fiscal years 2009-2013. As required by applicable law pertaining to the management of trust funds, Treasury oversees the investment of part of the net revenue from vaccine excise taxes.[62] Interest from these investments ranged from about $49 million in fiscal year 2012 to about $126 million in fiscal year 2011.

[60]In this report, investments in U.S. securities issued by the Bureau of Fiscal Service and the fund balance with Treasury comprise the balance of the trust fund at the end of the fiscal year.

[61]Net revenue from vaccine excise taxes and interest on investments comprise income for the trust fund. Disbursements to HRSA—for compensation to petitioners, attorneys' fees and costs, and administrative expenses, and to DOJ and the USCFC for the Office of Special Masters—for expenses associated with processing National Vaccine Injury Compensation Program (VICP) claims, comprise disbursements from the trust fund.

[62]See 26 U.S.C. § 9602.

Figure 4: Vaccine Injury Compensation Trust Fund Income, Disbursements, and Balance for Fiscal Years 2009–2013



Source: GAO analysis of Treasury data. | GAO-15-142

Note: This figure presents the Vaccine Injury Compensation Trust Fund balance (in terms of investment in U.S. securities issued by the Bureau of Fiscal Service and the fund balance with Treasury) at the end of the fiscal year. It also presents the income to trust fund (in terms of net revenue from excise taxes on vaccines and interest on investments) as well as disbursements to the

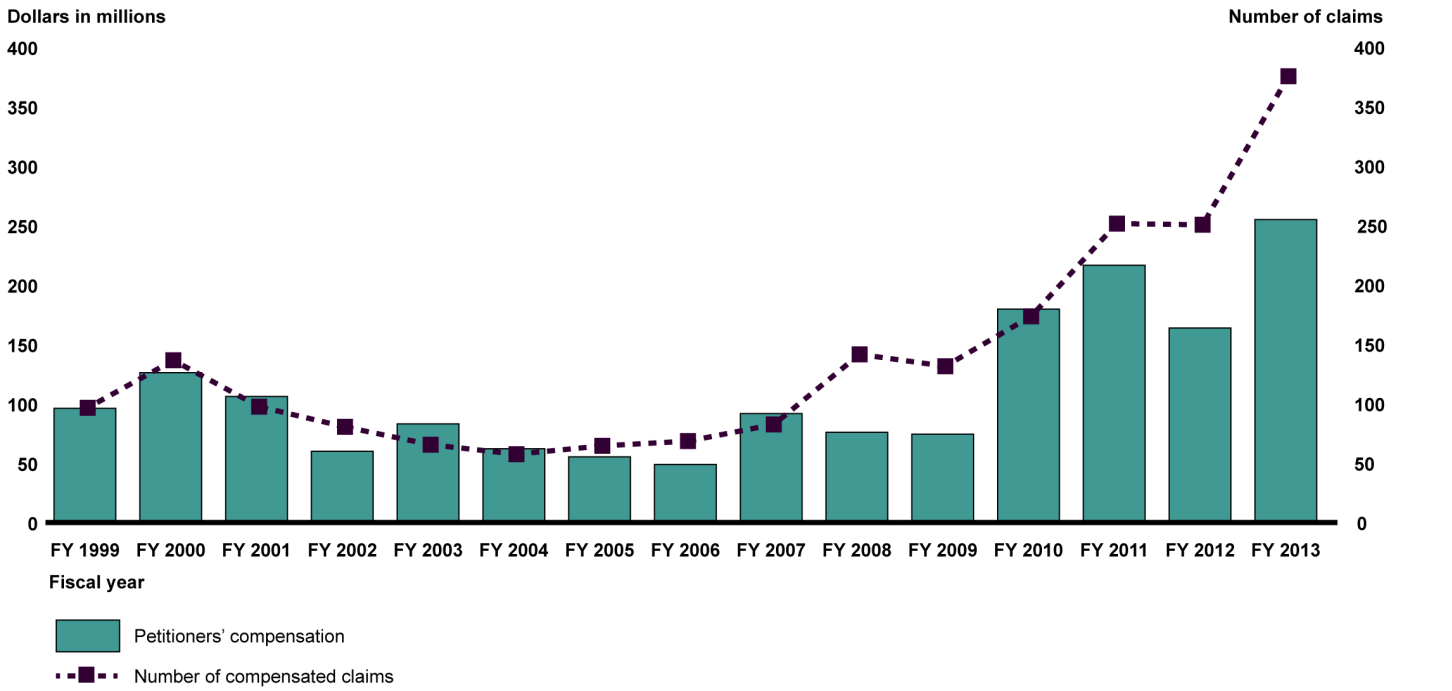
Health Resources and Services Administration (HRSA)—for compensation to petitioners, attorneys' fees and costs, and administrative expenses, and to the Department of Justice (DOJ) and the U.S. Court of Federal Claims (USCFC) for the Office of Special Masters—for expenses associated with processing National Vaccine Injury Compensation Program (VICP) claims, as reported in the Treasury reports.

Spending on Compensation to Petitioners and Attorneys Has Increased since Fiscal Year 1999

Total compensation to petitioners and the number of claims compensated have both increased since fiscal year 1999. Petitioners' compensation paid by HRSA using appropriations from the trust fund increased to over $254 million in fiscal year 2013. With the exception of fiscal year 2000, the total amount spent on compensation awarded to petitioners remained under $125 million between fiscal years 1999 and 2009. The total amount spent on compensation to petitioners increased to nearly $180 million in fiscal year 2010 and to more than $250 million in fiscal year 2013 (see fig. 5 and app. III).[63]

[63]There is no cap on the amount of an award in a vaccine injury case, but the law does provide certain restrictions, such as a prohibition on punitive damages and limits on pain and suffering and emotional distress. Awards may include compensation for actual and anticipated loss of earnings. In some cases, compensation may be provided in the form of an annuity. In the event of a vaccine-related death, VICP will award $250,000 to the estate of the deceased. See 42 U.S.C.§ 300aa–15. Injury-related damages in addition to the statutory death benefit may be awarded.

Figure 5: Compensation to Petitioners under the National Vaccine Injury Compensation Program



Source: GAO analysis of Health Resources and Services Administration data. | GAO-15-142

Note: This figure presents the total amounts and numbers of claims paid by the Health Resources and Services Administration to petitioners under the National Vaccine Injury Compensation Program for each of fiscal years 1999-2013. Data are presented by the fiscal year in which the compensation was paid.

According to the Office of Special Masters, the increase in the total amount paid to petitioners in compensation and number of compensated claims is related to the addition of the influenza vaccine to the vaccine injury table. The influenza vaccine, which is administered to millions of people each year, was added to the injury table in fiscal year 2005.

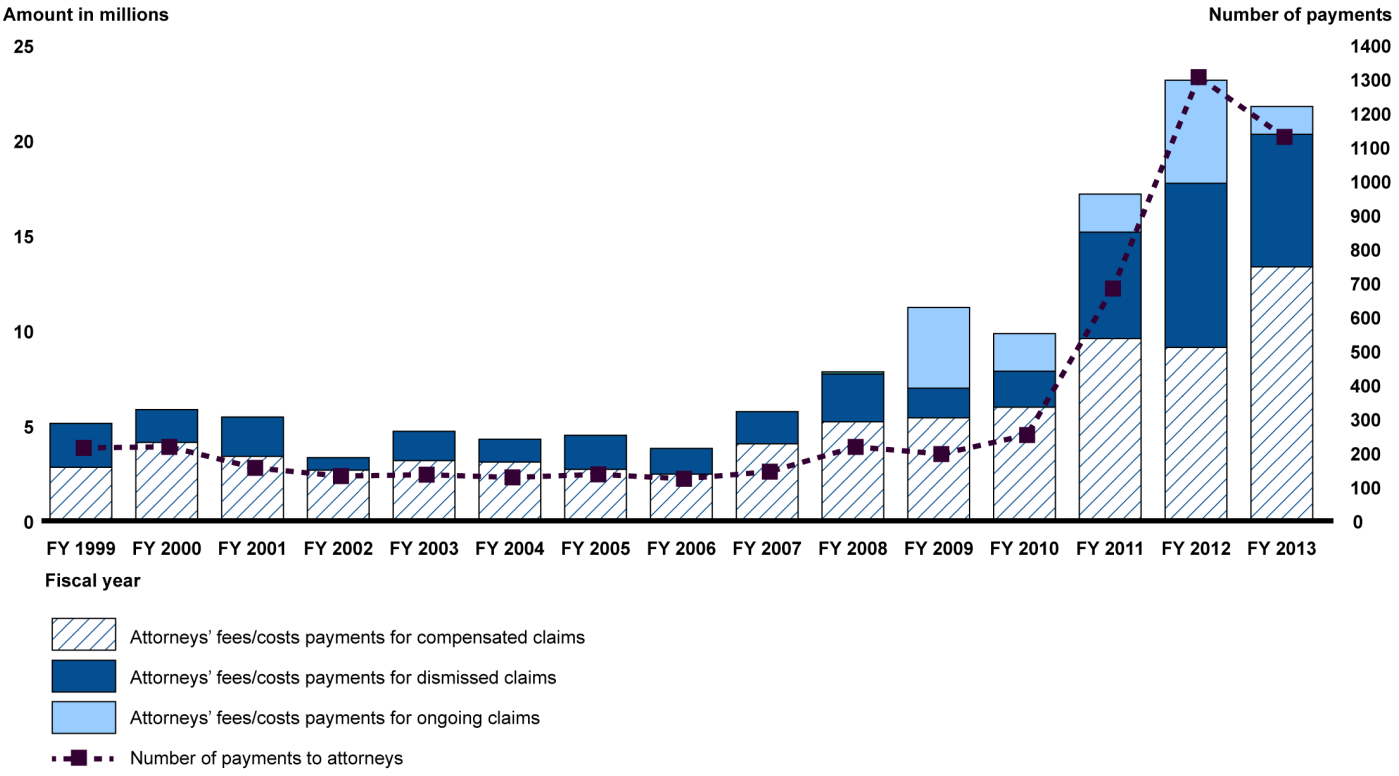
The annual amount the VICP program paid for attorneys' fees and costs remained relatively steady from fiscal year 1999 to fiscal year 2007, but started to increase in fiscal year 2008, consistent with an increase in the total number of payments to attorneys (see fig. 6 and app. III). In order to help ensure access to the program, VICP may pay for reasonable attorney fees and costs upon a determination that the petition was brought in good faith and there was a reasonable basis for the claim for

which the petition was brought, regardless of whether the petitioner's claim is compensated or dismissed.[64] The majority of VICP payments for attorneys' fees and costs have been for compensated or dismissed claims; however, since fiscal year 2008, VICP has also paid some interim attorneys' fees and costs for selected ongoing claims at the special master's discretion.[65] Compensation for attorneys' fees and costs must be reasonable such that it generally reflects the actual time and expense devoted to the case.

[64]Attorneys are prohibited from taking a contingent fee on compensation awarded to a petitioner. 42 U.S.C. § 300aa-15(e).

[65]According to the Office of Special Masters, interim awards are made at the special master's discretion, depending on a variety of factors, including but not limited to the duration of the litigation (e.g., lengthy proceedings), the stage of the proceedings, the amounts sought (e.g., demonstrating that substantial costs have been incurred), and the documented need for an interim award (e.g., demonstrating undue hardship).

Figure 6: Payments to Attorneys under the National Vaccine Injury Compensation Program



Source: GAO analysis of Health Resources and Services Administration data. | GAO-15-142

Note: This figure presents the total amounts paid in attorneys' fees and costs for each fiscal year (based on the fiscal year in which the payment was made). Attorneys' fees and costs reflect the actual time and expense devoted to the case as opposed to a percentage of the compensation.

Spending on Agency Staff and Other VICP-Related Expenses Has Increased

The total amount obligated by HRSA, DOJ, and USCFC (for the Office of Special Masters) to pay for staff and other expenses related to processing VICP claims increased from $17 million in fiscal year 2009 to about $19 million in fiscal year 2013.[66] The three departments obligated a total of about $91 million for expenses associated with processing VICP claims during those 5 fiscal years. About two-thirds of VICP-related expenses

[66]The total obligation to each agency may not match the amount that Treasury reported it disbursed from the trust fund during a given fiscal year because the agencies' obligations for petitioners' compensation, attorneys' fees, and other expenses associated with the program do not always occur in the same fiscal year that Treasury disburses funding to the agencies.

($61 million) was obligated to pay the salaries and benefits of full-time equivalent (FTE) agency staff and about one-third ($30 million) was obligated for other VICP-related expenses (see table 1).

Table 1: Amounts Obligated by HRSA, DOJ, and USCFC for the National Vaccine Injury Compensation Program Administrative Expenses

Dollars in millions

	HRSA[a]		DOJ		USCFC[b]		
Fiscal year	**FTE staff (number)**	**Other expenses**	**FTE staff (number)**	**Other expenses**	**FTE staff (number)**	**Other expenses**	**Total obligations**
2009	$2.8 (18)	$2.6	$4.5 (34)	$3.2	$3.2 (24)	$0.8	**$17.0**
2010	3.4 (22)	3.1	5.0 (34)	2.5	3.3 (25)	1.7	**19.0**
2011	3.8 (22)	2.7	5.4 (33)	2.4	3.4 (26)	0.8	**18.5**
2012	4.2 (22)	2.3	5.4 (34)	1.6	3.7 (29)	1.0	**18.1**
2013	3.8 (20)	2.5	5.5 (34)	2.1	3.7 (29)	1.1	**18.7**
Total	**$17.9**	**$13.2**	**$25.8**	**$11.9**	**$17.3**	**$5.4**	**$91.4**

Source: GAO summary of HHS, DOJ, and USCFC data. | GAO-15-142

Legend: HRSA = Health Resources and Services Administration; DOJ = Department of Justice; USCFC = U.S. Court of Federal Claims; FTE = Full-time equivalent.

Notes: Figures do not sum to totals due to rounding.

[a]Amounts obligated by HRSA do not include compensation to petitioners or attorney costs.

[b]Amounts obligated by USCFC were for the Office of Special Masters.

The amounts obligated for FTE salaries and benefits were for staff of HRSA, DOJ, and USCFC's Office of Special Masters who process the claims and represent the government's interest in legal proceedings. For example, USCFC's Office of Special Masters paid the salaries and benefits for special masters and clerks. The average number of full-time equivalent (FTE) staff supported across the three agencies was 81 per fiscal year.

Each agency also had other VICP-related spending reimbursed by the trust fund. For example, HRSA reported obligating about $9.6 million for medical experts to review petitioner claims and provide expert testimony during adjudication proceedings for fiscal years 2009 through 2013. HRSA also obligated funds to support the Advisory Commission on Childhood Vaccines, including compensation and travel expenses for commission members. The departments reported obligating funds for costs for travel, processing documents, maintaining records, rent, supplies, and equipment. For example, obligations include rental

payments to the General Services Administration by DOJ and the cost of court reporters funded by USCFC's Office of Special Masters.

Information on VICP Petitioner Experience Is Limited; HHS Is Taking Steps to Address Criticism of Its Outreach Efforts

Information on petitioners' experience with VICP is limited. HRSA has taken some steps to undertake outreach activities, but the agency has not yet assessed the effect of these efforts.

Information on Petitioners' Experiences with VICP Is Limited

Other than a study for HRSA on petitioners' satisfaction with VICP, the agency officials and stakeholders we interviewed and the documents we reviewed did not identify any data or studies regarding the experience of individuals who have filed VICP claims. The study prepared for HRSA, dated 2009, reported the responses from 107 petitioners whose claims were compensated or dismissed in fiscal years 2004-2008. Because this was a voluntary survey with a low response rate, its results cannot be generalized to all petitioners who completed the VICP process; instead, it reflects only the experience of the VICP petitioners who responded to the survey.[67] We also obtained comments from stakeholders, including officials from organizations representing providers, petitioners' attorneys, and parents. These stakeholder comments, while providing insight into petitioner experiences, are anecdotal and do not represent the experience of all petitioners who have filed VICP claims. Members of the Advisory Commission on Childhood Vaccines we interviewed expressed interest in obtaining additional information on petitioner's experience with VICP; however, they told us they had not done so, citing concerns about confidentiality and other issues.

[67]Altarum Institute, *Determining the Feasibility of Evaluating the National Vaccine Injury Compensation Program*. HRSA contracted for this study in 2005, which surveyed petitioners regarding their perceptions of access to VICP information, program implementation and processes, financial award decision, and overall satisfaction. According to HRSA, petitioners were included in the sample if they (1) had filed a claim that had been compensated or dismissed in fiscal years 2004-2008 and (2) were represented by an attorney. Of 716 petitioners the researchers identified as meeting their inclusion criteria, 107 responded to their survey.

The limited comments on petitioners' experience from those who responded to the survey prepared for HRSA and from stakeholders included the following:

- Some petitioners responding to the HRSA survey reported being dissatisfied with the claims process and some commented that the process places too great a burden on petitioners and family members, with requests for additional information after the claims were filed. Similarly, one stakeholder said that petitioners view the vaccine injury claims process as confusing, time-consuming, too lengthy, and traumatic. Another stakeholder, on the other hand, commented that while vaccine-related injuries do not happen often, the program handles them efficiently and fairly when they do happen.
- Other comments from petitioners responding to the HRSA survey and stakeholders were related to the payment process and amount of compensation. More than half of the 61 petitioners who responded to a question on the method of payment in the HRSA survey reported being somewhat or very satisfied with the method of award payment; however, 14 respondents suggested more timely and flexible payment mechanisms. About half of the 63 respondents to the question on the amount of compensation reported the award amount was inadequate to cover past and future medical care. Similarly, stakeholders we interviewed reported concerns with the amounts petitioners receive, the method of payment, and a perceived lack of transparency regarding how the money from the Vaccine Injury Compensation Trust Fund has been spent. For example, one stakeholder told us that petitioners felt forced to settle for less than what it will cost them to care for their children or themselves for their lifetimes, and another stakeholder raised concerns about the choice of annuities for petitioners.
- Other comments on the program from stakeholders were related to the perception of an adversarial or unfriendly environment throughout the process, the use of settlements and perceived pressure to settle claims, the use of omnibus proceedings to group claims together, and concerns about confidentiality of the medical information filed by the petitioner. Some petitioners responding to the HRSA survey and some stakeholders also reported difficulties finding an attorney to represent petitioners in the process; however, petitioners responding to the survey were split on this issue—about the same number reported that finding an attorney was difficult as reported that finding an attorney was easy.

HHS Is Taking Steps to Address Criticism of Its Efforts to Inform the Public of the Program

HRSA has acknowledged being criticized for years for not adequately promoting public awareness of VICP, and has recently taken some steps, such as developing and starting to implement an outreach plan for fiscal year 2014 and developing an outreach plan for fiscal year 2015, to improve its efforts to reach out to providers and the public.[68] In its 2006 VICP strategic plan, HRSA noted that one of the critical issues facing the program from 2005 to 2010 was that many parents, the general public, attorneys, and health care professionals were not aware VICP existed.[69] In 2009, HRSA contracted for the development of a comprehensive national marketing and outreach communication plan; the contactor presented the plan to HRSA in November 2010.[70] According to HRSA, the agency used this plan to guide outreach efforts.[71] Prior to the fiscal year 2014 plan, HRSA also reported exhibiting at professional conferences; updating the VICP website and the VICP booklet that is available from the website (including translating the booklet into Spanish); facilitating the review of vaccine information statements (which include a statement on VICP) by the Advisory Commission on Childhood Vaccines; and responding to media inquiries and inquiries received via e-mail, letters, and the program's toll-free number.[72] HRSA officials also noted the need to carefully balance messages that increase awareness of VICP with public health messages that encourage and promote immunizations.

[68]In each of HRSA's annual justification of estimates for appropriations committees for fiscal years 2011-2014, HRSA noted that the agency has been criticized for not adequately promoting public awareness of the VICP.

[69]Division of Vaccine Injury Compensation, *National Vaccine Injury Compensation Program Strategic Plan* (April 2006).

[70]Banyan Communications, Inc., *The Comprehensive National Vaccine Injury Compensation Program Marketing and Outreach Communication Plan*, a report prepared for the Health Resources and Services Administration, (Nov. 2010).

[71]According to HRSA officials, the agency has been implementing some of the activities recommended in the November 2010 plans since that plan was issued, but the agency did not formally document its outreach efforts until the fiscal year 2014 VICP outreach plan. Agency officials report that the 2014 plan was developed because HRSA is taking a more strategic approach to its outreach and wanted to formally document these efforts.

[72]As part of its fiscal year 2011 budget justification, HRSA reported that exhibiting at conferences had proven beneficial in increasing knowledge of the availability of the program and that it planned exhibiting at medical and legal conferences in fiscal year 2011.

HRSA shared an overview of its outreach plans with its Advisory Commission on Childhood Vaccines in September 2014. HRSA reported that many of the activities in the agency's 2014 outreach plan were in process at the end of the fiscal year. These activities included reviewing the VICP booklets to use plain language and make them more user-friendly, reviewing and upgrading the VICP website to improve navigation, developing VICP message points for target audiences and slides about the program to be used in speeches and other presentations by HRSA staff, and requesting federal websites to provide information on the program and to link to the VICP website. In its outreach plan for fiscal year 2015, the agency is targeting health care providers, parents and expectant parents, adults aged 50 years and older (including Spanish-speaking older adults), and civil litigation and health attorneys, with the goal of informing target audiences of the availability of the program. According to HRSA, these target audiences were selected because they include individuals who administer vaccines and individuals (or their caregivers) who receive vaccinations. HRSA has identified a number of measures to assist in tracking performance of its fiscal year 2015 plan, including website metrics, the number of "retweets" and "shares" from social media initiatives, the number of media inquiries, and the number of attendees or participants at outreach events. Because the agency has not completed many of its planned efforts to improve how it informs the public of the availability of the program, it is too early to determine the effect of HRSA's current and planned outreach efforts.

Without awareness of the program, individuals who might otherwise receive compensation for a vaccine-related injury or death could be denied compensation because of a failure to file their claim within the statutory deadlines. One stakeholder commented that the public is largely unaware of the program, and this lack of awareness contributes to missing filing deadlines and individuals being denied the opportunity for compensation. Members of the Advisory Commission on Childhood Vaccines also told us that many individuals may not know there is a statute of limitations on filing a claim and many miss the opportunity to file

a claim because of the statute of limitations.[73] In December 2013, the commission recommended extending the statute of limitations for vaccine-related injuries and deaths. Extending the statute of limitations would require amending the applicable statutory provision.[74]

Concluding Observations

It has been more than 25 years since VICP went into effect in 1988. In that time, the program has awarded more than $2.8 billion to thousands of petitioners. Several aspects of the program have changed over the years. First, while claims alleging injuries on the vaccine injury table made up the majority of claims filed in the first decade of the program, today—after the addition of new vaccines, particularly influenza vaccine, to the table without associated injuries—the majority of the claims filed involve off-table injuries. Stakeholders report that the program has an adversarial environment, as petitioners are required to demonstrate a covered vaccine caused the injury on their VICP claim when there are no associated injuries on the table. The extent to which this will change if HHS updates the vaccine injury table to include more injuries, as expected, is yet to be seen. Second, most of the compensated cases are now adjudicated through negotiated settlement, rather than contested decisions before the special master. And while the vaccines covered by the program are included because they are recommended for children, many of the program's petitioners in recent years are adults who received covered vaccines.

Addressing one criticism of the program by stakeholders—specifically the need to increase the statute of limitations—would require a statutory change in the program. Regardless of whether the statute of limitations is

[73]The current statute of limitations, in general, requires that claims be filed within 3 years of the date of the first symptom or manifestation of the onset or significant aggravation of an injury and within 2 years of a death (and within 4 years of the date of the first symptom or manifestation of the onset or significant aggravation of the injury from which a death resulted). Generally, when a vaccine or injury is added to the vaccine injury table, petitioners are required to file claims within 2 years from the date the vaccine or injury is added to the table for injuries or deaths that occurred up to 8 years before the table change. See 42 U.S.C. § 300aa-16.

[74]HHS has proposed extending the statutory time limits for filing a VICP claim in the past. For example, in commenting on a draft of our 1999 report, the department stated that the legislative proposals it had sent to the Congress included doubling the statutory time limit for filing a claim. GAO/HEHS-00-8, 39. DOJ officials also reported they believed their department had supported previous proposals to extend the program's statute of limitations.

increased, HHS's efforts to increase awareness of the availability of the program will be important to help ensure that potential petitioners are aware of the program and can file claims in time. While HHS has recently taken or planned steps to improve its outreach activities, what effect, if any, these efforts will have remains to be seen. As the agency moves forward, it will be important for HRSA to identify which activities are reaching its target audiences.

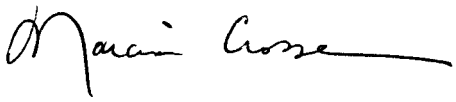
Agency Comments

We provided a draft of this report to HHS, DOJ, USCFC, and Treasury. HHS and USCFC agreed with our findings and provided written comments, which are reprinted in appendixes IV and V, respectively. In its comments, HHS emphasized that it administers VICP jointly with DOJ and USCFC, with HHS responsible for reviewing petitioners' claims, providing recommendations for entitlement to compensation, and making payments to petitioners and attorneys. In commenting on our identification of its efforts on VICP outreach, HHS noted that it is strengthening its outreach efforts by implementing its fiscal year 2015 VICP outreach plan, which increases outreach to target populations and includes performance measures. In its written comments, USCFC noted that the Administrative Office of the United States Courts and USCFC both supply administrative support to the Office of Special Masters and VICP without reimbursement from the trust fund. The court also commented that, while considerable strides have been made in reducing the average processing time for claims in recent years, the climbing and changing nature of the caseload, coupled with the statutory cap on the number of special masters, present a continuing challenge to the Office of Special Masters' ability to continue to reduce average processing times. USCFC also commented that following omnibus proceedings, claims have been resolved more expeditiously in recent years, and often through settlements. USCFC also commented that the Office of Special Masters strives to resolve all cases fairly and expeditiously. HHS, USCFC, DOJ, and Treasury also provided technical comments that were incorporated, as appropriate.

We are sending copies of this report to the Secretary of Health and Human Services, the Attorney General of the United States, the Chief Judge of the United States Court of Federal Claims, and the Secretary of the Treasury. In addition, the report is available at no charge on the GAO website at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or crossem@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix VI.

Sincerely yours,



Marcia Crosse
Director, Health Care

Appendix I: Vaccine Injury Table, September 2014

Vaccine	Injury[a]	Time period[b]
Vaccines against tetanus (e.g., DTaP, DTP, DT, Td, or TT)	Anaphylaxis or anaphylactic shock	4 hours
	Brachial neuritis	2-28 days
Vaccines against pertussis (e.g., DTP, DTaP, P, DTP-Hib)	Anaphylaxis or anaphylactic shock	4 hours
	Encephalopathy (or encephalitis)	72 hours
Vaccines against measles, mumps, rubella in any combination (e.g., MMR, MR, M, R)	Anaphylaxis or anaphylactic shock	4 hours
	Encephalopathy (or encephalitis)	5-15 days
Vaccines against measles (e.g., MMR, MR, M)	Thrombocytopenic purpura	7-30 days
	Vaccine-strain measles viral infection in an immunodeficient recipient	6 months
Vaccines against rubella (e.g., MMR, MR, R)	Chronic arthritis	7-42 days
Vaccines against polio (polio live virus-containing (OPV))	Paralytic Polio	
	—In a nonimmunodeficient recipient	30 days
	—In an immunodeficient recipient	6 months
	—In a vaccine-associated community case	Not applicable
	Vaccine-strain polio viral infection	
	—In a nonimmunodeficient recipient	30 days
	—In an immunodeficient recipient	6 months
	—In a vaccine-associated community case	Not applicable
Vaccines against polio (polio inactivated virus-containing (IPV))	Anaphylaxis or anaphylactic shock	4 hours
Vaccines against hepatitis B	Anaphylaxis or anaphylactic shock	4 hours
Vaccines against hemophilus influenzae type b (Hib conjugate vaccine)	No condition specified	Not applicable
Vaccines against varicella	No condition specified	Not applicable
Vaccines against rotavirus[a]	No condition specified	Not applicable
Vaccines against pneumococcal disease (pneumococcal conjugate vaccine)[a]	No condition specified	Not applicable
Vaccines against hepatitis A[a]	No condition specified	Not applicable
Vaccines against influenza (trivalent vaccine)[a,c]	No condition specified	Not applicable
Vaccines against meningococcal disease[a]	No condition specified	Not applicable
Vaccines against human papillomavirus (HPV)	No condition specified	Not applicable

Source: GAO summary of information from the Health Resources and Services Administration. | GAO-15-142

Notes: In addition to the specific vaccines currently listed on the table, the National Vaccine Injury Compensation Program (VICP) also covers new vaccines recommended by the Centers for Disease Control and Prevention for routine administration to children after publication by the Secretary of a notice of coverage, effective on the date of an applicable excise tax.

[a]This column includes the illness, disability, injury, or condition covered by the program. In addition, covered injuries include any acute complication or sequela (including death) of the listed injuries (for all but the Hib, varicella, rotavirus, pneumococcal conjugate, hepatitis A, trivalent influenza, meningococcal, and HPV vaccines).

[b]For first symptom, onset, or aggravation of injury after vaccination.

[c]Trivalent influenza vaccine was added to the table effective July 1, 2005. All additional seasonal influenza vaccines, including quadrivalent vaccine, are covered by VICP, effective November 12, 2013.

Appendix II: Covered Vaccines and Injuries on the Vaccine Injury Table, Fiscal Years 1999-2014

	Fiscal year															
Vaccine	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**[a]
Vaccines and Injuries Added to the Table before Fiscal Year 1999																
Tetanus-containing	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Pertussis-containing	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Measles, mumps, rubella in any combination	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Measles-containing	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Rubella-containing	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Polio live virus-containing	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Polio inactivated virus-containing	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Hepatitis B	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Hemophilus influenza type b (Hib) conjugate[b]	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
Varicella[b]	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
Vaccines and Injuries Added and Proposed to be Added to the Table During and After Fiscal Year 1999																
Rotavirus[c]	○	○	○	○	○	○	○	○	○	○	○	○	○	○	◐[c]	◐[c]
Pneumococcal conjugate	—	○[d]	○	○	○	○	○	○	○	○	○	○	○	○	○	○
Hepatitis A	—	—	—	—	—	—	○	○	○	○	○	○	○	○	○	○
Trivalent influenza[e]	—	—	—	—	—	—	○	○	○	○	○	○	○	○	○	○
Meningococcal	—	—	—	—	—	—	—	—	○	○	○	○	○	○	○	○
Human Papillomavirus	—	—	—	—	—	—	—	—	○	○	○	○	○	○	○	○
Vaccines and Injuries Added and Removed from the Table since Fiscal Year 1999																
Hib polysaccharide (unconjugated)	●	●	●	●	—	—	—	—	—	—	—	—	—	—	—	—
Rotavirus rhesus-based	—	—	—	●	●	●	●	●	●	●	●	—	—	—	—	—

Source: GAO analysis. | GAO-15-142

Legend:

● = at least one injury specified for this vaccine on the table at any point during the fiscal year

◐ = HHS issued a proposed rule to add an injury to the table during the fiscal year

○ = there are no table injuries specified for this vaccine

— = the vaccine is not on the table

Notes: When no injury is identified or specified for the vaccine, the petitioner must prove that the injury was caused by the vaccine. In addition to the vaccines listed on the table, the National Vaccine Injury Compensation Program (VICP) may also cover any new vaccines that are recommended by the Centers for Disease Control and Prevention's for routine administration to children and which are subject to an excise tax, but are not yet specifically listed on the vaccine injury table.

[a]The information in this column is up to date as of September 17, 2014.

[b]Hemophilus influenza type b conjugate and varicella vaccines were added to the table effective August 6, 1997.

[c]Rotavirus was added to the table effective October 22, 1998. HHS issued a proposed rule on July 24, 2013, to add an injury to the table associated with rotavirus vaccine. However, the rule was not finalized before the end of fiscal year 2014.

[d]Pneumococcal conjugate vaccine was added to the table effective December 18, 1999.

[e]Trivalent influenza vaccine was added to the table effective July 1, 2005. All additional seasonal influenza vaccines, including quadrivalent vaccine, are covered by VICP, effective November 12, 2013.

Appendix III: Compensation to Petitioners and Attorneys' Fees and Costs, Fiscal Years 1999-2013

This appendix shows the total amount paid in compensation to petitioners under the National Vaccine Injury Compensation Program and the number of compensated claims in fiscal years 1999-2013 (see table 2). It also shows the amounts the program paid in attorneys' fees and costs for those same fiscal years (see table 3).

Table 2: Compensation to Petitioners under the National Vaccine Injury Compensation Program, Fiscal Years 1999-2013

Fiscal year	Petitioners' award amount	Number of compensated claims
1999	$95,917,681	96
2000	$125,945,196	136
2001	$105,878,633	97
2002	$59,799,604	80
2003	$82,816,240	65
2004	$61,933,764	57
2005	$55,065,797	64
2006	$48,746,163	68
2007	$91,449,434	82
2008	$75,716,552	141
2009	$74,142,491	131
2010	$179,387,341	173
2011	$216,319,428	251
2012	$163,511,999	250
2013	$254,666,327	375
Total	**$1,691,296,649**	**2,066**

Source: HRSA Data and Statistics Report, August 1, 2014. | GAO-15-142

Table 3: Payments to Attorneys under the National Vaccine Injury Compensation Program, Fiscal Years 1999-2013

Fiscal year	Compensated attorneys' fees/cost payments	Dismissed attorneys' fees/cost payments	Interim attorneys' fees/cost payments	Number of payments to attorneys
1999	$2,799,911	$2,306,957	$0.00	213
2000	$4,112,369	$1,724,451	$0.00	216
2001	$3,373,866	$2,066,225	$0.00	154
2002	$2,653,599	$656,245	$0.00	130
2003	$3,147,755	$1,545,655	$0.00	134
2004	$3,079,329	$1,198,616	$0.00	126
2005	$2,694,664	$1,790,587	$0.00	135
2006	$2,441,199	$1,353,633	$0.00	122
2007	$4,034,154	$1,692,020	$0.00	143
2008	$5,191,771	$2,511,313	$117,265	216
2009	$5,404,712	$1,557,140	$4,241,363	195
2010	$5,961,744	$1,886,240	$1,978,804	251
2011	$9,572,043	$5,589,417	$2,001,771	682
2012	$9,104,489	$8,621,182	$5,420,258	1,304
2013	$13,333,180	$6,970,279	$1,454,852	1,128
Total	**$76,904,784**	**$41,469,960**	**$15,214,312**	**5,149**

Source: HRSA Data and Statistics Report, August 1, 2014. | GAO-15-142

Appendix IV: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

NOV 6 2014

Marcia Crosse
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Crosse:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "Vaccine Injury Compensation: Most Claims Took Multiple Years and Many Were Settled through Negotiation" (GAO 15-142).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S REPORT ENTITLED: VACCINE INJURY COMPENSATION: MOST CLAIMS TOOK MULTIPLE YEARS AND MANY WERE SETTLED THROUGH NEGOTIATION (GAO-15-142)

The U.S. Department of Health and Human Services (HHS) appreciates the opportunity to review and comment on this draft report.

HHS is pleased that the U.S. Government Accountability Office (GAO) recognized that the National Vaccine Injury Compensation Program (VICP) is jointly administered. HHS administers certain aspects of the VICP (e.g., reviews petitioners' claims, provides recommendations for entitlement to compensation, and makes payments to petitioners and/or attorneys when so ordered by the Court). The remaining aspects of the program are overseen by the Department of Justice and the U.S. Court of Federal Claims. It is important that this distinction is noted consistently throughout the report.

HHS is also pleased that GAO identified some of the efforts that HHS has implemented in the past to inform the public and providers of the VICP. GAO also recognized the strategic approach that HHS has taken to increase efforts to inform providers and the public of the VICP by implementing its FY 2014 outreach plan. Currently, HHS is strengthening its VICP outreach efforts by implementing its FY 2015 VICP outreach plan, which emphasizes leveraging the work of HHS programs and other federal programs and increasing outreach to target VICP populations. The plan also includes performance measures to ensure that the components and activities within the strategy have been implemented successfully.

1

Appendix V: Comments from the United States Court of Federal Claims

United States Court of Federal Claims
717 MADISON PLACE, NW
WASHINGTON, DC 20439

CHAMBERS OF
CHIEF JUDGE
PATRICIA E. CAMPBELL-SMITH

(202) 357-6357
FAX: (202) 357-6551
patricia_campbell-smith@ao.uscourts.gov

November 5, 2014

Ms. Marcia Crosse
Director, Health Care
United States Government Accountability Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Ms. Crosse:

Thank you for the opportunity to review the United States Government Accountability Office (GAO) draft report (Vaccine Injury Compensation (GAO-15-142)). Some technical corrections to the report are included as an enclosure to this letter. Overall, the report is fair and balanced, providing the perspectives of the many stakeholders in the Vaccine Program.

As reflected in the report, the Judiciary has been a good steward of the Vaccine Program Trust Fund using only a small percentage of the interest income from the Trust Fund to support personnel costs. Both the Administrative Office of the United States Courts and the United States Court of Federal Claims supply administrative support to the Office of Special Masters and the Vaccine Program without reimbursement from the Trust Fund.

The resolution of thousands of claims in the fifteen-year period that this report covers has been accomplished with less than 30 full time equivalents, including eight special masters. The number of petitions filed since 2009 has continued to climb, reflecting the more than doubling of the number of vaccinations administered annually for which a claim may be filed. Although considerable strides in reducing the average processing time for claims have been made in recent years, the climbing and changing nature of the caseload, coupled with the statutory cap on the number of special masters, presents a continuing challenge to the Office of Special Masters' ability to continue to do so.

Notwithstanding the fact that over half of the claims filed since 1999 have taken more than five years to resolve, this occurred in the context of three significant omnibus proceedings, all of which proceeded at a pace consistent with petitioners' requests. In more recent years, claims have been resolved far more expeditiously, and often through

settlements that result in compensation to petitioners, in keeping with the Congressional admonition that proceedings be less adversarial.

Settlements in the Vaccine Program in recent years have been a success story. This achievement rests on the cooperative efforts of counsel for both parties. Nevertheless, some cases are not amenable to settlement. Causation in fact cases often present questions that have to be resolved through litigation, and ultimately a decision by the special master, that may or may not result in compensation. The Office of Special Masters strives to resolve all cases fairly and expeditiously, consistent with the spirit and intent of the Vaccine Act.

Sincerely,

Patricia E. Campbell-Smith
Chief Judge

cc: Director, Administrative Office of the Courts

Appendix VI: GAO Contact and Staff Acknowledgments

GAO Contact

Marcia Crosse, (202) 512-7114 or crossem@gao.gov

Staff Acknowledgments

In addition to the contact named above, Kim Yamane, Assistant Director; George Bogart; Carolyn Garvey; Cathleen Hamann; Katherine Perry; Fatima Sharif; and Eric Wedum made key contributions to this report.