

**ADVISORY COMMISSION ON CHILDHOOD VACCINES (ACCV)**  
**U.S. Department of Health and Human Services**

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December 2, 2020

The Honorable Alex M. Azar II  
Secretary of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Secretary Azar:

In accordance with the provisions of the charter for the Advisory Commission on Childhood Vaccines (ACCV or Commission), and pursuant to its obligations under the National Childhood Vaccine Injury Act of 1986 as amended (the Vaccine Act, 42 U.S.C. § 300aa-19), we respectfully submit for your consideration a recommendation regarding the implementation of the National Vaccine Injury Compensation Program (VICP).

At its September 2020 quarterly meeting, the ACCV discussed issues related to the functioning of the VICP. Due to the significant increase in VICP claims without comparable increases in administrative budgets, the workload for the Health Resources and Services Administration (HRSA), the Department of Justice (DOJ), and the Office of Special Masters (OSM), U.S. Court of Federal Claims (Court) staff involved in VICP claims resolution has more than tripled since Fiscal Year (FY) 2011. This has contributed to an ever-worsening backlog of claims awaiting review, and it has directly resulted in a worsening, unreasonable delay in the review and processing of vaccine injury claims. Based on this increased workload without a concomitant increase in staffing and funding resources, the ACCV recommends that the Secretary support an increase in the number of Special Masters and the amount of staffing and funding resources for the VICP. In May 2020, December 2018, and December 2016, the commissioners sent the attached recommendations to the Secretary, and the Commission is once again sending an updated version of these requests for your consideration. Information to support these recommendations is attached.

Recommendation 1

The ACCV once again recommends that the Secretary propose an amendment to the Vaccine Act to authorize appointing eight or more special masters. The current provision states, “*There is established within the United States Claims Court an office of special masters which shall consist of not more than 8 special masters.*” (Sec. 2112(c)(1) of the Public Health Service Act [42 U.S.C. § 300aa-12(c)(1)]).

The proposed provision would state, “*There is established within the United States Court of Federal Claims an office of special masters which shall consist of at least 8 special masters.*”

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Recommendation 2

The ACCV once again recommends that the Secretary support efforts to increase the annual appropriations of HRSA, DOJ, and the OSM of the Court to provide the necessary resources to timely and efficiently implement the VICP.

Sincerely,

John Howie  
Chair, ACCV

Karen Kain  
Vice Chair, ACCV

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**Information to Support Additional Special Masters and Increased Funding, Staffing and/or Funding Resources for the National Vaccine Injury Compensation Program (VICP)**

Background

The number of claims filed has tripled (or increased by 205%) from 386 claims filed in FY 2011 to 1,191 claims filed in FY 2020. During the same period, administrative funding has increased by only 57 percent from \$6.5 million to \$10.2 million, as shown in Table 1. This dramatic upsurge is primarily due to the increase in the number of claims alleging seasonal influenza vaccine injuries, which account for approximately 70 percent of claims filed annually. Because of the large number of influenza vaccines administered each year, when the influenza vaccine was added to the Vaccine Injury Table (Table), many more people became eligible to file a claim with the VICP.

In FY 2017, HRSA began a backlog of vaccine injury claims awaiting medical review since the volume of claims exceeded resources available to conduct medical reviews. This backlog results in delays in compensating petitioners since claims remain in backlog status for about 14 months awaiting review. The cumulative claims backlog was 880 claims at the end of FY 2019. Even though the HRSA funding to administer the VICP, increased by \$1 million from \$9.2 in FY 2019 to \$10.2 million in FY 2020, the backlog grew to 966 by the end of FY 2020.

We strongly agree with inclusion of the influenza vaccine in the VICP, but wish to note the resulting increase in workload because of the addition of this vaccine to the Table. The Centers for Disease Control and Prevention (CDC) reports that the number of adults and children administered seasonal flu vaccines increases every year; this suggests that the high volume of claims filed with the VICP is not a temporary trend and the annual number of claims filed may grow.

**Table 1. Five-Year Trend in Number of Claims Filed and Administrative Costs**

<b>Fiscal Year (FY)</b>	<b>No. of Claims Filed</b>	<b>Administrative Funding</b> <i>(\$ in millions)</i>
<b>2011</b>	386	\$6.50
<b>2012</b>	401	\$6.50
<b>2013</b>	504	\$6.50
<b>2014</b>	633	\$6.50
<b>2015</b>	803	\$7.50
<b>2016</b>	1,120	\$7.50
<b>2017</b>	1,243	\$7.75
<b>2018</b>	1,238	\$9.20
<b>2019</b>	1,282	\$9.20
<b>2020</b>	1,191	\$10.20

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Due to the significant increase in VICP claims filed, the workload for components of the Department of Justice (DOJ) and the Office of Special Masters (OSM) of the U.S. Court of Federal Claims (Court) involved in the VICP has also tripled since FY 2011. HRSA, DOJ, and the Court endeavor to resolve claims efficiently, fairly, and quickly despite the increased workload. The Court is concerned that the ratio of claims filed each month as compared to the number of claims closed each month will grow, as the ability to expediently resolve cases becomes increasingly difficult due to the increased caseload.

While DOJ has had some success obtaining additional funding to hire attorneys, it is critical that DOJ receive the funding requested for FY 2021 to help resolve the backlog. Moreover, the present level of funding limits the ability of HRSA to hire medical officers who are necessary to resolve the backlog of claims, even if DOJ's funding request for FY 2021 is granted. In addition, the National Childhood Vaccine Injury Act of 1986 (Vaccine Act) contains a provision limiting the number of special masters who can be appointed, which further contributes to the backlog. The personnel shortage requires a permanent solution for HRSA, DOJ, and the Court because the average number of claims filed from FY 2016 - FY 2020 increased to 1,212 compared to 545, the average number of claims filed from FY 2011 - FY 2015.

Although the size of DOJ's attorney staff has gradually increased by 31% from FY 2012 to FY 2019, the case filings in FY 2019 (1,282) exceeded the case filings in 2012 (401) by more than 200%, bringing the total number of cases filed during that period to 7,224 cases. While the HRSA FY 2020 budget increase allowed the VICP to review more claims than in FY 2019, the unprecedented growth in claims filed continues to far outpace funding levels. The backlog has continued to increase, resulting in delays in compensating petitioners, since claims are on a waiting list for about 14 months pending review.

Even though VICP claims have increased, resources for HRSA, DOJ, and the Court have not had commensurate increases. Without such increases in funding, specifically to hire additional staff, the rise in the number of claims filed and the backlog of claims to be reviewed will continue to result in delays in compensation to petitioners.

The Vaccine Injury Compensation Trust Fund (Trust Fund) provides funding to compensate vaccine-related injury or death claims. It also provides funding to pay the administrative expenses for HRSA, DOJ, and the Court. However, Congress is required to appropriate separate funding from the Trust Fund for each of these Federal entities as demonstrated in Table 2 on the next page. The current Trust Fund balance is over \$3.9 billion.

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**Table 2. Congressional Appropriations for HRSA, DOJ, and the Court’s Administrative Expenses**

<b>Fiscal Year</b>	<b>HRSA</b>	<b>DOJ</b>	<b>Court</b>	<b>Total</b>
2016	\$7,500,000	\$9,358,000	\$6,050,000	\$22,908,000
2017	\$7,750,000	\$9,358,000	\$6,510,000	\$23,618,000
2018	\$9,200,000	\$10,000,000	\$8,230,000	\$27,430,000
2019	\$9,200,000	\$10,000,000	\$8,475,000	\$27,017,019
2020	\$10,200,000	\$13,000,000	\$9,070,000	\$32,270,000

The ACCV recommends that the Secretary support efforts to increase funding to provide more resources, particularly to hire more staff for HRSA, DOJ, and the Court, specifically the 1) Division of Injury Compensation Programs, HRSA, 2) Vaccine Litigation Section, Torts Branch, Civil Division, DOJ, and 3) OSM of the Court. Also, the ACCV recommends that the Secretary propose an amendment to the Vaccine Act to authorize the OSM of the Court to consist of eight or more special masters.