

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

DRAFT RECOMMENDATION

**Please note that this is a draft recommendation which will be discussed during the
ACCV Meeting on September 1, 2022.**

September 1, 2022

The Honorable Xavier Becerra
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Becerra:

In accordance with the provisions of the charter for the Advisory Commission on Childhood Vaccines (ACCV or Commission), and pursuant to the Commission's 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 June 2022 meeting, the ACCV discussed issues related to the functioning of the VICP. Due to the significant increase in the number of VICP claims filed, without comparable increases in administrative budgets, 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 experienced more than a fivefold increase in workload since Fiscal Year (FY) 2011. This has contributed to an ever-expanding backlog of claims awaiting review, which has directly resulted in lengthier delays in the review and processing of vaccine injury claims. Given this increased administrative workload, without a concomitant increase in staffing and funding resources, the ACCV recommends that the Secretary support legislation to increase the number of Special Masters permitted by statute and the amount of staffing and funding resources for the VICP. In December 2020, 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 more special masters, and/or support any pending legislation to increase the number of the number of 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)]).

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The proposed revised provision would state, *“There is established within the United States Court of Federal Claims an office of special masters which shall consist of no fewer than ten special masters.”*

Recommendation 2

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

Sincerely,

CDR George Reed Grimes, MD
Director, Division of Injury Compensation Programs
Designated Federal Officer and Temporary 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 increased by 412% from 402 claims filed in FY 2012 to 2,057 claims filed in FY 2021. During the same period, HRSA’s administrative funding has increased by only 72 percent, from \$6.5 million to \$11.2 million, as shown in Table 1. This dramatic upsurge is due to the increase in the number of claims alleging seasonal influenza vaccine injuries and/or shoulder injuries related to vaccine administration (SIRVA). 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. Over 75 percent of petitions filed in the VICP in the last two years allege an injury from the influenza vaccine. Over 68 percent of petitions filed in the VICP in the last two years allege SIRVA.

In FY 2017, because the volume of claims exceeded resources available to conduct medical reviews, HRSA began a waitlist of vaccine injury claims awaiting medical review (backlog). This backlog results in delays in compensating petitioners since a claim remains in the backlog for approximately 13 months before it undergoes medical review. The cumulative claims backlog was 1,004 claims at the end of FY 2020. Even though the HRSA funding to administer the VICP increased by \$1 million from \$10.2 in FY 2020 to \$11.2 million in FY 2021, the backlog grew to 1,568 by the end of FY 2021.

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

Fiscal Year (FY)	No. of Claims Filed	Administrative Funding (<i>\$ in millions</i>)
2012	402	\$6.50
2013	504	\$6.50
2014	633	\$6.50
2015	803	\$7.50
2016	1,120	\$7.50
2017	1,243	\$7.75
2018	1,238	\$9.20
2019	1,282	\$9.20
2020	1,192	\$10.20
2021	2,057	\$11.20

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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 increased since FY 2012. 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 2023 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 2023 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 2017- FY 2021 increased to 1,402 compared to 692, the average number of claims filed from FY 2012 - FY 2016.

Although the size of DOJ's attorney staff has gradually increased by 126% from FY 2012 to FY 2021, the case filings in FY 2021 (2,057) exceeded the case filings in 2012 (402) by more than 400%, bringing the total number of cases filed during that period to 10,474 cases. While the HRSA FY 2021 budget increase allowed the VICP to review slightly more claims than in FY 2020, the unprecedented number of petitions being filed continues to far outpace funding levels, yet resources for HRSA, DOJ and the Court have not commensurately increased. The result has been a growing backlog of claims awaiting medical review. Without additional funding, particularly to hire additional staff, the backlog of claims will continue to result in significant 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 below. The current Trust Fund balance is over \$4.2 billion.

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

Fiscal Year	HRSA	DOJ	Court	Total
2016	\$7,500,000	\$9,358,000	\$6,050,000	\$22,908,000
2017	\$7,750,000	\$10,000,000	\$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
2021	\$11,200,000	\$17,000,000	\$9,900,000	\$38,100,000

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 no fewer than ten special masters, and/or support any pending legislation to increase the number of special masters.