DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857
Healthcare Systems Bureau

DEC 19 2018

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 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 March 2018 quarterly meeting, the ACCV discussed the formation of a Workgroup to examine prior ACCV recommendations to the Secretary and to present consolidated, updated, or new recommendations to the ACCV for its consideration, deliberation, and recommendation. This Workgroup is chaired by an ACCV member, who is a representative of the general public and the parent of a vaccine-injured child. Other ACCV members on the Workgroup include two health care provider representatives, one representative who is an attorney representing vaccine manufacturers, one representative who is an attorney representing petitioners, and one representative who is a non-affiliated attorney. Representatives from the Division of Injury Compensation Programs and the Department of Health and Human Services (HHS), the Office of the General Counsel (OGC), the Department of Justice (DOJ), the Immunization Safety Office, the Centers for Disease Control and Prevention (CDC), and the Office of Vaccines Research and Review, Food and Drug Administration (FDA) participate in the Workgroup as consultants.

The Workgroup met by telephone monthly beginning in May 2018. The Workgroup discussed issues related to the functioning of the VICP and proposals for its improvement, with a focus on resources. Due to the significant increase in VICP claims filed annually, the workload for the Health Resources and Services Administration (HRSA), DOJ, and the Office of Special Masters (OSM), U.S. Court of Federal Claims (Court) staff involved in VICP claims resolution has more than doubled since Fiscal Year (FY) 2013. Based on this increased workload, the Workgroup proposed the ACCV recommend that the Secretary support an increase in the number of Special Masters and the amount of staffing and funding resources for the VICP. The ACCV unanimously approved and adopted the Workgroup's recommendations at the December 6, 2018 ACCV meeting.

The ACCV's recommendations are attached for your consideration.

Sincerely,

/s/

Karlen Beth Luthy
Chair, ACCV

/s/

Herman Cody Meissner
Co-Chair, ACCV

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

Background

From FY 2014 through FY 2018, the number of VICP claims filed has nearly doubled from 633 to 1,238, as shown in Table 1. This dramatic upsurge is primarily due to the increase in the number of claims filed resulting from receipt of the seasonal influenza vaccine, which accounts for approximately 60 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.

Table 1. Five-Year Trend in Number of Claims Filed versus Health Resources and Services Administration (HRSA) Administrative Costs

Fiscal Year (FY)	No. of Claims Filed	HRSA Administrative Funding *($ in millions)*
2014	633	$6.46
2015	803	$7.50
2016	1,120	$7.50
2017	1,243	$7.75
2018	1,238	$9.20

We strongly agree with inclusion of the influenza vaccine in the VICP, but wish to note the resulting increase in workload as a consequence of the addition of this vaccine. Due to the significant increase in VICP claims filed annually, the workload for components of HRSA, 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 nearly doubled since 2014. HRSA, DOJ, and the Court endeavor to adjudicate/resolve claims efficiently, fairly, and quickly despite the increased workload. Nevertheless, a backlog of unresolved claims is leading to delays in compensation. The Court is concerned that the gap between the number of claims filed each month as compared to the number of claims closed each month will continue to widen.

The present level of funding limits the ability of HRSA and DOJ to hire medical officers and attorneys who are necessary to resolve the backlog of claims. 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 because HRSA, DOJ, and the Court expect that VICP claims will continue to increase. The majority of VICP claims filed are those of adults claiming seasonal flu vaccine-related injuries. 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 increase in the volume of claims filed with the VICP is not a temporary trend and will continue to grow. For example, HRSA anticipates 1,720 claims will be filed in FY 2019, a nearly 40% increase over the FY 2018 level of 1,238 claims filed. The Final Rule modifying the Table was

published on March 21, 2017, and, under the Vaccine Act, petitioners are permitted an alternate filing deadline of two years from the effective date of a Table change to file certain claims for injuries or deaths that occurred up to eight years preceding the Table modification date. The anticipated number of FY 2019 claims accounts for this statutory deadline for filing claims related to specific changes to the Table.

In addition, the number of claims filed is expected to continue to increase because the 21st Century Cures Act (Cures Act) which was enacted in December 2016. The Cures Act expanded VICP coverage to include new categories of vaccines that previously were not covered by the VICP -- vaccines recommended by the CDC for routine administration to pregnant women (but not for routine administration in children) and subject to a federal excise tax. The Cures Act also clarified that vaccine-injury claims may be filed both with respect to injuries alleged to have been sustained by women receiving covered vaccines during pregnancy and with respect to injuries alleged to have been sustained by live-born children who were in utero at the time those women were administered such vaccines.

While the number of claims filed has more than doubled over the last five years, HRSA's administrative funding has increased by only 19 percent from FY 2014 to FY 2018, as shown in Table 2. The size of DOJ's staff has increased by only 30% since FY 2012, even though there has been a 300% increase in the number of cases filed since FY 2012, when compared to the number of cases filed between FY 2006 and FY 2012. Beginning in FY 2017, the VICP experienced a backlog of claims because the increased number of claims filed exceeded the level of funding available to conduct medical reviews. In FY 2018, HRSA's administrative resources increased by 19 percent as compared to FY 2017 funding. While the HRSA FY 2018 budget increase allows the VICP to review more claims than in FY 2017, the unprecedented growth in claims filed continues to outpace funding levels. The backlog will continue to increase, resulting in delays in compensating petitioners, since claims are on a waiting list for more than six 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 will result in continued and growing 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. The current Trust Fund balance is over $3.8 billion.

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

Fiscal Year	HRSA	DOJ	Court	Total
2014	6,464,000	7,833,000	5,327,000	19,624,000
2015	7,500,000	7,833,000	5,423,000	20,756,000
2016	7,500,000	9,358,000	6,050,000	22,908,000
2017	7,750,000	10,000,000	6,510,000	24,260,000

2018	9,200,000	10,000,000	8,230,000	27,430,000

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.

Recommendation 1

The ACCV 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."*

Recommendation 2

The ACCV 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 implement the VICP.