

DRAFT

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

Background

From FY 2013 to FY 2017, the number of VICP claims filed has more than doubled from 504 to 1,243, 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 <i>(\$ in millions)</i>
2013	504	\$6.48
2014	633	\$6.46
2015	803	\$7.50
2016	1,120	\$7.50
2017	1,243	\$7.75

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, Department of Justice (DOJ), and the Office of the Special Masters (OSM) of the U.S. Court of Federal Claims (Court) involved in the VICP has more than doubled since 2013. HRSA, DOJ and the Court struggle to adjudicate/resolve claims efficiently, fairly and quickly. But the backlog of unresolved claims is lead 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 from hiring medical officers and attorneys who are necessary to resolve the backlog of claims. Another issue that would need to be addressed is that 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 for 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 vaccine 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 filed in FY 2019, a 25% increase over the projected FY 2018 level of 1,380 claims filed. The Final Rule modifying the Table was published on March 21, 2017, and, under the Vaccine Act, petitioners

have two years from the effective date of Table changes to file claims for injuries or deaths that occurred up to eight years preceding the Table modification date. The FY 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 requires the Secretary to revise the Table to include vaccines recommended by the CDC for routine administration in pregnant women (and subject to an excise tax by Federal law). It also permits both a woman who received a covered vaccine while pregnant and any live-born child who was in utero at the time such woman received the vaccine to be considered persons to whom the covered vaccine was administered. The Cures Act also mandates that a covered vaccine administered to a pregnant woman constitutes more than one vaccine administration—one to the mother and one to each live-born child who was in utero at the time the woman received the vaccine.

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 2013 to FY 2017, as shown in Table 2. The size of DOJ’s staff has increased by only 35% 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 on the next page.

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 Claims Court 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 the HRSA, DOJ and the OSM of the Court to provide the necessary resources to implement the VICP.