



The Honorable Sylvia Mathews Burwell  
Secretary of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

RE: Recommendation of the Advisory Commission on Childhood Vaccines

Dear Secretary Burwell:

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 June 2012 quarterly meeting, the ACCV formed the Process 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, a representative of the general public who is also the parent of a vaccine-injured child. Other ACCV members on the Workgroup include one health care provider representative; one representative of the general public who is also the parent of a vaccine-injured child; one representative who is an attorney representing petitioners; and one representative who is a non-affiliated attorney. Liaison representatives from the Division of Injury Compensation Programs and the Department of Health and Human Services (HHS) Office of the General Counsel (OGC) participate in the workgroup as consultants.

The Process Workgroup met by telephone in June 2016 and September 2016. The Workgroup discussed issues related to the functioning of the Program and proposals for 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) and Department of Justice (DOJ) and the Office of the Special Masters (OSM), U.S. Court of Federal Claims (Court) staff involved in VICP claims resolution has more than doubled since 2013. Based on this increased workload, the ACCV is recommending that the Secretary support an increase in the number of Special Masters, and in the amount of staffing and funding resources for the VICP.

The recommendations developed by the Workgroup and approved unanimously by the ACCV at its meeting on September 20, 2016 are attached for your consideration.

Sincerely,

/s/

Kristen Feemster  
Chair, ACCV

/s/

Jason Smith  
Co-Chair, ACCV

## **Recommendation to Support an Increase in National Vaccine Injury Compensation Program (VICP) Special Masters, Staffing and/or Funding Resources**

### **Background**

After a relatively stable annual average of 200 non-autism VICP claims filed from Calendar Year (CY) 2002 through CY 2008, the number of non-autism claims filed began to significantly increase in CY 2013. From CY 2013 to CY 2015, the number of non-autism claims filed increased from 525 to 945 which is an 80% increase over a three-year period.

Due to the significant increase in VICP claims filed annually, the workload for the Health Resources and Services Administration (HRSA) and Department of Justice (DOJ) and the Office of the Special Masters (OSM), U.S. Court of Federal Claims (Court) staff involved in VICP claims resolution has more than doubled since 2013. HRSA, DOJ and the Court struggle to manage the workload with limited resources; consequently, there is a backlog of unresolved claims which may lead to delays in compensation. The Court is concerned that the gap between the numbers of claims filed each month as compared to the number of claims that are closed each month will continue to widen.

Inadequate funding and the National Childhood Vaccine Injury Act of 1986 (the Act) provision which currently limits the number of special masters that can be hired, prevents HRSA, DOJ, and the Court from hiring needed medical officers, attorneys and special masters to resolve the backlog of claims and eliminate the potential delay in compensation to vaccine injured persons. The Act limits the number of special masters to a total of eight, and this number has not been changed in 30 years, in spite of the increased workload and increase in the number of vaccines added to the Vaccine Injury Table (Table).

The shortage of resources requires a permanent solution because the HRSA, DOJ and the Court expect the increases in claims filed will continue indefinitely. An estimated 1,200 claims will be filed in 2016, a 27% increase over 2015. The majority of VICP claims being filed are adults claiming seasonal flu vaccine injuries. The Centers for Disease Control and Prevention reports 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 will continue to grow. In addition, HRSA has increased outreach efforts, following the 2014 Government Accountability Office study of the program, which will also likely result in sustained increases in VICP claims filed. Furthermore, proposed changes to the Table will allow people who previously missed the VICP filing deadline additional time to file a claim, likely leading to a significant temporary increase in claims filed.

Even though the workload of staff has drastically increased, the staffing and funding resources for HRSA, DOJ, and the Court involved in resolving VICP claims have not had commensurate increases. Without commensurate increases in staffing and funding resources, the rise in the number of claims filed will result in the inability to resolve claims in a timely manner; and thus, delays in compensation to petitioners.

The ACCV recommends that the Secretary support efforts to increase staffing and funding resources for HRSA, DOJ and the Court – 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 support a legislative proposal to the National Childhood Vaccine Injury Act of 1986, as amended, permitting the hire of 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 adequate staffing and funding and staffing resources to enable the timely resolution of VICP claims.