DEPARTMENT OF HEALTH & HUMAN SERVICES **Health Resources and Services Administration**

Advisory Commission on Childhood Vaccines **Rockville, Maryland 20857**

DEC 0 3 2013

The Honorable Kathleen Sebelius
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 Sebelius:

In accordance with the provisions of the charter for the Advisory Commission on Childhood Vaccines (ACCV or Commission) and pursuant to its obligations under § 300aa-19 of the National Childhood Vaccine Injury Act of 1986 (the Act, 42 U.S.C. §§ 300aa-1 *et seq.*), I respectfully submit for your consideration a recommendation relative to the implementation of the National Vaccine Injury Compensation Program (VICP or Program).

The ACCV formed the Maternal Immunization Working Group in June 2012, consisting of 13 members, to address the need for the VICP to address evolving recommendations for vaccination during pregnancy. This Working Group is chaired by an ACCV member, a health care provider who is the Assistant Professor at the University of Pennsylvania School of Medicine. Other ACCV members of this Workgroup include two representatives of the general public and one is the parent of a vaccine-injured child; one representative who is a health care provider; one representative who is a non-affiliated attorney. Liaison representatives from the Division of Vaccine Injury Compensation, HHS Office of the General Counsel, the Food and Drug Administration, the Centers for Disease Control and Prevention and the National Vaccine Program Office are also members of the Workgroup. The Working Group met at least every two months and reviewed over 15 articles related to vaccines and pregnancy, developed a working relationship with the National Vaccine Advisory Committee's Maternal Immunization Working Group and received presentations on new vaccines under development for Respiratory Syncytial Virus (RSV) and Group B Streptococcus.

To address evolving recommendations for vaccination during pregnancy, the Working Group focused on the following areas:

1. Eligibility for compensation for injuries from vaccines not currently covered by the VICP. This would include vaccines recommended for pregnant women but not recommended for routine administration to children. Under the statute, such vaccines would not be covered by the Program. There are no currently recommended vaccines that fit this condition. However, it is likely that both an RSV and Group B *Streptococcus* vaccine will be licensed for exclusive administration to pregnant women in the future.
2. Eligibility for compensation for injuries sustained by a live-born infant from covered vaccines received by the mother while the infant was *in utero*. This would include covered vaccines currently recommended for administration during pregnancy as well as covered vaccines that are not routinely recommended but may be sometimes given

inadvertently during pregnancy. While the mother is a recipient of such vaccines, the group also considered eligibility of the infant.

3. Review the current vaccine safety monitoring infrastructure in light of expanding recommendations for maternal immunization.
4. Review ACCV membership guidelines and consider inclusion of individuals who provide care to pregnant women to reflect changes in VICP.

The Working Group prepared a response to four charges from the Commission to address evolving recommendations for vaccines administered during pregnancy. The ACCV proposes the recommendation below which was unanimously approved at its meeting on June 7, 2013 and addresses one of the four charges of the Working Group.

Charge 2: Compensability of In Utero Injuries from Covered Vaccines

The primary issue related to this charge includes consideration of who is eligible to pursue compensation for in utero injuries from covered vaccines. Specifically, this issue stems from statutory requirement that the petitioner must prove that the injured person "received" a vaccine, and the statutory limit that only one petition may be filed per administration of a vaccine ("one petition rule"). Pregnant women who receive a covered vaccine are eligible to file a claim for their own injuries. The Working Group considered eligibility to pursue compensation for injuries sustained by the mother's live born infant as well. This would match the evolution of the VICP and recognize live born infants as a primary beneficiary of maternal immunization. Such eligibility would also provide public reassurance that injuries from new vaccines recommended for pregnant women may be pursued under the VICP and compensable and support continued vaccine development, marketing and adequate vaccine supply.

Recommendation

The ACCV recommends that the Secretary should support eligibility to pursue compensation for injuries sustained by a live-born infant whose mother receives a vaccine while the infant is in utero. In order to further her support, we recommend that the Secretary take whatever steps are necessary and within her legal authority. A few options that the Secretary may wish to consider are supporting a statutory amendment, pursuing administrative rulemaking, or supporting a litigation strategy. As each approach comes with unique benefits and challenges, we recommend that the Secretary solicit input from the public, vaccine manufacturers and immunization program administrators.

This recommendation is for your consideration. We look forward to you receiving your response.

Very truly yours,

David King
Chair, ACCV

Michelle A. Williams
Co-Chair, ACCV