



DEC 03 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 and presented them to the ACCV.

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 Maternal Immunization Working Group.

Charge 1: Compensability of In Utero Injuries from Vaccines Not Currently Covered

Injuries from vaccines that are not currently covered under the VICP are not compensable. The primary issue related to this charge includes the expansion of coverage to vaccines that are recommended for categories other than children (such as pregnant women) and are not specifically recommended for routine administration in children. The benefits of an expansion elicited by the Working Group included recognition that expanding coverage to such vaccines would match the evolution of the VICP and the National Vaccine Program, especially as an increasing number of vaccines are recommended for adults and a significant portion of VICP claims are submitted by adults.

Recommendation

The ACCV recommends that the Secretary work to expand coverage under the VICP to include vaccines that are recommended for routine administration to pregnant women and are not specifically recommended for routine administration in children. We recommend that the Secretary take whatever steps are necessary and within her legal authority to attain such expansion. A few options that the Secretary may wish to consider are supporting a statutory amendment and pursuing administrative rulemaking. We recommend that the Secretary solicit input from the public, vaccine manufacturers, and administrators.

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

Very truly yours,

/S/

David King
Chair, ACCV

/S/

Michelle A. Williams
Co-Chair, ACCV