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. For Charge 3 below, the ACCV did not make any recommendations.

Charge 3: Vaccine Safety Monitoring Infrastructure

Monitoring for safety events during pregnancy already takes places through Vaccine Event Reporting System (VAERS) and pregnancy registries maintained by vaccine manufacturers. Active surveillance through the Vaccine Safety Datalink provides another mechanism for safety monitoring. Lastly, another initiative entitled the Vaccines and Medications in Pregnancy Surveillance System (VAMPSS) was recently established to provide prospective and case-control surveillance to study the safety of exposures to vaccines and medications during pregnancy (http://www.pregnancystudies.org/what-is-vampss/).

For Charge 4, the ACCV proposes the recommendation below which was unanimously approved at its meeting on June 7, 2013.

Charge 4: ACCV Membership

As the immunization program continues to expand, it is important that the membership of the ACCV also evolves to ensure that appropriate perspective and expertise is represented within ACCV membership. The VICP authorizing statute and ACCV charter states that the ACCV shall be composed of 9 members as follows:

a. three members who are health professionals, who are not employees of the U.S., and who have expertise in the health care of children, the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines, of whom at least 2 shall be pediatricians.

b. three members of the general public, of whom at least two shall be legal representatives of children who have suffered a vaccine-related injury or death.

c. three members who are attorneys, of whom at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death and of whom one shall be an attorney whose specialty includes representation of vaccine manufacturers.

Recommendation

The ACCV recommends that the Secretary consider having a health professional with expertise in obstetrics as one of the health professionals under the current charter.

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

Very truly yours,

/S/

David King
Chair, ACC

/S/

Michelle A. Williams
Co-Chair, ACCV

ACCV Maternal Immunization Working Group ACCV Recommendations- Final Report September 5, 2013

Background

The Advisory Commission on Immunization Practices (ACIP) currently recommends that all pregnant women at a gestational age of 27 through 36 weeks receive a tetanus-diptheria-acellular pertussis (Tdap) immunization during each pregnancy and that all pregnant women receive inactivated influenza vaccine. New vaccines against respiratory syncytial virus (RSV) and Group B *Streptococcus* (GBS) are currently under development and, if approved, would likely be exclusively recommended for pregnant women. These current (and potential future) recommended vaccines can reduce the risk of influenza among pregnant women who are at increased risk of morbidity and mortality from infection and also protect young infants by preventing transmission of pertussis, influenza, RSV, GBS, and tetanus. Maternal immunization is effective in preventing many of these diseases in infants.(1) Young infants, who are too young to be vaccinated, are especially at risk for poor outcomes associated with these diseases. Maternal immunization can decrease the risk of exposure by preventing disease in mothers and also by providing protection to the young infant through the passage of maternal antibodies. These circulating antibodies provide protection when infants are most at risk for significant morbidity and mortality and before they would be able to mount their own protective response to vaccination. For example, exposure to GBS can occur at the time of delivery such that early protection is crucial.

Successful implementation of recommendations for maternal immunization will require that women and health care providers trust the safety of vaccines during pregnancy. It is therefore important to ensure that current safety assessment and monitoring processes can effectively define, identify and respond to safety issues. This includes ensuring that the Vaccine Injury Compensation Program is available to mothers and their infants when vaccines are administered during pregnancy. Such coverage will also contribute to the sustainability of the vaccine program and continued development of new vaccines by addressing unsettled liability concerns for vaccine manufacturers and immunization program administrators.

Safety and Immunogenicity of Vaccines Administered During Pregnancy[1]

It is known that transplacental passage of maternal IgG antibodies substantially increases in the last 4 to 6 weeks of gestation. IgG1 subclass antibodies can be higher in term newborns than in mothers, (2) and maternal immunization enhances this passive protection. Current studies show that maternal immunization benefits the mother and the infant; these studies have not identified any vaccine-related adverse events specific to vaccinated pregnant women or their infants (1, 3-4). Key safety-related outcomes to assess include the potential for teratogenicity, growth or functional impairment, or impaired viability due to *in utero* exposure to vaccines. Many of these outcomes occur at high rates in the general population (5-8), including:

[1] This section refers to vaccines routinely recommended for the general population, exclusive of special situations such as bioterrorism, travel or pandemic settings

- Spontaneous abortion (10.4-22.4%);
- Preterm birth (11.9%);
- Small for gestational age (8-16%); and
- Congenital anomalies (3%).

As indicated in general recommendations from the ACIP, there is no evidence that inactivated virus vaccines, bacterial vaccines or toxoids in vaccines present a risk to the fetus for these or other outcomes.(9) In fact, some studies suggest that influenza vaccination during pregnancy may decrease the risk for preterm birth and small for gestational age.(10) There is a theoretical risk that administration of live virus vaccines could result in transmission of vaccine virus to a fetus,. Therefore, live virus vaccines are contraindicated for administration to women 28 days before conception through pregnancy and no live-virus vaccines are currently recommended for pregnant women. However, there has been no evidence from pregnancy registries of fetal infection or malformation when live virus vaccines routinely recommended for the general population are inadvertently administered during pregnancy.(4)

In summary, the Maternal Immunization Working Group of the ACCV agreed that current evidence supports the safety and effectiveness of maternal immunization, both for pregnant women and their infants.

Current Statutory Framework

Under the Vaccine Act, "No person may bring a civil action…against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine…unless a petition has been filed in accordance with [the statute of limitations], for compensation under the [Vaccine Injury Compensation Program] for such injury or death[.]" 42 U.S.C. 300aa-11(a)(2). The statute specifies that this requirement only applies to individuals who are qualified to file a petition. 42 U.S.C. 300aa-11(a)(9). The statute sets forth requirements that the petitioner must meet in order to be eligible to pursue compensation. Thus, generally, individuals who do not meet eligibility requirements may file a suit directly against a manufacturer or administrator in civil court. If they do file a claim first in the VICP, and they are found ineligible, their case is dismissed.

The question of eligibility is particularly at issue in VICP claims involving immunization of pregnant women. The eligibility requirements that are most relevant to immunization of pregnant women are as follows: "A petition for compensation under the Program for a vaccine-related injury or death shall contain…an affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died—(A) received a vaccine set forth in the Vaccine Injury Table or, if such person did not receive such a vaccine, contracted polio, directly or indirectly, form another person who received an oral polio vaccine[.]" 42 U.S.C. 300aa-11(c)(1). The statute also states that "Only one petition may be filed with respect to each administration of a vaccine." (the "one petition rule.") 42 U.S.C. 300aa-11(b)(2).

Cases involving immunization of pregnant women generally fall under two categories: cases in which the mother seeks compensation for her own injuries, and cases in which the mother seeks compensation on behalf of her child for injuries sustained *in utero*. In the case of immunization of pregnant women, it is clear that the mother received the vaccine. But can the fetus be said to have "received" the vaccine"? Also, does the one petition rule preclude both the mother and the child from seeking compensation from the same vaccine administration?

Throughout the Program, the Government has taken the litigation position that the statute does not contemplate eligibility to pursue *in utero* injury claims. Petitioners have argued that the statute does allow *in utero* injury claims to be pursued in the VICP. In every case, the special masters hear the arguments, and make the ultimate decisions (which can be appealed). Special masters and judges that have addressed these specific questions pertaining to *in utero* injuries have not come to a consensus. Some have concluded that *in utero* injuries can be pursued—one rationale is that the term "received" should be interpreted broadly to include indirect receipt because the Vaccine Act is meant to remedy harms, and one rule of statutory construction says that remedial statutes should be interpreted broadly to achieve their remedial goals. Others have concluded that *in utero* injuries cannot be pursued—one rationale is that the term "received" must mean "direct receipt" because the statute specifies the oral polio exception, and one rule of statutory construction says that "the expression of one is the exclusion of all others." Thus, the expression of one indirect method is the exclusion of others. The one petition rule has not been widely addressed by special masters. None of these cases, however, has been appealed to the Federal Circuit, so none of the existing decisions are binding. One way or the other, the issue has not been settled.

The other issue related to maternal immunization under the VICP is coverage of vaccines. As discussed above, new vaccines against RSV and GBS are currently under development and, if approved, could be exclusively recommended for use in pregnant women, and not for routine administration in children. The statute authorizing the VICP specifies that compensation is only available for injuries and deaths from "covered vaccines." A vaccine is "covered" when it is recommended by the CDC for "routine administration to children" and the Secretary adds the vaccine to the Vaccine Injury Table through rule-making. Coverage is effective upon passage of an excise tax by Congress. With regard to such vaccines that are being developed for use exclusively in pregnant women and would not also be recommended for routine use in children, the question is how can these vaccines attain coverage under the Program?

Working Group Charge and Recommendations

To address evolving recommendations for vaccination during pregnancy, the maternal immunization working group focused upon the following areas:

1. Eligibility for compensation for injuries from vaccines not currently covered by the Vaccine Injury Compensation Program. 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 GBS 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 the VICP

To develop draft recommendations for each charge for consideration by the ACCV, the working group reviewed:

1) available data about mechanisms of protection, efficacy and safety of vaccines administered during pregnancy;
2) available data from pre-licensure trials for RSV and GBS vaccines;
3) vaccine safety infrastructure;
4) activities of the National Vaccine Advisory Committee (NVAC) Maternal Immunization Working Group (MIWG); and
5) current statute(s) guiding program activities.

This information informed discussions regarding the opportunities and challenges related to expanding coverage to include compensability for injuries from vaccines administered during pregnancy and resulted in the following draft recommendations.

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 such an expansion elicited by the group included recognition that expanding coverage to such vaccines would match the evolution of VICP and the National Immunization Program, especially as an increasing number of vaccines are recommended for adults and a significant portion of VICP claims are submitted by adults. Expansion may also provide public reassurance that injuries from new vaccines recommended for pregnant women may be pursued under the VICP. Lastly, expansion would address barriers that the vaccine industry faces regarding liability. This would, in turn, foster vaccine development, support marketing and ensure an adequate supply of vaccines. Challenges explored by the group included the potential administrative cost to the injury compensation program. Expanding coverage would require an additional excise tax on new vaccines and additional resources drawn from the Trust Fund for any additional claims due

to expanded coverage. The group also considered potential repercussions from a public perception that the government is "pushing" more vaccines and is signaling safety problems with maternal immunization. However, the group felt that expanding coverage is not equivalent to recommending a new vaccine. Also, the potential benefit to the public through the protection of pregnant women and young infants also should be emphasized.

Based upon these considerations, the working group suggests recommending that the Secretary work to expand coverage under the VICP to include vaccines that are routinely recommended for pregnant women and are not specifically recommended for routine administration in children. We suggest recommending 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:

1. Supporting an amendment to the statute that would explicitly include language to expand coverage to vaccines that are recommended for categories other than children (i.e. pregnant women). To achieve this end, the Secretary of Health and Human Services could propose legislation through the A19 process. We note that this would be a definitive path but could take a significant amount of time, it may not come to fruition, and it may not produce the desired outcome as the Secretary may have little control over the ultimate statutory change, should it occur.

2. Administrative rule-making to adopt a broader interpretation of the current statute. The statute currently gives the Secretary the authority to add vaccines to the Vaccine Injury Table that are recommended by the CDC "for routine administration to children." We recommend that in the Secretary's promulgation of regulations adding vaccines to the Table, the Secretary consider interpreting "routine administration to children" to include administration of vaccines to pregnant women, because such a pregnant population may include individuals in the pediatric age range (i.e. adolescents) Secondly, one of the main objectives of vaccine administration during pregnancy is to benefit the young infant. Therefore, an infant could be considered the beneficiary of a vaccine during pregnancy since they receive a primary product through the passage of maternal antibodies. This approach requires the Secretary to have the authority to take such an interpretation. The Secretary would need to consider whether such a broad interpretation is legally permissible and is consistent with the Congressional intent of the statute to provide compensation for injuries and deaths related to childhood vaccines. To the extent the Secretary does not have such legal authority, we recommend that the Secretary pursue a statutory amendment to provide such authority. To the extent she does have the authority, we note that this approach would be expeditious and provides flexibility for the VICP to adapt to changes in the immunization program. However, expanding VICP to include vaccines recommended for pregnant women may set a precedent for the inclusion of other vaccines recommended for individuals other than children. This could require significant changes in program operation and expenditure of resources.

As each approach comes with unique benefits and challenges, we suggest recommending that the Secretary solicit input from the public, vaccine manufacturers and immunization program administrators.

Recommendation 1: 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. 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.

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 "receive" 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 groups considered eligibility to pursue compensation for injuries sustained by the mother's live born infant as well. Benefits of such eligibility elicited by the group were similar to those detailed above. 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.

The working group identified live-born infants (as opposed to miscarriages or stillbirths) in its recommendation based upon the following considerations:

- The term clearly defines the infant as a separate individual from the mother and therefore, should be considered a separate injured individual
- A fetus is dependent upon the mother and it is difficult to separate the injury from the mother
- Miscarriages and/or stillbirth do not present the same challenge or liability as injury claims for a live born infant since these can be pursued as the mother's claim

Based upon these considerations, the working group suggests recommending 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*. This will provide the opportunity to seek compensation under the program to a live born infant whose mother received a covered vaccine, and will address manufacturer liability concerns and barriers to research and development of new vaccines to be administered to pregnant women. In order to further her support, we suggest recommending that the Secretary take whatever steps are necessary and within her legal authority. Options that the Secretary may wish to consider are:

1. Supporting a statutory amendment that would explicitly include language to specify eligibility of live born infants whose mother received a vaccine while the infant was *in utero*. We again note that this would be a definitive path but could take a significant amount of time, it may not come to fruition, and it may not produce the desired outcome as the Secretary may have little control over the ultimate statutory change, should it occur.

2. Administrative rule-making to adopt a broader interpretation of the current statute. We suggest recommending that the Secretary consider promulgating a rule that sets forth a position on eligibility to pursue *in utero* injury claims based upon the principle that maternal vaccination is intended to benefit the young infant through the development and passage of maternal antibodies to the young infant. As such, infants directly receive a product of maternal vaccination. This approach requires the Secretary to have the authority to issue such regulations. The statute currently gives the Secretary the authority to issue regulations that add vaccines, and add, delete, and modify injuries listed on the Vaccine Injury Table. The Secretary would need to consider whether the Vaccine Act or other legal authority would permit her to issue a regulation that interprets the provisions of the statute addressing eligibility to pursue compensation. To the extent the Secretary does not have such legal authority, we recommend that the Secretary pursue seeking a statutory amendment to provide such authority. To the extent she does have the authority, we note that this approach would be expeditious and supports flexibility of the VICP to match changes in the national immunization program. Additionally, issuing a rule is a public and formal statement which may provide reassurance to the public and vaccine manufacturers and administrators. On the other hand, we note that an administrative rule could be non-binding, as the Court is the final adjudicator of claims and is ultimately responsible for interpreting the law.

4. Support a litigation strategy to seek a binding decision on this issue in the U.S. Court of Appeals for the Federal Circuit. Such a litigation strategy would entail communicating a position to the court on a case-by-case basis on eligibility to pursue in utero injuries, and the court would make the ultimate determination of eligibility. This would require a party to challenge decisions of the special masters and Court of Federal Claims until it reaches the Federal Circuit. If a case arises and determination of eligibility is appealed up to the U.S. Court of Appeals, this could yield a decision that would be binding and set precedent. This approach, however, could also take a significant amount of time as it would first require such a case and multiple appeals. The Secretary could also consider supporting a litigation strategy that would allow petitioners to pursue *in utero* injury claims and proceed to an adjudication of the merits (which may or may not result in compensation, because the petitioners may or may not be able to prove causation or a Table injury), while not resulting in a binding Federal Circuit decision. This approach provides the opportunity for special masters to find against eligibility. However, this approach may result in the ability to pursue *in utero* injury claims in the VICP.

As each approach comes with unique benefits and challenges, we suggest recommending that the Secretary solicit input from the public, vaccine manufacturers and immunization program administrators.

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. 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.

Charge 3: Vaccine Safety Monitoring Infrastructure

The current safety monitoring infrastructure for the national immunization program and the VICP has been recently summarized in a 2011 publication in the journal *Pediatrics*.(11,12) Recent publications also specifically explore the use of current vaccine safety monitoring tools for maternal immunization.(13-15) Monitoring for safety events during pregnancy already occurs through the Vaccine Adverse Event Reporting System (VAERS) and pregnancy registries maintained by vaccine manufacturers. Active surveillance through the Vaccine Safety Data Link provides another mechanism for safety monitoring. Lastly, another initiative entitled The Vaccines and Medications in Pregnancy Surveillance System (VAMPSS) was recently established to provide prospective and case-control surveillance to study the safety of exposures to vaccines and medications during pregnancy (http://www.pregnancystudies.org/what-is-vampss/).

Charge 4: ACCV membership

As the immunization program continues to expand, it is important that the membership of the ACCV also evolves to ensure that appropriate perspective and expertise is represented within ACCV membership. The VICP authorizing statute and ACCV charter state that the ACCV shall be composed of 9 members as follows:

a. 3 members who are health professionals, who are not employees of the U.S., and who have expertise in the health care of children, the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines, of whom at least 2 shall be pediatricians.

b. 3 members of the general public, of whom at least two shall be legal representatives of children who have suffered a vaccine-related injury or death.

c. 3 members who are attorneys, of whom at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death and of whom one shall be an attorney whose specialty includes representation of vaccine manufacturers.

Recommendation: The ACCV recommends that the Secretary consider having a health professional with expertise in obstetrics as one of the health professionals under the current Charter.

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