



Health Resources and Services Administration
Department of Health and Human Services
Attention: HRSA Regulations
Officer, 5600 Fishers Lane, Room 13N82
Rockville, MD 20857

The undersigned organizations write in support of RIN HRSA-0906-AB14, which would add to the National Vaccine Injury Compensation Program the category of vaccines recommended for pregnant women to the Vaccine Injury Table. The addition of vaccines given to pregnant women, do not have VICP coverage through a recommendation for children, (as is the case for Tdap and influenza vaccines) is essential to ensure the protections under the VICP for any vaccine given maternally.

Vaccines save lives. Because vaccines are given to healthy people, they are held to the highest standards of medical safety testing. The Food and Drug Administration (FDA) licenses vaccines on the basis of extensive clinical trials that demonstrate safety and effectiveness with a very wide safety margin. Once the FDA approves a vaccine, the Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP) conducts its own thorough evaluation of the safety, effectiveness and optimal timing of the vaccine before recommending that it be added to the immunization schedule.

Once a vaccine is in use, there are a number of post-market surveillance systems which create a robust infrastructure to rapidly detect whether there are any unexpected safety issues with the vaccine. These include the Vaccine Safety Datalink (VSD), which is a collaboration between CDC and nine other healthcare organizations that began in 1990 and analyzes up to 10 million immunization records each year to ensure ongoing vaccine safety; the Clinical Immunization Safety Assessment (CISA) Network, which is a national network of CDC, seven medical research centers and others with expertise in immunization safety conducting clinical research on immunization associated health risks. In addition, the Vaccine Adverse Event Reporting System (VAERS), accepts reports from any provider, patient, parent, or other person who is aware of any problem after vaccination.

While vaccines are very safe, as with any drug, they may cause rare side effects that can cause serious injuries. In the 1980's vaccine manufacturers were threatening to leave the vaccine business because of increasing litigation. In 1986, Congress responded to this potential crisis by creating an innovative compensation model as an alternative to the tort system. The Vaccine Injury Compensation Act gave companies

limited liability protection from claims alleging injuries by vaccines and at the same time created a system to fairly and expeditiously compensate people who were injured by vaccines.

The Vaccine Injury Compensation Program (VICP) has been highly successful in creating a stable environment for vaccine companies. Since its passage we have seen important innovation in vaccine development, including vaccines to protect against meningitis, hepatitis A and B, rotavirus, pneumonia, and HPV, the virus that causes cervical cancer. According to HRSA and the CDC, from 2006 to 2016 over 3.1 billion doses of covered vaccines were distributed in the U.S. For every 1 million doses of vaccine that were distributed, 1 individual was compensated through the VICP. Since 1988, over 19,772 petitions have been filed with the VICP. Over that 30-year time period, 17,380 petitions have been adjudicated, with 6,159 of those determined to be compensable, while 11,221 were dismissed. Total compensation paid over the life of the program is approximately \$3.9 billion. The protections offered under VICP have clearly benefited the general public.

Now companies are developing vaccines to administer to pregnant women, for the purposes of ensuring that babies are protected from serious diseases such as Respiratory Syncytial Virus (RSV) and Group B strep from the moment they are born. RSV is a lung infection that is particularly dangerous to newborns, causing more than 57,000 hospitalizations among children younger than 5 years old each year. Group B strep, a bacterial infection that babies can be exposed to during birth, is the leading cause of meningitis (infection of the fluid and lining around the brain) and sepsis (infection of the blood) in a newborn's first week of life. About 25% of pregnant women carry group B strep with no symptoms. While these diseases do have more devastating consequences for newborns, it is also important to provide protection for RSV, influenza, and other future diseases that impact pregnant women. RSV can cause severe maternal illness, and influenza can cause maternal mortality and morbidity. Including protection for maternal vaccines under VICP will encourage innovation in vaccines, particularly in vaccines given to pregnant women, for the purpose of protecting pregnant women and vulnerable newborn babies against potentially serious diseases.

Currently the CDC recommends that women receive influenza and Tdap (tetanus/diphtheria/pertussis) vaccine during each pregnancy in order to protect both themselves and their newborns from these deadly diseases. By vaccinating women in their third trimester with pertussis-containing vaccine (Tdap), the vaccine stimulates antibodies that transfer through the placenta to the newborn, protecting the baby until he/she is old enough to receive the vaccine at two months of age. In addition, every year, about 20,000 children under five are hospitalized and approximately 100 die due to the flu. Since babies under 6 months of age are too young to get their own flu vaccine, it is critical that pregnant women are vaccinated in order to protect their newborns, who are at high risk of severe complications from the flu – in addition to protecting themselves from this serious disease. Both Tdap vaccine and influenza vaccines already are covered under VICP when administered to a person of any age because they were previously included on the VICP Table of Injuries through their recommendation for children.

The immunization community was highly supportive of the passage of the 21st Century Cures provision adding maternal immunizations to the VICP, which also ensures that both the vaccinated woman and her infant are permitted to submit a claim under the VICP. Two federal advisory committees, the Advisory Commission on Childhood Vaccines (ACCV), which advises the VICP, and the National Vaccine Advisory Committee (NVAC), which reports to the Assistant Secretary for Health (ASH), have both formally recommended ensuring that vaccines with recommendations for this population are covered by VICP. The organizations listed below also concur with the ACCV's recommendation to add the following wording to the Vaccine Table in Item XVII "and/or pregnant women" after "Children". Offering protection to pregnant women for vaccines given during pregnancy is the right thing to do for the public and will also inspire the production of new life-saving vaccines aimed at protecting newborns into the future.

Sincerely,

American College of Obstetricians and Gynecologists

Every Child By Two – Carter/Bumpers Champions for Immunization

Immunization Action Coalition

March of Dimes

National Association of County & City Health Officials

National Foundation for Infectious Diseases

National Meningitis Association

Pediatric Nurse Practitioner House Calls

The Arizona Partnership for Immunization

The California Immunization Coalition

The Immunization Partnership

Voices for Vaccines