

The Honorable Lamar Alexander
Chairman
Senate Health, Education, Labor, and
Pensions Committee

The Honorable Patty Murray
Ranking Member
Senate Health, Education, Labor and
Pensions Committee

Dear Chairman Alexander and Ranking Member Murray:

We, the undersigned organizations, are writing in support of a provision in your bill, the “Promoting Biomedical Research and Public Health for Patients Act,” to add maternal immunizations to the Vaccine Injury Compensation Program. This provision will encourage vaccine innovation, specifically innovation of vaccines given to pregnant women for the purposes of protecting vulnerable newborn babies against potentially serious diseases.

We know that vaccines are one of the most important tools we have to keep our children, our parents and our communities healthy. We eradicated smallpox in 1980 through intensive worldwide immunization efforts. And just this month Africa declared that it has been polio free for a full year, a major step towards eradicating this debilitating disease.

Vaccines save lives. Because vaccines are given to healthy people, they are held to the highest standards of medical safety testing. It can take 15 or more years, and an average of \$800 million, to thoroughly test a new vaccine before it is licensed. 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) Advisory Committee on Immunization Practices conducts its own intense 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 any unexpected safety issues with the vaccine. This includes the Vaccine Safety Datalink (VSD), which has collected data from more than 7 million people in major health plans nationwide. It also includes the Clinical Immunization Safety Assessment (CISA) Network, a national network of six medical research centers with expertise in immunization safety, who conduct clinical research on immunization associated health risks. In addition, FDA’s Vaccine Adverse Event Reporting System (VAERS), accepts reports from any provider, patient, parent, or other person who is aware of any adverse event following a 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 (VICA) 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 manufacturing. 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. Since 1989, the VICP has compensated approximately 4,481 petitioners, paying out an average of \$68,894 in claims, totaling more than \$3 billion.

When Congress created the program, its focus was on immunizations routinely given to children. This made sense in 1986. Since then we have seen tremendous strides in vaccine innovation. Now companies are developing vaccines to administer to pregnant women. For example, Respiratory Syncytial Virus (RSV) and Group B strep vaccines are being developed to protect young babies from these serious diseases from the moment they are born. RSV is a viral lower respiratory infection that is particularly dangerous to newborns, causing more than 57,000 hospitalizations and 2.1 million outpatient visits among children younger than 5 years old each year. Group B strep, a bacterial infection 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.

Currently the CDC recommends that women receive vaccines for influenza and Tdap (tetanus/diphtheria/pertussis) during each pregnancy in order to protect their newborns from these potentially fatal diseases. Outbreaks of pertussis, which is particularly deadly to infants, have plagued our country in recent years, including approximately 33,000 cases in 2014, and more than 18,000 cases in 2015. Sadly, 90% of pertussis-associated deaths have been among infants younger than one year. By vaccinating women in their third trimester against pertussis containing vaccine (Tdap), women pass on antibodies that help protect the baby in the first few months of life, until he or 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 both themselves and their vulnerable newborns.

This provision will ensure that both the vaccinated woman and her infant are permitted to submit a claim under the VICP. This is a technical change that is entirely consistent with the original intent of the VICA, which was designed to encourage childhood immunizations by reducing the threat of litigation while at the same time ensuring that people injured by vaccines are compensated both fairly and in a timely manner. Two federal advisory committees, the Advisory Commission on Childhood Vaccines, which advises the VICP, and the National Vaccine Advisory Committee, which reports to the Assistant Secretary for Health, have both formally recommended ensuring that these types of vaccines are covered by VICP.

We are extremely supportive of this provision and we urge the Senate Health, Education, Pensions, and Labor Committee to adopt the provision as part of the "Promoting Biomedical Research and Public Health for Patients Act."

Sincerely,

Every Child By Two – Carter/Bumpers Champions for Immunization
Immunization Action Coalition
March of Dimes
National Association of County and City Health Officials
National Meningitis Association
Trust for America's Health