National Childhood Vaccine Injury Act

In 1986, Congress passed the National Childhood Vaccine Injury Act (NCVIA) to address concerns about vaccine supply, safety, and liability. Beginning in the 1970's, there had been an increase in lawsuits filed on behalf of those presumably injured by the diphtheria, tetanus, and pertussis (DTP) vaccine. Damages were awarded, often without scientific evidence to support vaccine injury claims. As a result of the litigation, prices soared and some manufacturers halted production, creating a vaccine shortage. The primary purpose of NCVIA was to create the National Vaccine Injury Compensation Program (VICP) to compensate those injured by vaccine on a no fault basis. People filing claims are not required to prove negligence on the part of either the health care provider or manufacturer to receive compensation. The program covers all routinely recommended childhood vaccinations. Settlements are based on the Vaccine Injury Table that summarizes the adverse events caused by vaccines. This table was developed by a panel of experts who reviewed the medical literature and identified the serious adverse events that are reasonably certain to be caused by vaccines. The Vaccine Injury Table was created to justly compensate those injured by vaccines while separating out unrelated claims. The Vaccine Injury Table is updated as information becomes available from research on vaccine side effects. Individuals and their families can qualify for compensation in three ways: show that an injury found on the Vaccine Injury Table occurred in the appropriate time interval following immunization; prove that the vaccine caused the condition; or prove the vaccine aggravated a pre-existing condition. In addition to establishing the VICP, NVCIA mandated reporting of adverse events included in the Vaccine Injury Table and events listed by manufacturers as contraindications to future vaccinations. The Vaccine Adverse Event Reporting System (VAERS) was created in 1990 to provide a database management system for the collection and analysis of these reports. It is operated jointly by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). These agencies monitor VAERS data to detect previously unknown adverse events or increases in known adverse events.

PLEASE NOTE THAT A REPORT TO VAERS DOES NOT INITIATE A REPORT TO OR FILE A CLAIM WITH VICP

What vaccines are covered? On March 24, 1997, a final rule was published which provided for the "automatic" addition of vaccines recommended by the CDC for routine administration to children. However, Congress must set an appropriate excise tax on any new vaccines before those vaccines are effectively covered under the Program. Under current statutory language, 8 years' retroactive coverage will be provided for those claiming injury or death resulting from a vaccine newly added to the VICP, and a deadline is established for filing retroactive claims. Diphtheria, tetanus, pertussis (DTP, DTaP, DT, TT, Tdap, or Td), measles, mumps, rubella (MMR or any components), and polio (OPV or IPV) were covered initially. Hepatitis B, *Haemophilus influenza* type b, and varicella vaccines were added, effective August 6, 1997, and rotavirus effective October 22, 1998. On May 22, 2001, the Secretary of Health and Human Services published a notice in the Federal Register announcing the addition of pneumococcal conjugate vaccines to the Vaccine Injury Table with an effective date of December 18, 1999. Hepatitis A vaccine was added to the VICP effective December 1, 2004, and trivalent influenza vaccines were added effective July 1, 2005. As of February 1, 2007, meningococcal (conjugate and polysaccharide) and human papillomavirus (HPV) vaccines were added to the table.

What events are covered? A claim may be made for any injury or death thought to be a result of a covered vaccine. There are three means to qualify for compensation: A petitioner must show that an injury found on the Vaccine Injury Table occurred; or prove that the vaccine caused the condition; or prove that the vaccine significantly aggravated a pre-existing condition. It is much easier to demonstrate a "Table Injury" than to prove that the vaccine caused the condition, and most claims allege that a Table Injury occurred. In contrast to civil liability suits, hearings to determine eligibility under the VICP usually last only 1 or 2 days. A case found eligible for compensation is scheduled for a hearing to assess the amount of compensation. Most claims found to be noncompensable receive awards for attorney's fees and costs.

How is the program funded? For vaccines administered prior to October 1, 1988, awards were compensated from Federal tax dollars that were allocated by Congress at $110 million per year. After October 1, 1988, awards are paid from the Vaccine Injury Compensation Trust Fund, funded from an excise tax on every dose of covered vaccine that is purchased.

Where can I get more information about the Program? Vaccine Information Statements (VIS) for vaccines that are covered by the Act bear a reference to the law (42 U.S.C. § 300aa-26) and contain information about the VICP. The law requires VIS to be given out each time covered vaccines are administered by all vaccine providers, both public and private. The National Vaccine Injury Compensation Program Internet Home Page can be found at http://www.hrsa.gov/vaccinecompensation/. Call VICP at (800) -338-2382 to obtain an information packet detailing how to file a claim, criteria for eligibility, and the documentation required. For information on the rules of the U.S. Court of Federal Claims, including requirements for filing a petition, call (202) 357-6400.