

# **U.S. COURT OF FEDERAL CLAIMS OFFICE OF SPECIAL MASTERS**

## **For Background Use Only**

### **Vaccine Program Background**

#### **General Information**

The National Vaccine Injury Compensation Program (VICP) is an innovative federal no-fault program enacted in 1986 (and since amended), which was designed to resolve a perceived crisis in vaccine tort liability claims that threatened the continued availability of childhood vaccines nationwide. In mandating that vaccine injury claims be considered first under VICP, the statute was intended to reduce lawsuits against physicians and manufacturers, while providing those claiming vaccine injuries a reduced burden of proof. Claimants under the VICP need not prove negligence, failure to warn, or other tort causes of action; they must only prove that a covered vaccine caused injury.

#### **Vaccines Covered Under the VICP**

The VICP originally covered vaccines against seven diseases - diphtheria, tetanus, pertussis, measles, mumps, rubella (German measles), and polio. Subsequently, coverage was extended to the following additional vaccines: hepatitis B, hemophilus influenza type b (Hib), varicella (chicken pox), rotavirus, human papillomavirus (HPV), hepatitis A (HAV), meningococcal vaccines (MCV4 and MPSV4), and pneumococcal conjugate (PCV7). In July 2005, the annual influenza (flu) vaccine became covered as well. In total, sixteen (16) vaccines are now covered under the VICP. An excise tax for each dose of vaccine sold funds a trust fund, which pays awards and administrative costs of the Program. See [www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation) for more information about the VICP.

#### **Litigation Process**

Under the VICP, rather than filing a lawsuit against the vaccine manufacturer or vaccine administrator in the civil tort system, individuals claiming injury from covered vaccines must first file a petition for “no-fault” compensation with the United States Court of Federal Claims. The petition must also be served upon the Secretary of Health and Human Services, who decides whether to concede or defend the claim. The Act creates the Office of Special Masters as an adjunct to the United States Court of Federal Claims. The Special Masters function in all respects as the trial judges in the vaccine cases, including having final decision authority. A Special Master’s ruling is appealable to a Judge of the Court of Federal Claims under an “arbitrary and capricious” standard, with further review available before the Court of Appeals for the Federal Circuit and ultimately before the United States Supreme Court.

## **Causation Under the VICP**

As in any product liability case, the initial question for decision is causation. There are two ways to prove causation under the Act. The VICP contains a Vaccine Injury Table, which is designed to minimize difficulties petitioners face in proving that their injury resulted from a vaccine. The Vaccine Injury Table lists certain injuries and conditions which, if found to occur within a prescribed period of time following vaccination, create a rebuttable presumption of causation. In such “on-Table” cases, petitioners do not need to provide proof of actual causation. For example, if a petitioner proves that her child received a DPT vaccine and that the child suffered an encephalopathy (brain injury) within three days thereafter, causation is presumed.

If the petitioner can demonstrate the receipt of one of the listed vaccines but claims that some medical condition other than those listed in the statute resulted, or that a listed condition occurred outside the statutory time frame, the petitioner may still pursue a claim but must establish “actual causation.” This proof is akin to traditional standards applied in tort litigation. The Act’s legislative history instructs that “evidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation for such a petitioner.”

## **Types of Compensation**

The VICP provides compensation for past and future medical expenses, rehabilitation, therapies, special education expenses, equipment and placement. For pain and suffering, the VICP provides a maximum of \$250,000. The VICP also provides compensation for “lost earnings.” The VICP provides a \$250,000 award for a vaccine-related death.

## **Statistics**

As of March 1, 2010, 13,330 cases have been filed, 5,617 representing autism cases. Of the total, 7,397 have been adjudicated, with 2,409 being compensated. Claims arising from vaccinations given prior to October 1, 1988, were paid from general appropriations. Petitioners filed 4,259 pre-1988 claims, with 1,187 being compensated. Over 900 million dollars of general revenue was paid for pre-October 1988 cases, including attorneys’ fees at a statutorily-capped level. Payments for post- October 1988 cases come from a trust fund supported by an excise tax on each antigen of vaccine that is covered by the Program. Thus far, 9,071 post-1988 claims have been filed, with 1,222 being compensated. 5,933 cases remain pending. Most of the pending claims involve autism; those petitioners have asked that the Special Masters defer proceedings on their claims until rulings in the “autism test cases” become final. Almost 2 billion dollars has been paid in compensation from the trust fund for the post- 1988 cases, including attorneys’ fees and costs. There is currently over 3 billion dollars in the trust fund. There is a wide range of awards depending on the severity of injury, with the highest award currently being \$9.1 million in present dollars. See [www.hrsa.gov/vaccinecompensation](http://www.hrsa.gov/vaccinecompensation) for more detailed statistical information regarding the VICP.