

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 these 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 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 replaces the vaccine manufacturer or vaccine administrator to 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 making authority under the Act. The Special Master’s rulings are appealable to the Court of Federal Claims on 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 adduce 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. The Act’s Qualifications and Aids to Interpretation further define the compensable conditions. Assuming a petitioner is able to meet the Table’s requirements, the respondent (the Secretary of HHS) may still defeat the compensation claim by establishing that the condition was more probably than not caused by a “factor unrelated” to the vaccine.

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 “[s]imple similarity to conditions or time periods listed in the Table is not sufficient evidence of causation; 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. For lost earnings, if the vaccine-recipient is injured prior to the age of 18, the VICP calculates lost earnings based upon “the average gross weekly earnings of workers in the private, non-farm sector, less appropriate taxes and the average cost of a health insurance policy.” If the injury occurred after the age of 18, lost earnings are determined utilizing “generally recognized actuarial principles and projections.”

The VICP provides a \$250,000 award for a vaccine-related death. Also, the VICP is a secondary payer; that is, compensation shall not be made to the extent payment is available from insurance, a state compensation program, or a Federal or State health benefits program, excluding Medicaid.

Statistics

As of January, 2009, 12,850 cases have been filed, 5,535 representing autism cases. Of the total, 6,979 have been adjudicated, with 2,260 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 dose of vaccine that is covered by the Program. Thus far, 8,591 post-1988 claims have

been filed, with 1,071 being compensated. Over 939 million dollars has been paid in compensation from the trust fund for the post- 1988 cases, including attorneys' fees and costs. There is currently nearly 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 for more detailed statistical information regarding the VICP.