National Vaccine Injury Compensation Program

http://www.hrsa.gov/osp/vicp/

1. What is the National Vaccine Injury Compensation Program (VICP)?

The National Childhood Vaccine Injury Act of 1986, as amended, (the Act) established the VICP. The VICP went into effect on October 1, 1988 and is a Federal "no-fault" system designed to compensate individuals or families of individuals, who have been injured by covered childhood vaccines, whether administered in the private or public sector.

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2. What vaccines are covered?

Diphtheria, tetanus, pertussis (DTP, DTaP, DT, TT, or Td), **measles, mumps, rubella** (MMR or any components), **polio** (OPV or IPV), **hepatitis B, *Haemophilus influenzae* type b (Hib), varicella (chicken pox), rotavirus** and **pneumococcal conjugate** vaccines. Eight years' retroactive coverage is provided for any vaccine or vaccine-related adverse event added for coverage under the VICP.

The only live, oral, rhesus-based rotavirus vaccine licensed in the U.S., which was routinely distributed beginning on October 1, 1998, was withdrawn from the market on October 15, 1999, and is no longer being administered in the U.S. Because the Secretary of Health and Human Services determined that a causal link existed between this vaccine and the injury of intussusception, the Secretary modified the Vaccine Injury Table (the Table) to add the injury of intussusception.

Specifically, effective as of August 26, 2002, the Secretary added vaccines containing live, oral, rhesus-based rotavirus as a separate category to the Table, with an associated injury of intussusception. Prior to this date, the Table already contained the general category of rotavirus vaccines, with no associated Table injury. The new Table injury of intussusception applies to all cases in which the injury occurred within 30 days of the administration of the vaccine, provided that the rotavirus vaccine was administered on or before August 26, 2002.

Under current law, petitioners may be eligible for compensation for vaccine-related intussusceptions if the condition: (i) had residual effects or complications lasting for more than 6 months; (ii) resulted in inpatient hospitalization and surgery; or (iii) resulted in death.

Petitioners wishing to file claims relating to injuries (or deaths) thought to be related to a rotavirus vaccine must generally comply with the statute of limitations contained at 42 U.S.C. 300aa-16 (which provides that injury claims must be filed within 36 months of the date of the first symptom or manifestation of the onset or significant aggravation of the injury). If the addition of the Table injury of intussusception will significantly increase a petitioner's likelihood of obtaining compensation with the VICP, a petitioner is also entitled to file a claim within 2 years of the effective date of the Table change (August 26, 2002), so long as the underlying vaccine-related injury or death occurred within an 8-year period before that date.

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3. How are new vaccines added for coverage under the VICP?

On March 24, 1997, a final rule was published which, in part, provided for the "automatic"

addition of future vaccines recommended by the Centers for Disease Control and Prevention (CDC) for routine administration to children. However, Congress will still need to set an appropriate excise tax on any new vaccines recommended by CDC before those vaccines are effectively covered under the Vaccine Injury Compensation Program. Under the current statutory language, 8 years' retroactive coverage will be provided for those claiming injury or death resulting from a vaccine or vaccine-related adverse event newly added to the VICP.

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4. Who may file a claim?

Any injured individual or a parent, legal guardian, or trustee of an injured child or an incapacitated person may file a claim. A claim may be made for any injury or death thought to be a result of a covered vaccine. These injuries may include, but are not limited to: **anaphylaxis, paralytic polio, and encephalopathy**.

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5. What is the time frame in which to file a claim?

For claims resulting from a vaccine administered on or after October 1, 1988, the following restrictions apply:

a. In the case of an injury, the effects must have continued at least 6 months after vaccine administration or the injury must have resulted in inpatient hospitalization and surgical intervention and the claim must be filed within 36 months after the first symptoms appeared.

b. In the case of a death, the claim must be filed within 24 months of the death and within 48 months after the onset of the vaccine-related injury from which the death occurred.

As of February 1, 1991, the time has expired for filing claims for injuries or deaths resulting from vaccines administered prior to October 1, 1988. Any claims filed for that time period are subject to dismissal by the U.S. Court of Federal Claims (the Court).

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6. Whom can I contact to get more information about the VICP?

a. This Web site (http://www.hrsa.gov/osp/vicp)
b. The toll-free number for the National Vaccine Injury Compensation Program is **1-800-338-2382** to obtain an information packet detailing how to file a claim, criteria for eligibility, and the documentation required. For further information write to:

   National Vaccine Injury Compensation Program
   Parklawn Building, Room 16C-17
   5600 Fishers Lane
   Rockville, Maryland 20857

c. For information on the rules of the U.S. Court of Federal Claims, including requirements for filing a petition, go to ttp://www.uscfc.uscourts.gov/osmPage.htm, call **1-202-219-9657** or write to:

U.S. Court of Federal Claims
717 Madison Place, N.W.
Washington, D.C. 20005

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7. How is the VICP funded?

Funding of vaccine claims **depends on the date of vaccination**:

a. For vaccines administered prior to October 1, 1988, awards are compensated from Federal tax dollars allocated by Congress at $110 million per year.
b. For vaccines administered on or after October 1, 1988, awards are paid from the Vaccine Injury Compensation Trust Fund, funded from an excise tax of $.75 on every dose of covered vaccine that is purchased.

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8. How does the VICP work?

The VICP is administered jointly by the U.S. Court of Federal Claims (the Court), the Department of Health and Human Services (HHS), and the Department of Justice (DOJ). The process is as follows:

a. An individual claiming injury or death from a vaccine files a petition for compensation with the Court;
b. A physician at the Division of Vaccine Injury Compensation, HHS, reviews each petition to determine whether it meets the criteria for compensation. This recommendation is provided to the Court through a report filed by the DOJ, although it is not binding.
c. The HHS position is represented by an attorney from the DOJ in hearings before a "special master" who makes the initial decision for compensation under the VICP. A special master is an attorney appointed by the judges of the Court.
d. Decisions may be appealed to the Court and then to the Federal Circuit Court of Appeals.

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9. How is eligibility for compensation determined?

There are three means to qualify for compensation:

a. A petitioner must show that an injury found on the Vaccine Injury Table (the Table) occurred; or
b. A petitioner must prove that the vaccine caused the condition; or
c. A petitioner must prove that the vaccine significantly aggravated a pre-existing condition.

The Table lists specific injuries or conditions and the time frames in which they must occur after vaccine administration. The Table is a legal mechanism for defining complex medical conditions and allows a statutory "presumption of causation." 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. Compensation is not awarded, however, if the Court determines that the injury or

death was due to a cause unrelated to the vaccine, even if it was a Table Injury.

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.

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10. What is the amount of an award under the VICP?

Awards to the estate in a vaccine-related death are limited to $250,000 plus attorney's fees and costs. Awards to individuals with an injury judged to be vaccine-related have averaged $824,463. There is no limitation on the amount of an award in a vaccine-related injury; however, the law does contain certain restrictions.

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11. How does the VICP protect vaccine administrators and vaccine manufacturers?

The Act requires that vaccine injury claims involving covered vaccines given on or after October 1, 1988 must first be filed with the VICP before civil litigation through the tort system can be pursued. If a petitioner accepts an award under the VICP, the claim cannot be brought subsequently to the tort system.

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12. Under what circumstances may a vaccine administrator or manufacturer be sued?

a. If the petition has been judged non-compensable or dismissed under the VICP; or
b. If the award granted by the VICP is otherwise rejected by the petitioner; or
c. If the vaccine is not covered under the VICP.

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13. Have there been changes to the Vaccine Injury Table?

On March 10, 1995, a modified Table (and the accompanying Qualifications and Aids to Interpretation) became effective for all claims filed on or after that date. Significant changes include the addition of chronic arthritis under vaccines containing rubella (e.g., MMR, MR, R vaccines), and the removal of Residual Seizure Disorder and Hypotonic-Hyporesponsive Episode (HHE) under the DTP vaccine. The definition of Encephalopathy was clarified in the Qualifications and Aids to Interpretation.

On March 24, 1997, further modifications to the Table took effect that include the addition of brachial neuritis and removal of encephalopathy for tetanus-containing vaccines, addition of thrombocytopenia and vaccine-strain measles virus infection, removal of residual seizure disorder for measles-containing vaccines, and addition of vaccine-strain poliovirus infection for live polio virus vaccine. Modifications also included the addition of three new vaccines: hepatitis B, *Haemophilus influenzae* type b, and varicella. Coverage for these three new vaccines went into effect August 6, 1997. The Rule also provided for "automatic" addition of future vaccines recommended by the Centers for Disease Control and Prevention for routine administration to

children, although injuries for such vaccines will be specified only after additional rulemaking. All other Table changes became effective for all claims filed on or after March 24.

On October 22, 1998, rotavirus vaccine was added to the Table for coverage.

On August 26, 2002, a modified Table (and the accompanying Qualifications and Aids to Interpretation) became effective for all claims filed on or after that date. A second category of rotavirus (live, oral, rhesus-based) vaccine was added to the Table with intussusception listed as an injury with a time interval of onset of 0-30 days. A separate category was added for pneumococcal conjugate vaccines with no condition specified. Haemophilus influenzae type b (Hib) polysaccharide vaccines was removed from the Table; however, Haemophilus influenzae type b (Hib) conjugate vaccines remains on the Table with no condition specified. Under the Table's Qualifications and Aids to Interpretation, early-onset Hib disease and residual seizure disorder were removed.

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14. What documentation are vaccine administrators required to keep?

The National Childhood Vaccine Injury Act of 1986 (as amended) requires that the date of administration; vaccine manufacturer; lot number; and name, address, and title of the health care provider be recorded in the patient's permanent medical record.

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15. What adverse events are health care providers required to report?

The Vaccine Adverse Event Reporting System (VAERS), operated by the Food and Drug Administration (FDA) and the CDC, should be notified of any adverse event by completing a VAERS reporting form. The following events are required to be reported:

a. Any event set forth in the Vaccine Injury Table that occurs within the time period specified or within 7 days, if that is longer.
b. Any contraindicating event listed in the manufacturer's package insert.

In addition, VAERS accepts all reports by any interested party of real or suspected adverse events occurring after the administration of any vaccine.

The VAERS form may be obtained by calling **1-800-822-7967** or from the FDA Website at www.fda.gov/cber/vaers/report.htm.

Please note: Submitting a reporting form to VAERS in **not** the same as filing a claim under the VICP as they are two separate programs.

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16. How many petitions have been filed under the VICP? Of those petitions filed, how many have been awarded compensation? How much money has been spent on compensation awards?

To obtain a copy of the most recent VICP "Monthly Statistics Report" please visit the VICP Website at www.hrsa.gov/osp/vicp/monthly.htm, telephone 1-800-338-2382, or write to the

National Vaccine Injury Compensation Program, Parklawn Building, Room 16C-17, 5600 Fishers Lane, Rockville, Maryland 20857.

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17. If I believe that the thimerosal (mercury) in a vaccine caused an injury or death, can I file a claim with the VICP?

For vaccines covered under the VICP, individuals alleging that the thimerosal in a vaccine caused an injury or death must first file a claim with the VICP before any civil litigation can be pursued. According to section 2133 of the Public Health Service Act (42 U.S.C. 300aa-33(5)), a "vaccine-related injury or death" eligible for compensation under the VICP does not include an injury or death associated with an adulterant or contaminant intentionally added to a vaccine. Components, such as thimerosal, that are added to microorganisms to create vaccines cannot and should not be considered adulterants or contaminants. Instead, preservatives and components, such as thimerosal, should be considered one of several elements that comprise vaccines.

Because thimerosal is not an adulterant to or a contaminant in vaccines, individuals who have claims relating to thimerosal in vaccines covered under the VICP are not statutorily barred from filing claims with the VICP. As such, the Department of Health and Human Services (HHS) believes individuals interested in filing such a claim must first file the claim with the VICP before pursuing any other civil litigation.

On October 11, the U.S Court of Federal Claims (the Court) ruled that thimerosal-related injury claims are subject to the Court's jurisdiction pursuant to the National Childhood Vaccine Injury Act of 1986, as amended. Plaintiffs had filed a petition for compensation in the Court, but then filed a motion to challenge the jurisdiction of the Court for thimerosal-related injuries. The Court found the plaintiff's arguments to be without merit. As such, the Court's Chief Special Master accepted HHS's arguments and found that the Court's jurisdiction was mandated on all fronts. *Leroy v. Secretary of HHS* is the first definitive statement by the Court that thimerosal-related vaccine injury claims are subject to its jurisdiction. For further information on the "Omnibus Autism Proceeding, visit the Cout's Website at http://www.uscfc.uscourts.gov/osmPage.htm.

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18. Where can I get information about anthrax or smallpox vaccines?

Currently, the anthrax and smallpox vaccines are not covered under the VICP. To obtain information about these vaccines, contact the National Immunization Program, Centers for Disease Control and Prevention (CDC) at 1600 Clifton Road, N.E., Mail Stop E-61, Atlanta, Georgia 30333. You may also contact them at 1-800-232-2522 or visit their Internet Website at: www.cdc.gov/nip.

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