The National Vaccine Injury Compensation Program

abstract

The National Childhood Vaccine Injury Act of 1986 established the National Vaccine Injury Compensation Program to compensate people thought to be injured by certain vaccines. The act's goals are to ensure an adequate supply of vaccines, to stabilize vaccine costs, and to establish and maintain an accessible and efficient setting for providing compensation to people found to have been injured by certain childhood vaccines. In addition, the legislation called for the reporting of adverse events after vaccination, the creation of vaccine-information materials that detail vaccine benefits and risks, and Institute of Medicine studies of possible vaccine-related injuries and encouraged research and development of new and safer vaccines. Over its 22-year history, the National Vaccine Injury Compensation Program has been a key component in stabilizing the US vaccine market through liability protection to both vaccine companies and health care providers and by providing a forum for people, no matter what age, to seek compensation. *Pediatrics* 2011;127:S74–S77

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KEY WORDS

vaccine injury, National Childhood Vaccine Injury Act of 1986

ABBREVIATIONS

VICP—National Vaccine Injury Compensation Program
MMR—measles-mumps-rubella
HHS—US Department of Health and Human Services
CFC—US Court of Federal Claims

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In response to a vaccine-liability crisis in the 1980s, the National Childhood Vaccine Injury Act of 1986 established the National Vaccine Injury Compensation Program (VICP) as a streamlined and less adversarial alternative to the traditional civil law system for resolving claims that arise from vaccine injury.[1]

The act's public-policy goals are to ensure an adequate supply of vaccines, stabilize vaccine costs, and establish and maintain an accessible and efficient setting for providing generous compensation to people found to have been injured by certain childhood vaccines. In addition, the legislation called for the reporting of adverse events after vaccination, the creation of vaccine-information materials that detail vaccine benefits and risks, and Institute of Medicine studies of possible vaccine-related injuries and encouraged research and development of new and safer vaccines.[2]

Operational since October 1988, the VICP has been a key component in stabilizing the US vaccine market through liability protection to both vaccine companies and health care providers. As a no-fault alternative to the traditional tort system, petitioners (claimants) must first file with the VICP before pursuing legal remedies in state or federal civil courts. In contrast to civil courts, compensation is not determined on the basis of negligence on the part of the vaccine manufacturer or administering physician (thus, the "no-fault" designation). Funding for the program is provided through an excise tax placed on covered vaccines.

The VICP covers all vaccines recommended by the Centers for Disease Control and Prevention for routine administration to children. As of January 2011, 16 vaccines were covered, including diphtheria, tetanus, pertussis (DTP, DTaP, TdaP, DT, TT, or Td), measles-mumps-rubella (MMR or any components), polio (oral polio vaccine [OPV] or inactivated polio vaccine [IPV]), hepatitis A, hepatitis B, Haemophilus *influenza* type b (Hib), varicella (chickenpox), rotavirus, pneumococcal conjugate, trivalent influenza (given annually), meningococcus, and human papillomavirus (HPV), whether administered individually or in combination. Although only vaccines recommended for routine use in children are covered by the VICP, there are no age restrictions on filing. In fact, more than half of the claims received annually are filed on behalf of adults.

The VICP comprises 3 government entities: the US Department of Health and Human Services (HHS), the US Department of Justice, and the US Court of Federal Claims (CFC). Within the HHS, the program is administered by the Health Resources and Services Administration. Petitioners, either through their attorney or on their own, may file a petition with the HHS and the CFC, which begins the review-and-adjudication process.

The National Childhood Vaccine Injury Act provides compensation to people who can demonstrate that a serious injury was related to a vaccine covered under the VICP and who file within the statute of limitations (information on filing deadlines for claims that allege an injury or death is available on the VICP Web site at www.hrsa.gov/vaccinecompensation/filing_deadlines.htm).

There are 3 means to qualify for compensation: (1) a petitioner must show that an injury found on the vaccine injury table (Table 1) occurred in the prescribed time interval; (2) prove that the vaccine caused the condition; or (3) prove that the vaccine significantly aggravated a preexisting condition. The table,[3] which lists specific injuries or conditions and the time frames of onset after a vaccine is administered, allows a legal "presumption of causation." If a petitioner cannot establish a table injury, or no table injuries are listed for a particular vaccine, a petitioner has the option of proving causation.

In addition to satisfying 1 of the 3 compensation qualifications, the petitioner must also demonstrate that the effects of the injury (1) lasted >6 months after the vaccine was administered, (2) resulted in a hospital stay and surgery, or (3) resulted in a death. Petitioners are not eligible for compensation if the court determines that there is greater evidence of a nonvaccine cause for the injury.

A HHS physician reviews medical records for each petition to determine if medical criteria for compensation are met. On the basis of these findings, a US Department of Justice attorney will present the HHS' position to 1 of 8 special masters, who are attorneys appointed by the CFC and have expertise in the legal and medical issues associated with adverse reactions to vaccines. The special master makes the final decision on whether to award compensation under the VICP. The special master can also approve settlements negotiated between the parties.

If a petition is found eligible for compensation, either by the HHS conceding the case or a special master's decision, the amount of the award is usually negotiated between the US Department of Justice and the petitioner or petitioner's attorney. If the parties cannot agree, the special master must determine the amount of compensation. Successful petitioners may receive compensation for unreimbursed past and unreimbursable future medical expenses, lost wages, and pain and suffering. Attorneys' fees and costs are also reimbursed by the program, even if the petitioner is not found eligible for compensation, provided the claim was filed in good faith and on a reasonable basis. For

TABLE 1 National Childhood Vaccine Injury Act Vaccine Injury Table[a]

Vaccine	Adverse Event	Time Interval
I. Tetanus toxoid-containing vaccines (eg, DTaP, TdaP, DTP-Hib, DT, Td, TT)	A. Anaphylaxis or anaphylactic shock	0–4 hours
	B. Brachial neuritis	2–28 days
	C. Any acute complication or sequela (including death) of above events	Not applicable
II. Pertussis antigen-containing vaccines (eg, DTaP, TdaP, DTP, P, DTP-Hib)	A. Anaphylaxis or anaphylactic shock	0–4 hours
	B. Encephalopathy (or encephalitis)	0–72 hours
	C. Any acute complication or sequela (including death) of above events	Not applicable
III. Measles, mumps and rubella virus-containing vaccines in any combination (eg, MMR, MR, M, R)	A. Anaphylaxis or anaphylactic shock	0–4 hours
	B. Encephalopathy (or encephalitis)	5–15 days
	C. Any acute complication or sequela (including death) of above events	NA
IV. Rubella virus-containing vaccines (eg, MMR, MR, R)	A. Chronic arthritis	7–42 days
	B. Any acute complication or sequela (including death) of above event	Not applicable
V. Measles virus-containing vaccines (eg, MMR, MR, M)	A. Thrombocytopenic purpura	7–30 days
	B. Vaccine-Strain Measles Viral Infection in an immunodeficient recipient	0–6 months
	C. Any acute complication or sequela (including death) of above events	Not applicable
VI. Polio live virus-containing vaccines (OPV)	A. Paralytic polio	
	—in a non-immunodeficient recipient	0–30 days
	—in an immunodeficient recipient	0–6 months
	—in a vaccine assoc. community case	Not applicable
	B. Vaccine-strain polio viral infection	
	—in a non-immunodeficient recipient	0–30 days
	—in an immunodeficient recipient	0–6 months
	—in a vaccine assoc. community case	Not applicable
	C. Any acute complication or sequela (including death) of above events	Not applicable
VII. Polio inactivated-virus containing vaccines (eg, IPV)	A. Anaphylaxis or anaphylactic shock	0–4 hours
	B. Any acute complication or sequela (including death) of above event	NA
VIII. Hepatitis B antigen-containing vaccines	A. Anaphylaxis or anaphylactic shock	0–4 hours
	B. Any acute complication or sequela (including death) of above event	NA
IX. Haemophilus influenzae type b polysaccharide conjugate vaccines)	A. No condition specified for compensation	Not applicable
X. Varicella vaccine	A. No condition specified for compensation	Not applicable
XI. Rotavirus vaccine	A. No condition specified for compensation	Not applicable
XII. Pneumococcal conjugate vaccines	A. No condition specified for compensation	Not applicable
XIII. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by Secretary, HHS of a notice of coverage[b,c]	A. No condition specified for compensation	
Not applicable		

[a] Effective date: November 10, 2008.

[b] As of December 1, 2004, hepatitis A vaccines have been added to the Vaccine Injury Table (table) under this category. As of July 1, 2005, trivalent influenza vaccines have been added to the table under this category. Trivalent influenza vaccines are given annually during the flu season either by needle and syringe or in a nasal spray. All influenza vaccines routinely administered in the US are trivalent vaccines covered under this category.

[c] As of February 1, 2007, meningococcal (conjugate and polysaccharide) and human papillomavirus (HPV) vaccines have been added to the table under this category. See *News* on the VICP Web site (www.hrsa.gov/vaccinecompensation).

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this reason, although a petitioner does not need an attorney to file a claim, most petitioners are represented by counsel.

Appeal of a special master's decision, by either party, goes first to a judge of the CFC and then to the US Court of Appeals for the Federal Circuit, and may be further appealed to the US Supreme Court.

Although a claim must first be filed with the VICP, petitioners retain their right to file a lawsuit in the civil court system if petitioners reject a decision, regardless of whether there was an award of compensation, or if a decision or judgment has not been rendered within the time period provided by law. The program is aware of only a small number of VICP claims that go on to the civil (tort) system.

Generally speaking, VICP claims are processed in a timely manner; the average time for adjudication of a compensable claim from filing to payment averages between 2 and 3 years. However, sometimes the court groups claims together, uses a small number of test cases, and applies the evidence from the test cases to a larger number of claims with similar facts. Such is the case with the Omnibus Autism Proceeding.

Beginning in 2001, petitioners began filing claims under the VICP alleging autism (or autism spectrum disorder) from MMR vaccine, thimerosal-containing vaccines, or both.[4] In 2002, the Chief Special Master of the Court created the Omnibus Autism Proceeding to adjudicate the thousands of claims expected. As of January 2011, more than 5600 autism cases have been filed.[5] Of these 5600 cases, more than 4800 cases are pending, and more than 800 claims have been dismissed at the request of petitioners or dismissed by the court because they were filed outside the VICP statute of limitations for injury claims. Some families have gone on to the tort system to pursue legal remedies. Several hundred suits alleging vaccine-related autism were pending adjudication at the beginning of 2010.

Entitlement hearings on general causation and 3 test cases for each theory under consideration were held in 2007

and 2008. In February 2009, 3 special masters ruled in favor of the HHS on the first theory (a combined theory that both MMR vaccines and thimerosal-containing vaccines cause autism or autism spectrum disorder). Appeals in each case were made to judges of the CFC, who all ruled in favor of the HHS. Appeals in two of the three cases to US Court of Appeals for the Federal Circuit also resulted in decisions in favor of HHS.[6]

Special master's decisions for general causation and 3 test cases for the second theory (thimerosal-containing vaccines cause autism or autism spectrum disorder) were handed down in favor of HHS in March 2010. None of the test cases was appealed by petitioners.[6] A general causation hearing for the third theory (MMR vaccine alone causes autism or autism spectrum disorder) was cancelled after petitioners indicated that they did not plan to introduce new evidence and would rely on the evidence presented for the first theory.

As of January 2011, the VICP has awarded compensation to more than 2500 families and individual people totaling more than $2.1 billion.[5] The vaccine marketplace remains healthy; liability-related vaccine shortages are a distant memory, new vaccines are being licensed, and many are in various stages of development. A number of lawsuits alleging autism from either MMR vaccine or the thimerosal in vaccines are pending in more than 20 states. In contrast, non–autism-related vaccine litigation remains quite low and averaged approximately 1 dozen lawsuits per year from 2000 to 2005 for all VICP-covered vaccines. Therefore, the VICP continues to fulfill the intent of Congress by providing an accessible and efficient alternative for people found to be injured by certain childhood vaccines and ensuring viability of the vaccine marketplace.

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