



## Vaccine law: where it came from, how it works

By Kathleen M. Loucks

Special to Minnesota Lawyer

The National Childhood Vaccine Injury Act of 1986 established the National Vaccine Injury Compensation Program after lawsuits against manufacturers threatened to cause vaccine shortages. See 42 U.S.C. §§ 300aa-1 to -34.



Kathleen M. Loucks

In an effort to maintain a supply of vaccines, as well as develop new ones, this unique program was created. The Vaccine Act, effective Oct. 1, 1988, established the Vaccine Program as a no-fault program under which petitions for monetary compensation may be brought by or on behalf of those injured or killed through the administration of certain vaccines.

### Preemption and jurisdiction

The act preempts all design-defect claims against vaccine manufacturers based on injury or death caused by a vaccine's side effects. See *Bruesewitz et al v. Wyeth LLC*, (2011). It states:

"No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. §§300aa-22(b)(1).

The act requires that vaccine injury claims involving covered vaccines given on or after Oct. 1, 1988, be filed with the Vaccine Court *before* civil litigation through the tort system can be pursued.

If a petitioner accepts an award under the Vaccine Program, the claim cannot later be brought through the tort system.

### When may a vaccine administrator or manufacturer be sued?

A vaccine administrator or manufacturer may be sued if:

1. The petition has been judged non-compensable or dismissed under the Vaccine Program.
2. The award granted by the Vaccine Program is otherwise rejected by the petitioner.
3. The vaccine is not covered under the Vaccine Program.

The Vaccine Program is managed and adjudicated by the congressionally created Office of Special Masters, which consists of eight special masters

who are appointed to serve for four-year terms. The Office of Special Masters is established within the U.S. Court of Federal Claims, which appoints and removes the special masters and to which the special masters' decisions are appealed. Ultimately the petitioner can decide whether to accept the court's judgment or reject it and seek tort relief from the vaccine manufacturer (assuming the claim is not one for which manufacturers have immunity under the act).

## Number of cases filed and average time to completion

The United States Government Accountability Office has issued one report analyzing claims filed with the Vaccine Program from 1999 through March 31, 2004. The GAO found that the more than 9,800 claims filed have taken multiple years to adjudicate. More than 11 percent of claims filed since 1999 were still pending as of March 31, 2014. Since 2006 about 80 percent of compensated claims have been resolved through negotiated settlement. According to the U.S. Department of Health and Human Services' latest statistics released Jan. 1, 2017, it takes an average two to three years to adjudicate a petition after it is filed.

According to the CDC, over 2.5 billion doses of covered vaccines were distributed in the U.S from 2006 to 2014. For petitions filed in this time period, 3,672 petitioners were adjudicated by the Vaccine Court, and of those 2,310 were compensated.

Since 1999 over 17,732 petitions have been filed with the Vaccine Court. Over that 27 year period, 15,312 petitions have been adjudicated, with 5,143 determined compensable and 10,169 dismissed. The total compensation paid over the life of the program is approximately \$3.5 billion.

## Which vaccines are covered?

Only covered vaccines are handled under the Vaccine Program. (See sidebar for list of vaccines.)

The Vaccine Program uses a vaccine injury table that lists the injuries

and conditions that are presumed to be caused by vaccines covered by the program and thus may entitle the petitioner to compensation. For example, in the case of vaccines containing the tetanus toxoid (e.g. DTaP, DTP, DT or Td or TT), if the petitioner suffers anaphylaxis or anaphylactic shock within four hours, this is a "table injury" and causation is presumed. The program also compensates petitioners for injuries or conditions that are not on the vaccine injury table; however, in those cases causation is not presumed and the petitioner must demonstrate that the vaccine caused the injury or condition.

Claims must be brought within 36 months from the onset of first symptoms of the vaccine injury. In a case of a vaccine-related death, a claim must be filed no later than two years from the date of death.

## What compensation is due?

Under the act petitioners can receive compensation for:

- Medical expenses, including rehabilitation and counseling (past and future).
- Pain and suffering (past and future—maximum recovery of \$250,000).
- Lost wages (past and future).
- Out-of-pocket costs (past and future).
- Death cases—statutory death benefit (maximum recovery of \$250,000).
- Death cases—Pain and suffering of decedent (maximum recovery of \$250,000).

## Attorney requirements

Unlike typical personal injury or wrongful death cases, vaccine claims cannot be taken on a contingent or hourly basis. If a petition is filed with a reasonable basis, the Vaccine Program pays reasonable attorney fees and costs. Notably, the program pays reasonable costs and attorney fees regardless of whether a case is successful or not. Attorney fees and costs are *not* taken out of a petitioner's compensation, but are paid separately.

Attorneys representing petitioners must be separately admitted to the

## Current covered vaccines under 42 U.S.C. §§300aa-22(b)(1)

- Diphtheria (e.g., DTP, DTaP, Tdap, DT, Td, TT).
- Haemophilus Influenza type B Polysaccharide conjugate vaccines (e.g., Hib).
- Hepatitis A (e.g., HAV).
- Hepatitis B (e.g., HBV).
- Human Papillomavirus (e.g., HPV).
- Seasonal influenza (e.g., Flu).
- Measles (e.g., MMR).
- Mumps (e.g., MMR, MR, M).
- Meningococcal (e.g., MCV4, MPSV4, MenB FHbp, MenB-4C).
- Pertussis (e.g., DTP, DTap, Tdap).
- Pneumococcal Conjugate (e.g., PCV).
- Polio (e.g., OPV or IPV).
- Rotavirus (e.g., RV).
- Rubella (e.g., MMR, MR, R).
- Tetanus (e.g., Td).
- Varicella (e.g., VAR) (Chicken Pox).

U.S. Court of Federal Claims and to the Vaccine Petitioners Bar. Attorneys do not need to represent petitioners in a particular state; any attorney who is admitted to the U.S. Court of Federal Claims and a member of the Vaccine Bar can represent any petitioner anywhere in the United States.

Given the special time requirements and issues related to preemption and exclusive jurisdiction, practitioners who face inquiries on vaccine-related injuries should have a basic understanding of the issues and be able to refer these cases to practitioners who have the requisite experience and necessary admissions to handle these unique claims. For a directory of attorneys representing petitioners by state, go to: <https://www.vipbar.org/member-directory>.

*Kathleen M. Loucks is a partner at Lommen Abdo and a member of the Vaccine Petitioners Bar.*