

# THE CRANKY LAWYER LEGAL LIVESTREAM

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**December 4, 2017 Question: The Vaccine Court! (yes, there is such a thing)**

**If you have suffered death or injury because of compulsory childhood vaccines, you are required to bring your case in a special court—the Vaccine Court.**

**What is the Vaccine Court?**

*h/t to Bill Bunting, via Sandra Looney on Facebook for the suggestion*

## Vaccine Court

### A. Background

- Established by the National Childhood Vaccine Injury Act (NCVIA) of 1986 (<http://www.uscfc.uscourts.gov/vaccine-programoffice-special-masters>)
- Codified as: 42 U.S.C. §§ 300aa-1 to 300aa-34 (<http://www.uscfc.uscourts.gov/vaccine-programoffice-special-masters>)
- Established a no fault compensation system for claims by or on behalf of persons who suffered death or injury as a result of compulsory childhood vaccines (<http://www.uscfc.uscourts.gov/vaccine-programoffice-special-masters>)

### B. Adjudicated by Office of Special Masters

- 8 Special masters serve 4 year terms (<http://www.uscfc.uscourts.gov/vaccine-program-readmore>)
- U.S. Court of Federal Claims appoints masters and also has power to remove them (<http://www.uscfc.uscourts.gov/vaccine-program-readmore>)
- Appeals are taken to the U.S. Court of Federal Claims (<http://www.uscfc.uscourts.gov/vaccine-program-readmore>)
- Special masters deal directly with the parties' attorneys and the system is more informal than U.S. courts (<http://www.uscfc.uscourts.gov/vaccine-program-readmore>)
  - Special Masters can even tell the parties his or her tentative conclusions and findings (<http://www.uscfc.uscourts.gov/vaccine-program-readmore>)

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### C. Filing a Petition

- There are special rules that govern the proceedings under the Vaccine Act (<http://www.uscfc.uscourts.gov/sites/default/files/170801VaccineRules.pdf>)
- First part of process is filing a petition that highlights relevant facts and identifies the vaccine, the cause, when/where vaccine was administered, the injury, and whether the injury is contained in the Vaccine Injury Table (<http://www.uscfc.uscourts.gov/sites/default/files/170801VaccineRules.pdf>)
- A petitioner must also pay a filing fee, currently set at \$400.00 ([http://www.uscfc.uscourts.gov/sites/default/files/161201FeeSchedule\\_0.pdf](http://www.uscfc.uscourts.gov/sites/default/files/161201FeeSchedule_0.pdf))
- A petition must attach several documents: (<http://www.uscfc.uscourts.gov/sites/default/files/170801VaccineRules.pdf>)
  - All available medical Records relating to:
    - the vaccination
    - the injury/death alleged, including any autopsy report, death certificate
    - post-vaccination treatment
    - and in cases where the injured person was younger than 5, the mother's pregnancy delivery records and infant's lifetime records (including any notes by physicians and nurses, growth charts, etc.) until the date of the vaccination.
  - Affidavits
    - If the petitioner did not submit all the required record, they must include an affidavit explaining their efforts to obtain the record and reasons they were unable to.
    - If petitioner's claim relies on more than just the medical records, then they must also submit an affidavit regarding any persons' observations and proposed testimony
  - Proof of Authority to file
    - If a petition is filed on behalf of another person (example a parent of an injured minor or a petition filed on behalf of a deceased person), the petitioner must include documents that establish their authority to file on behalf of the injured party.
  - Certificate of Service
    - A statement that certifies the document has been served to the Secretary of Health and Human Services by first class or certified mail at the following address:
      - Secretary, Health and Human Services Director, Division of Injury Compensation Programs Health Resources and Services Administration National Vaccine Injury Compensation Program (VICP) 5600 Fishers Lane, 08N146B Rockville, MD 20857.

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- A certificate must comply with the Rules of the United States Court of Federal Claims  
[http://uscfc.uscourts.gov/sites/default/files/court\\_info/20130813\\_rules/13.08.30%20Final%20Version%20of%20Rules.pdf](http://uscfc.uscourts.gov/sites/default/files/court_info/20130813_rules/13.08.30%20Final%20Version%20of%20Rules.pdf)
- All documents that accompany a petition filed in paper format, must be assembled into one or more **bound** volumes or three ring notebooks with each volume containing the caption of the case and a table of contents (all pages of the volumes must be numbered sequentially) (<http://www.uscfc.uscourts.gov/sites/default/files/GUIDELINES-FOR-PRACTICE-4212016.pdf>)
- Once all the medical records are filed, the petitioner must file a statement of completion indicating all the pertinent records have been filed.  
<http://www.uscfc.uscourts.gov/sites/default/files/Statement%20of%20Completion.pdf>

#### D. Assignment of Special Master

- After the petition is filed the chief special master will assign the case to a special master (<http://www.uscfc.uscourts.gov/sites/default/files/170801VaccineRules.pdf>)
- Assignment to the Special Processing Unit (<http://www.uscfc.uscourts.gov/sites/default/files/GUIDELINES-FOR-PRACTICE-4212016.pdf>)
  - After a petition is filed it is review to see if it is a candidate for the Special Processing Unit (“SPU”)
    - This is when a case looks to be a good candidate for expedited settlement or subject to dismissal.
      - Appropriate cases include
        - Table injuries
        - Cases that have historically been conceded or settled
    - They are assigned to the Chief Special Master which then delegates to a staff attorney who will manage the case on a daily basis and can assist the parties
    - Cases in the SPU follow a different timeline and the parties cannot retain an expert without first consulting with each other and the court.
    - The staff attorney conducts status conferences and keeps the chief special master abreast of the progress
    - If the respondent does not agree entitlement and is not amenable to informal resolution, a petitioner may then opt to proceed with litigation and may be ordered to file an expert report supporting the claim.

#### E. Post Filing Procedures

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- Within 30 days of the filing of a petition, the respondent must review all the documents and determine whether they have all the necessary documents.  
(<http://www.uscfc.uscourts.gov/sites/default/files/170801VaccineRules.pdf>)
  - If there are missing documents that are relevant, the petitioner must be immediately notified.
    - If the parties disagree over the completeness of the record either party may request to have the special master resolve the issue.
      - Generally, questions are resolved in favor of production.  
(<http://www.uscfc.uscourts.gov/sites/default/files/GUIDELINES-FOR-PRACTICE-4212016.pdf>)
      - The standard is: “whether the requested records might shed light on any issues relating to petitioner’s claim.”  
(<http://www.uscfc.uscourts.gov/sites/default/files/GUIDELINES-FOR-PRACTICE-4212016.pdf>)
    - Every time petitioner supplements the record they must file a new statement of completion
- A special master may call an early status conference within 45 days of the filing
  - This is called an “Initial Status Conference”  
(<http://www.uscfc.uscourts.gov/sites/default/files/GUIDELINES-FOR-PRACTICE-4212016.pdf>)
    - Purposes of the status conference
      - Gauge the completeness of the petition and supporting documents;
      - Develop a timeline for completing the development and resolution of the case;
      - advising the parties of any practices or procedures unique to the assigned special master;
      - discussing the Vaccine Act’s requirements, including the need to document time and expenditures for fees and costs applications;
      - assessing the parties’ desires as to settlement negotiations;
      - and answering any appropriate questions the parties may have about the procedures
    - Most conferences are followed by an order providing deadlines
- Within 90 of the filing (unless the special master sets a different schedule) the respondent must file a report that includes a complete statement of its position as to whether an award should or should not be granted.  
(<http://www.uscfc.uscourts.gov/sites/default/files/170801VaccineRules.pdf>)
  - The Report must contain the respondent’s medical analysis

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- The report must also contain all the legal arguments that respondent may have in opposition to the petition.
  - General denials of the allegations are not sufficient.
- This is called a “Rule 4” report  
<http://www.uscfc.uscourts.gov/sites/default/files/GUIDELINES-FOR-PRACTICE-4212016.pdf>
  - A Special master may defer ordering the respondent to file a Rule 4 Report until petitioner files an expert report
- The Rule 4 Report must usually contain an expert report and if it does not respondent must notify the special master ahead of time

#### F. Order and Status Conferences

- At this stage the special master will begin to issue orders and conduct status conference and will be an active participant in developing the evidentiary record.  
<http://www.uscfc.uscourts.gov/sites/default/files/GUIDELINES-FOR-PRACTICE-4212016.pdf>
- Status conferences are usually conducted via telephone and not recorded, however at the discretion of special master or the request of a party they may be digitally recorded.

#### G. The “Rule 5 Conference”

- After reviewing the petition and the evidence, a special master may conduct an informal conference where he/she may:  
<http://www.uscfc.uscourts.gov/sites/default/files/GUIDELINES-FOR-PRACTICE-4212016.pdf>
  - give each party an opportunity to address the other’s position;
  - state the special master’s tentative view as to the merits of the case; and
  - establish with the parties what issues remain to be addressed and the most efficient means for deciding those issues.
- These conclusions are tentative and off the record.

#### H. Determining Entitlement

- The petitioner has the burden of proof  
<http://www.uscfc.uscourts.gov/sites/default/files/GUIDELINES-FOR-PRACTICE-4212016.pdf>
  - The burden is a preponderance of the evidence
- Hearings are not always required, and the parties do not have the right to file a brief, however a special master may order briefs to be filed  
<http://www.uscfc.uscourts.gov/sites/default/files/GUIDELINES-FOR-PRACTICE-4212016.pdf>

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- The special masters are not bound by the rules of evidence or any formal rules (<http://www.uscfc.uscourts.gov/sites/default/files/GUIDELINES-FOR-PRACTICE-4212016.pdf>)
- Testimony (factual or opinion) may be presented in an affidavit or sworn declaration, but a party may also present video testimony (<http://www.uscfc.uscourts.gov/sites/default/files/GUIDELINES-FOR-PRACTICE-4212016.pdf>)
- There are typically no evidentiary hearings (<http://www.uscfc.uscourts.gov/sites/default/files/GUIDELINES-FOR-PRACTICE-4212016.pdf>)
  - If there is the hearing may be held in Washington D.C. or even somewhere else at the discretion of the special master
    - In fact, if several witnesses live in the same area, a special master may hold the hearing at or near them to minimize costs.
  - Testimony can also be taken orally via telephone or video conferencing

#### I. Table Cases

- Cases that involve table injuries are referred to as “table cases” (<https://www.hrsa.gov/sites/default/files/vaccinecompensation/vaccineinjurytable.pdf>)
- In such cases, if the injury is listed for that vaccine, the injury occurred within the time frame specified on the table, and the injury matches the description on the table then vaccine causation is presumed. (<http://www.uscfc.uscourts.gov/sites/default/files/GUIDELINES-FOR-PRACTICE-4212016.pdf>)
  - This presumption is rebuttable and the petitioner still has the burden to show entitlement.
- In most table cases no expert report is required and these cases see an expedited resolution. (<http://www.uscfc.uscourts.gov/sites/default/files/GUIDELINES-FOR-PRACTICE-4212016.pdf>)

#### J. Entitlement Hearings

- The primary objective is the presentation of expert testimony, if no fact hearings have taken place then these hearings may start with the testimony of other witnesses (<http://www.uscfc.uscourts.gov/sites/default/files/GUIDELINES-FOR-PRACTICE-4212016.pdf>)
- The formal rules of evidence do not apply (<http://www.uscfc.uscourts.gov/sites/default/files/GUIDELINES-FOR-PRACTICE-4212016.pdf>)

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- Petitioner usually goes first  
(<http://www.uscfc.uscourts.gov/sites/default/files/GUIDELINES-FOR-PRACTICE-4212016.pdf>)
- The hearing are conducted in the presence of a court reporter who transcribes the hearing and the parties can order transcripts  
(<http://www.uscfc.uscourts.gov/sites/default/files/GUIDELINES-FOR-PRACTICE-4212016.pdf>)

#### K. Entitlement Decisions

- Most special masters will issue a written decision, but they may also issue a bench ruling  
(<http://www.uscfc.uscourts.gov/sites/default/files/GUIDELINES-FOR-PRACTICE-4212016.pdf>)
- Special masters try to issue decisions within 6 months of the hearing transcript's filing but the time may vary (<http://www.uscfc.uscourts.gov/sites/default/files/GUIDELINES-FOR-PRACTICE-4212016.pdf>)

#### L. Publication of the Decision

- When the special master issues a decision the decisions are made available to the public in their entirety (<http://www.uscfc.uscourts.gov/sites/default/files/GUIDELINES-FOR-PRACTICE-4212016.pdf>)
- If a party would like redactions, they must propose them within 14 days  
(<http://www.uscfc.uscourts.gov/sites/default/files/GUIDELINES-FOR-PRACTICE-4212016.pdf>)

#### M. Exiting the Vaccine Program and Filing a Civil Action

- Within 90 day of an entry of judgment on the special master's decision on entitlement, a petitioner may file an election to file a civil action  
(<http://www.uscfc.uscourts.gov/sites/default/files/Election%20to%20File%20a%20Civil%20Action.pdf>) (<http://www.uscfc.uscourts.gov/sites/default/files/GUIDELINES-FOR-PRACTICE-4212016.pdf>)
  - This petition rejects the judgment and must be filed to preserve petitioner's right to file a civil action in another court.

#### N. Damages

- If entitlement is found, then the special master will issue an order setting a schedule for the submission of information on the amount of compensation  
(<http://www.uscfc.uscourts.gov/sites/default/files/GUIDELINES-FOR-PRACTICE-4212016.pdf>)
- Available Damages

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- Damages are set by statute (<https://www.law.cornell.edu/uscode/text/42/300aa-15>)
  - Death cases
    - \$250,000
    - May also award for injuries incurred prior to the vaccine related death in some cases.
  - Injury Cases
    - Four categories
      - Pain and suffering-up to \$250,000
      - Lost Wages
      - Past out of pocket medical expenses
      - Actual future medical needs not reimbursable by any other source
        - Usually compensated through an annuity
  - Attorneys' Fees and Costs
    - The statute allows for the payment of attorneys fees and costs (<https://www.law.cornell.edu/uscode/text/42/300aa-15>)
      - In fact, 42 U.S.C. §300aa-15(e) provides for the fees and prohibits attorneys from charging for filing a petition under 300aa-11 if that amount is in addition to compensation awarded by a special master.
    - Even in cases where entitlement to compensation is not found, fees and costs may still be awarded if the petitioner had a good faith basis (<http://www.uscfc.uscourts.gov/sites/default/files/GUIDELINES-FOR-PRACTICE-4212016.pdf>)
      - This is at the discretion of the special master

#### O. Post Judgment Remedies

- Notice of Appeal (<http://www.uscfc.uscourts.gov/sites/default/files/170801VaccineRules.pdf>)
  - A party must file the petition within 60 of the date of entry of judgment
    - The appeal is taken to the United States Court of Federal Claims
- Motion for new trial, reconsideration or rehearing
  - Must be filed pursuant to the Rules of the United States Court of Federal Claims Rule 59 ([http://uscfc.uscourts.gov/sites/default/files/court\\_info/20130813\\_rules/13.08.30%20Final%20Version%20of%20Rules.pdf](http://uscfc.uscourts.gov/sites/default/files/court_info/20130813_rules/13.08.30%20Final%20Version%20of%20Rules.pdf))

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Interesting Issues

No right to jury in Vaccine Court.

No right to any other court of law for design-defect cases against vaccine manufacturers (see *Bruesewitz v. Wyeth*, February 22, 2011 U.S. Supreme Court case)

The National Institute of Health has published an article on its website which discusses suing the public on a class action basis to failure to vaccinate one's children through religious or philosophical exemptions as a remedy to the potential loss of herd immunity:

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2553651/>

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A discussion of Florida and California Vaccine Statutes and *Bruesewitz v. Wyeth*

**Vaccines Covered Under Vaccine Court**

1. Diphtheria (e.g., DTP, DTaP, Tdap, DT, Td, TT)
2. Haemophilus influenza type b polysaccharide conjugate vaccines (e.g., Hib)
3. Hepatitis A (e.g., HAV)
4. Hepatitis B (e.g., HBV)
5. Human papillomavirus (e.g., HPV)
6. Seasonal influenza (e.g., Flu)
7. Note: Non-Seasonal Flu Vaccines are not VICP-covered vaccines.
8. Measles (e.g., MMR)
9. Mumps (e.g., MMR, MR, M)
10. Meningococcal (e.g., MCV4, MPSV4, MenB-FHbp, MenB-4C)
  - a. Note: All other formulations of meningococcal vaccines, such as vaccines produced by recombinant DNA technology, are covered under the VICP in otherwise eligible individuals.
11. Pertussis (e.g., DTP, DTaP, Tdap)
12. Pneumococcal conjugate (e.g., PCV)
  - a. Note: Pneumococcal polysaccharide vaccine (PPSV, PPV) is not a VICP-covered vaccine.
13. Polio (e.g., OPV or IPV)
14. Rotavirus (e.g., RV)
15. Rubella (e.g., MMR, MR, R)
16. Tetanus (e.g., Td)
17. Varicella (e.g., VAR)
  - a. Note: Herpes zoster (shingles) vaccine is not a VICP-covered vaccine.

Source: <https://www.hrsa.gov/vaccine-compensation/covered-vaccines/index.html>

**Florida School Vaccination Requirements**

- Fla. Stat. 1003.22(4)
  - o (4) Each district school board **and the governing authority of each private school shall establish and enforce as policy that, prior to admittance to or attendance in a public or private school, grades kindergarten through 12, or any other initial entrance into a Florida public or private school, each child present or have on file with the school a certification of immunization for the prevention of those communicable diseases for which immunization is required by the Department of Health and further shall provide for appropriate screening of its students for scoliosis at the proper age.** Such certification shall be made on forms approved and provided by the Department of Health and shall become a part of each student's permanent record, to be transferred when the student transfers, is promoted, or

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changes schools. The transfer of such immunization certification by Florida public schools shall be accomplished using the Florida Automated System for Transferring Education Records and shall be deemed to meet the requirements of this section.

- (5) The provisions of this section shall not apply if:
  - (a) The parent of the child objects in writing that the administration of immunizing agents conflicts with his or her religious tenets or practices;
  - (b) A physician licensed under the provisions of chapter 458 or chapter 459 certifies in writing, on a form approved and provided by the Department of Health, that the child should be permanently exempt from the required immunization for medical reasons stated in writing, based upon valid clinical reasoning or evidence, demonstrating the need for the permanent exemption;
  - (c) A physician licensed under the provisions of chapter 458, chapter 459, or chapter 460 certifies in writing, on a form approved and provided by the Department of Health, that the child has received as many immunizations as are medically indicated at the time and is in the process of completing necessary immunizations;
  - (d) The Department of Health determines that, according to recognized standards of medical practice, any required immunization is unnecessary or hazardous; or
  - (e) An authorized school official issues a temporary exemption, for up to 30 school days, to permit a student who transfers into a new county to attend class until his or her records can be obtained. Children and youths who are experiencing homelessness and children who are known to the department, as defined in s. 39.0016, shall be given a temporary exemption for 30 school days. The public-school health nurse or authorized private school official is responsible for follow-up of each such student until proper documentation or immunizations are obtained. An exemption for 30 days may be issued for a student who enters a juvenile justice program to permit the student to attend class until his or her records can be obtained or until the immunizations can be obtained. An authorized juvenile justice official is responsible for follow up of each student who enters a juvenile justice program until proper documentation or immunizations are obtained.
- Required Vaccines
  - Childcare and/or Family Daycare
    - Diphtheria-tetanus-acellular pertussis (DTaP)
    - Inactivated polio vaccine (IPV)
    - Measles-mumps-rubella (MMR)
    - Varicella (chickenpox)
    - Haemophilus influenzae type b (Hib)
    - Pneumococcal conjugate (PCV13)
    - Hepatitis B (Hep B)
  - Public/Non-public Preschool Entry

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- DTaP
  - IPV
  - MMR
  - Hepatitis B (Hep B)
  - Varicella
  - Hib
- Public/Non-public Schools Kindergarten Through 12th Grade
  - Four or five doses of DTaP
  - Four or five doses of IPV
  - Two doses of MMR
  - Three doses of Hep B
  - One Tetanus-diphtheria-acellular pertussis (Tdap)
  - Two doses of Varicella (kindergarten effective with 2008–2009 school year, then an additional grade is added each year thereafter). Varicella vaccine is not required if there is a history of varicella disease documented by the health care provider.
- Additional Immunization Requirements for 7th Grade Entry
  - One Tetanus-diphtheria-acellular pertussis (Tdap)
- Higher Education
  - Meningitis
  - Hepatitis B vaccine
- Exemptions
  - Religious Reasons
  - Health reasons

### California School Vaccination Requirements

- California Code, Health and Safety Code - HSC § 120338
  - **(b) The governing authority shall not unconditionally admit any person as a pupil of any private or public elementary or secondary school, child care center, day nursery, nursery school, family day care home, or development center, unless, prior to his or her first admission to that institution, he or she has been fully immunized.** The following are the diseases for which immunizations shall be documented:
    - (1) Diphtheria.
    - (2) Haemophilus influenzae type b.
    - (3) Measles.
    - (4) Mumps.
    - (5) Pertussis (whooping cough).
    - (6) Poliomyelitis.
    - (7) Rubella.

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- (8) Tetanus.
- (9) Hepatitis B.
- (10) Varicella (chickenpox).
- (11) Any other disease deemed appropriate by the department, taking into consideration the recommendations of the Advisory Committee on Immunization Practices of the United States Department of Health and Human Services, the American Academy of Pediatrics, and the American Academy of Family Physicians.
- (c) Notwithstanding subdivision (b), full immunization against hepatitis B shall not be a condition by which the governing authority shall admit or advance any pupil to the 7th grade level of any private or public elementary or secondary school.
- (d) The governing authority shall not unconditionally admit or advance any pupil to the 7th grade level of any private or public elementary or secondary school unless the pupil has been fully immunized against pertussis, including all pertussis boosters appropriate for the pupil's age.
- (e) The department may specify the immunizing agents that may be utilized, and the way immunizations are administered.
- (f) This section does not apply to a pupil in a home-based private school or a pupil who is enrolled in an independent study program pursuant to Article 5.5 (commencing with Section 51745) of Chapter 5 of Part 28 of the Education Code and does not receive classroom-based instruction.
- (g) (1) A pupil who, prior to January 1, 2016, submitted a letter or affidavit on file at a private or public elementary or secondary school, child day care center, day nursery, nursery school, family day care home, or development center stating beliefs opposed to immunization shall be allowed enrollment to any private or public elementary or secondary school, child day care center, day nursery, nursery school, family day care home, or development center within the state until the pupil enrolls in the next grade span.
- Exemptions
  - Students enrolled in private home school programs
  - Students enrolled in independent study
  - Health reasons
  - California abolished the religious belief exemption (<http://www.latimes.com/science/sciencenow/la-sci-sn-vaccine-medical-exemptions-20170905-story.html>)

### ***Bruesewitz v. Wyeth***

- Case Background
  - Russell and Robalee Bruesewitz claimed their daughter suffered from seizures and permanent disability after the DTP vaccine
  - Filed their case in vaccine court, but the court denied an award finding no causation

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- Russell and Robalee Bruesewitz then opted to reject the decision of the vaccine court and filed suit in Pennsylvania state court claiming that the vaccine manufactured by Lederle Laboratories (later bought by Wyeth) had a defective design which caused their daughter's seizures and disabilities.
  - Wyeth removed to federal court and filed summary judgment motion which the court granted.
    - Court held:
      - Pennsylvania law was preempted by 42 U. S. C. §300aa-22(b)(1), which provides that "[n]o 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."
  - Third Circuit affirmed.
  - Supreme Court granted certiorari and held that The Vaccine Act (42 U.S.C. §§ 300aa-1 to 300aa-34) preempts all design-defect claims against vaccine manufacturers brought by plaintiffs seeking compensation for injury or death caused by a vaccine's side effects.
- Effect
- Design-defect claims can **only** be pursued in Vaccine Court
  - Insulates manufacturers from tort liability for design defects in vaccines