OFFICE OF THE SPECIAL MASTERS

September 30, 1997

Ronald C. Homer, Boston, MA, for petitioners.

Eleanor A. Barry, Washington, DC, for respondent.

DECISION

MILLMAN, Special Master

Petitioners Marcella and Daniel Schwarz, on behalf of their minor daughter, Hannah Schwarz (hereinafter, "Hannah"), filed a petition on March 9, 1995 for compensation under the National Childhood Vaccine Injury Act of 1986⁽¹⁾ (hereinafter, the "Vaccine Act" or the "Act"). Petitioners initially alleged that Hannah suffered anaphylaxis, anaphylactic shock, encephalopathy, shock collapse, hypotonic-hyporesponsive collapse, neurological sequelae, and death as a consequence of DPT and MMR vaccinations administered ten days before she died. At the hearing, petitioners alleged that DPT significantly aggravated Hannah's immuno-compromised state, which could have occurred on- or off-Table, but petitioners would adhere to off-Table. In addition, MMR allowed measles virus to fulminate and cause sepsis, an off-Table injury, leading to her death.

The parents have satisfied the prima facie criteria enunciated in 42 U.S.C. § 300aa-11(c) of the Act, i.e., that they have not previously collected an award or settlement of a civil action for Hannah's death, and that Hannah received her DPT and MMR vaccinations in the United States.

The court heard the evidence in this case on June 23, 1997. Testifying for petitioners were Marcella Schwarz, Daniel Schwarz, and Dr. Lewell Brenneman. Testifying for respondent were Dr. Raoul Wientzen, Jr. and Dr. Virginia Anderson.

FACTS

Hannah was born on December 9, 1991. Med. recs. at Ex. 17, p. 1. On October 15, 1993, when she was 22 months old, she received her fourth DPT vaccination and MMR vaccination (as well as her third polio vaccination, HIB, and hepatitis B). Med. recs. at Ex. 5, p. 1.

The pediatric records show that Hannah had constant fevers, upper respiratory infections, and otitis media (ear infections) during her life. Med. recs. at Ex. 5, pp. 2-17; Ex. 6, p. 1-9.

The ambulance trip report, dated October 25, 1993, at 8:34 a.m., states that she had semi-bloody fluid running out of her nose, and down her mouth and right cheek. Med. recs. at Ex. 9, p. 1. The last time her mother saw Hannah alive was that morning. *Id.* Mrs. Schwarz put Hannah to bed at about 7:00 p.m. Med. recs. at Ex. 9, p. 2. Hannah made noises during the night, which was normal for her. *Id.* She was congested and Mrs. Schwarz gave her some cold medicine. *Id.* Mrs. Schwarz stated Hannah did not have a medical history. *Id.*

Hannah was brought to St. Vincent Hospital. Med. recs. at Ex. 10, p. 1. She was dead on arrival. Med. recs. at Ex. 10, p. 3. The history given was that she had been ill for the last several days with a runny nose and low-grade fever. *Id.* Mrs. Schwarz said it was not a very high fever. *Id.* She was quite congested with greenish drainage from her nose. *Id.* She was in bed at 6:30 p.m. with Dimetapp and Pediaprofen. *Id.* Mrs. Schwarz switched Hannah to soy milk the day before. *Id.* Hannah moaned a little during the night, but Mrs. Schwarz said she usually did this. *Id.* Mrs. Schwarz found her face down in her crib, unresponsive and blue. *Id.* She had been dead for some time. *Id.*

The autopsy stated that the cause of death was unknown. Med. recs. at Ex. 10, p. 15. Hannah had prominent lymphoid tissue and follicular hyperplasia of her spleen, gastrointestinal tract and upper airway. *Id.* She had a possible conducting system abnormality of her heart. *Id.* Random sections from her cerebral cortex were within normal limits. *Id.* The brain was not swollen. Med. recs. at Ex. 10, p. 18; Ex. 11, p. 3.

In a letter dated November 8, 1993 to the Air Force Institute of Pathology (AFIP), Dr. Kenneth H. Mueller said that Hannah's history showed fairly severe colic for six to seven months. Med. recs. at Ex. 11, p. 5. In March 1993, she had high fevers which were sometimes accompanied by spots. *Id.* This continued for approximately one month. *Id.* Dr. Mueller questioned whether Hannah had roseola. *Id.* She had atelectasis or a small focus of pneumonia. *Id.* There was elevation in her sedimentation rate. *Id.* Hannah had otitis media and an upper respiratory infection in late September or early October. *Id.* She went to bed tired on October 24, 1993. *Id.*

A letter dated December 1, 1993 from Dr. Eric S. Suarez, a pediatric pathologist (AFIP consultation report), states that he cannot determine the cause of death. Med. recs. at Ex. 12, p. 1. Hannah's death certificate states the cause of death is unknown. Med. recs. at Ex. 13, p. 1.

TESTIMONY

Marcella Schwarz testified first for petitioners. Tr. at 12. She was practicing law in 1993, as was her husband, Daniel L. Schwarz. Tr. at 21-22. After Hannah's first DPT vaccination on February 17, 1992, she had a low-grade fever. Tr. at 16. She was always sick. Tr. at 16-18. Her congestion started before her first DPT vaccination. Tr. at 16-17. She also had colic. Tr. at 17. Hannah had her second DPT vaccination on July 1, 1992 and had congestion. Tr. at 18. She had her third DPT on September 15, 1992 and had congestion and a fever. Tr. at 19. Her vaccination sites were also sore. *Id.* In the spring of 1993, Hannah experienced joint pain. Tr. at 14. She would say "Ow" when they touched her. Tr. at 14-15. On April 5, 1993, Hannah turned blue at day care. Tr. at 21. During the last week of her life, she cried. Tr. at 20.

Daniel L. Schwarz testified next for petitioners. Tr. at 22. He went to the day care center and took Hannah to the doctor. Tr. at 23. She had ear infections all the time. *Id.* There were traces of blue around her lips when he got to the day care center. Tr. at 24. When Hannah was asleep, they had a hard time waking her up. Tr. at 24-25.

Mrs. Schwarz added that Hannah liked baths and swimming pools. Tr. at 26. From April 1993 - October 1993, Hannah had high fevers in both the morning and afternoon. Tr. at 26-27. After Hannah turned blue, they took her off Bactrim. Tr. at 27. Hannah contracted pneumonia in April of 1993. Tr. at 28. She was on a machine three times a day for breathing to help clear up her congestion. Tr. at 27. Her fever was high. *Id.* The day care measured it. *Id.* The fevers lasted for several weeks. *Id.*

Hannah was approximately thirty pounds when she died. Tr. at 28. Her birth weight was nine pounds, six ounces. *Id.* Mrs. Schwarz took Hannah to her brother's wedding in Boston. *Id.* She seemed better, but still whined. *Id.* She also slept a lot and sweated profusely. *Id.* When they returned from the wedding, her nose was running. *Id.* On May 4, 1993, her fever shot up after going back on Bactrim. Tr. at 29-30. Mrs. Schwarz gave her Tylenol. Tr. at 30. Hannah's movements were jerky. *Id.* When she was sick, she cried constantly. *Id.*

In the summer of 1993, Hannah slept an awful lot. Tr. at 33. She was congested but not febrile. *Id.* She slept from 7:30 or 8:00 p.m. until 7:30 a.m., plus a two- to three-hour nap in day care. Tr. at 34. Thus, Hannah was sleeping fourteen to fifteen hours a day in the spring and summer of 1993. *Id.* By contrast, in the winter of 1992, she was sleeping twelve to fourteen hours a day. Tr. at 34-35.

Hannah had her fourth DPT with MMR on October 15, 1993. Tr. at 36. She cried inconsolably for thirty minutes. *Id.* The vaccine site was sore. *Id.* She had a fever, but it was not high. Tr. at 36-37. The fever lasted two to three days. Tr. at 37. She slept the night of October 15, 1993 and she also ate. *Id.* The only difference in her condition was the fever. *Id.* During the week, she began crying again. *Id.*

Mr. Schwarz continued testifying. Tr. at 38. Hannah was in day care that week. *Id.* At night, all she wanted was to be held. *Id.* She slept and was a little cranky. Tr. at 39. She was in day care from 8:30 a.m. to 5:30 p.m. Tr. at 40. Day care would call when she had a fever. Tr. at 42.

Hannah moaned at night. *Id.* She always slept on her back. Tr. at 43. In March 1993, she had spots on her arms and legs and in the vaginal area. Tr. at 43-44. In the spring of 1993, when she had joint pain, Hannah continued to walk without trouble. Tr. at 45. She did not have any trouble playing. *Id.* During the summer of 1993, Hannah whined and slept a lot. Tr. at 33. Mr. Schwarz did not tell the doctor about the whining or excessive sleep during a September 28, 1993 doctor's visit. Tr. at 45-46. Mr. Schwarz assumed that if you slept a lot, you were getting well. Tr. at 46. His main concern was her fevers and ear infections. *Id.* In the summer of 1993, Hannah sweated profusely and slept a lot; however, she did not have ear infections. *Id.*

From April - October of 1993, Hannah had high fevers all the time. Tr. at 26-27. The Schwarzes were going to take her to the doctor on October 25, 1993 (a Monday). Tr. at 47. She had had a fever only over the past weekend. *Id.* During her last weekend, Hannah slept sixteen hours a night, while also napping. Tr. at 49. Throughout the summer, she experienced vague tiredness and needed to be carried downstairs. Tr. at 50. Hannah's older sister Emily was born with a cleft palate and had several ear infections. Tr. at 51. There is no family history of lupus or rheumatoid arthritis. *Id.*

Dr. Lewell D. Brenneman testified for petitioners. Tr. at 52. He has a Ph.D in immunology. Tr. at 53. He mainly practices medical immunology. *Id.* In his opinion, Hannah's October 15, 1993 vaccinations caused her death. Tr. at 54-55. The basis of his opinion is that Hannah was immune-compromised early in her life. Tr. at 55. She had frequent infections which began at the age of eight weeks. *Id.* She went to the doctor thirty times over a twenty-three month period. *Id.* She had upper respiratory infections, otitis media, and viral infections. *Id.* Hannah had common variable immune deficiency (CVID). *Id.* This condition varies with a broad level of symptoms. Tr. at 56. It was mild, as distinguished from severe immune deficiencies, like AIDS. *Id.*

The three DPT vaccinations in 1992 aggravated her immune-compromised condition. Tr. at 57. Medical literature says that these vaccines, ie., DPT, can cause immune suppression. *Id.* In his opinion, Dr. Brenneman stated that DPT caused the suppression of Hannah's immune compromised condition. Tr. at 62. Adverse effects could require time, depending on the antigen, the susceptibility and the state of the patient's immune system. Tr. at 59. DPT caused aggravation of her immune compromised condition. Tr. at 62.

Hannah's immune system did not keep her free from disease. Tr. at 63. The normal intent of vaccination is to protect the body, but vaccines can cause suppression. Tr. at 64. The sequence of Hannah's termination began with her MMR on October 15, 1993. Tr. at 65. The MMR caused sepsis (her inflamed intestinal mucosa). *Id.* In an immune-compromised patient, a virus causes inflammation, especially in the gastrointestinal tract. Tr. at 67-68. This can occur in a few hours. Tr. at 69.

Hannah had patchy pulmonary edema and lymphocytes in her lungs. Tr. at 70. None were fulminating or overwhelming. *Id.* She had Waterhouse-Fredricksen syndrome, in which there is gram negative sepsis and the body is overwhelmed. Tr. at 70, 73. She had petechie in her heart. (Petechiae are characteristic of coagulation.) Tr. at 70, 73-74. Hannah was ill with a mild measles infection. Tr. at 70. She did not show typical bacterial signs and did not have a primary bacterial infection. Tr. at 70-71. Most children experience multiple vaccinations and infections, but do not have the same susceptibility as Hannah did. Tr. at 72-73.

Hannah's turning blue on May 4, 1993 showed that she was a fragile, unhealthy child. Tr. at 74. Joint pain is fairly frequent in immune deficiency. *Id.* The septic response from the MMR is a gradually increasing process. Tr. at 77. She had patchy infiltrates in her lungs, similar to that of pneumonia. Tr. at 79. Sepsis killed her. Tr. at 80. Sepsis causes bacteria from the intestines to release lethal toxins. *Id.* When these toxins are released, a decline in blood pressure, shock, and death can ensue. *Id.*

DPT aggravates immune suppression. Tr. at 81. Immunocompromised patients can have a higher rate of reaction to substances. Tr. at 84. Hannah had a deficient immune system. *Id.* If a person with HIV receives hepatitis vaccine, it can aggravate the HIV. Tr. at 91. The person must go on anti-viral therapy. *Id.* Measle virus can affect multiple tissues, including the gastrointestinal tract. Tr. at 92. Hannah had a high lymphocyte count in her gastrointestinal mucosa. *Id.* A process was ongoing in the lining of her gut. *Id.* She had lymphocyte infiltration. *Id.* Lymphocytes often indicate a viral infection. Tr. at 92-93. She did not have a florid massive bacterial infection. Tr. at 93. The virus permeated the lining of her gastrointestinal tract, allowing bacteria to enter her bloodstream, causing sepsis. Tr. at 93-94. If Hannah

had not received MMR, she would have lived. Tr. at 94. Similarly, if she had not received DPT, she would have lived. *Id*.

On cross-examination, Dr. Brenneman admitted he is not board-certified in immunology. *Id.* Currently, ten percent of his patients are children. *Id.* He is not a pathologist. *Id.* Mrs. Schwarz then testified that Hannah had one blood test in April 1993 when she had pneumonia and a high white count. Tr. at 97.

Dr. Brenneman testified that Hannah had normal growth. Tr. at 100. She did not have chronic diarrhea (although Mrs. Schwarz stated that on antibiotics, Hannah had diarrhea). Tr. at 100-101. CVID (common variable immune deficiency) usually occurs in the second decade. Tr. at 101. Dr. Brenneman stated that, in his opinion, Hannah most likely had measles approximately ten days after her vaccination. Tr. at 104. This viral illness led to sepsis which, in turn, led to her death. Tr. at 103. In Dr. Brenneman's opinion, the MMR caused her death, even without CVID. Tr. at 103. It is well-known that measles causes immune suppression. Tr. at 104. Immune deficiencies do not stay at the same level. *Id.* Hannah recovered from pneumonia. *Id.* In one week, her pneumonia cleared on x-ray. Tr. at 104-105. Hannah was probably born with a certain amount of immune deficiency. Tr. at 109. The vaccines significantly aggravated this deficiency. Tr. at 109. The measles virus then opened the door to sepsis. Tr. at 110. She did not have an immune system to fight either the sepsis or the measles virus. *Id.* She went downhill. Tr. at 112. At twenty-three months, she was dead from sepsis, with the major aspects of sepsis occurring on the night of her death. *Id.* In Dr. Brenneman's opinion, the MMR caused Hannah to develop sepsis, which resulted in her death. Tr. at 110.

Medical literature does not associate CVID with measles death, but there is a risk of septicemia death. Tr. at 122-1123. CVID is typically associated with a low white count. Tr. at 125. Hannah was atypical during florid infection, having a high white count. *Id*.

Dr. Raoul Wientzen testified for respondent. Tr. at 127. He is board-certified in pediatrics and pediatric infectious diseases. Tr. at 128. He is chief at Georgetown and teaches residents. *Id.* In his opinion, Hannah was not immune-compromised. Tr. at 129. His diagnosis is that CVID depends on the history of recurrent infections. Tr. at 129-130. CVID is a series of infections that are difficult to treat and invasive of many of the body's organs. *Id.* The pediatricians did not think Hannah's illnesses were serious enough to work her up for an immune disorder. Tr. at 130.

Hannah was growing spectacularly well. *Id.* Children with immune deficiency typically have a failure to thrive. *Id.* By her twenty-month visit, she was above the 99th percentile for weight. *Id.* In serious immunodeficiency, the patient has chronic diarrhea. *Id.* Hannah did not have mild immunodeficiency. Tr. at 131. She had many upper respiratory infections. *Id.* The most common reasons for upper respiratory infections are exposure to illnesses in day care and an underlying allergic problem. *Id.* Allergy is essentially hyperimmunity, where the immune system overreacts to various stimuli, such as, dust, viruses or mold. *Id.* Hannah was exposed to illnesses and was probably allergic to tobacco. Tr. at 132. She was also allergic to Bactrim and soy milk. Tr. at 29, 143.

All of Hannah's allergies are common in children with recurrent otitis media. Tr. at 132. She was not allergic to MMR . *Id.* She ate eggs. *Id.* Hannah died because of overwhelming sepsis in a short period of time. Tr. at 133. She had petechiae on her chest. *Id.* Sepsis occurs in healthy people. *Id.* Immune deficiency is not necessary to contract sepsis. *Id.* The most common reason for sepsis is an upper respiratory infection which causes inflammation in the nose and back of the throat. Tr. at 133-134. The average child has five upper respiratory infections in his or her first year. Tr. at 134.

There is no evidence of measles infection in Hannah's inner organs. Tr. at 135. Children with severe

combined immunodeficiency (SCIDS), who are going to die of measles, contract giant cell pneumonia. *Id.* In Dr. Wientzen's opinion, Hannah did not have this nor did she have an aggressive form of measles induced by purported immune deficiency. Tr. at 136. Hannah did not have any immune deficiency in the summer of 1993. Tr. at 137. Children with serious immune disorders that could be fatal with the introduction of a measles vaccine do not have long respites of good health. *Id.*

When she developed a lower respiratory problem (possibly pneumonia), Hannah got better on erythromycin in a week. Tr. at 139. Thus, she did not have an immune system problem. *Id.* People with severe immunodeficiency disease rupture their ear drums. Tr. at 140.

This did not happen to Hannah. *Id.* Dr. Wientzen did not have an answer for Hannah's bone pain. *Id.* Her excessive sleeping could be due to her allergic diathesis. Tr. at 142.

There was a tremendous amount of normality in Hannah's autopsy. Tr. at 145. There is a good history of an upper respiratory infection before she died. *Id.* She had a very rapid death. *Id.* Her lymph tissue was normal for her age. Tr. at 146. There is no evidence that DPT aggravates immune deficiency in a child. Tr. at 147. DPT boosts immunity; it does not suppress it. Tr. at 153. There is no evidence that measles was the viral illness that predated or antedated Hannah's sepsis. Tr. at 148.

CVID can appear at any age, but it typically appears at the second and third decade. Tr. at 154. Hannah had recurrent otitis media. Tr. at 155. Her disease began before the DPT vaccination. Tr. at 155. She had thirty-one visits to the pediatrician and clinic in twenty-three months. Tr. at 157. Dr. Wientzen sees children with recurrent otitis media, like Hannah, all the time. *Id.* Exposure and allergies, however, are the underlying cause of their infections. *Id.* It is more common for Dr. Wientzen to treat children with infections caused by exposure and allergies than by CVID. *Id.*

On April 1, 1993, Hannah was diagnosed as having prolonged viral illness. Tr. at 158. She had mycoplasma (walking) pneumonia. *Id.* This was diagnosed on April 7, 1993. Tr. at 159. In Dr. Wietzen's opinion, Hannah did not have a compromised immune system. *Id.* Children with underlying allergic diathesis react poorly to colds. Tr. at 164. Allergies can cause fever. Tr. at 165. Any vaccine and almost any infection turns on the immune system. Tr. at 165-166. SCIDS is a congenital immune disorder of the T and B cells. Tr. at 166. AIDS is a T cell disorder in adults. Tr. at 166. SCIDS is not a model for HIV. *Id.* The pathophysiology of AIDS is very peculiar. Tr. at 165. The virus infects cells best when they are stimulated. *Id.*

Measles and measles vaccine can cause an upper respiratory infection. Tr. at 166-167. A viral infection can break down the gastrointestinal tract to permit sepsis. *Id.* Hannah's gastrointestinal tract was intact to the pathologist who did the autopsy. Tr. at 168. Her lymphocytes were normal in her gastrointestinal tract. *Id.*

One does not need an upper respiratory infection to have sepsis, although most of the time, the person has a cold. Tr. at 171. Measles does not have a symptomatic gastrointestinal tract infection. *Id.* There is no evidence that measles vaccine reactions are associated with sepsis from the upper respiratory manifestations that occur during the course of such reaction two weeks after the vaccination was administered. Tr. at 173. After receiving a measles vaccine, children can have a fever, a mild upper respiratory infection, and a trivial rash. Tr. at 174.

Many viral infections cause sepsis. *Id.* Millions of children receive MMR. Tr. at 175. No measles vaccine correlates with sepsis. *Id.* In the vast majority of children who get sepsis, organisms in the upper respiratory tract, not the gastrointestinal tract, enter the blood from inflammation in the nose and throat.

Tr. at 177-179.

Dr. Virginia Anderson testified for respondent. Tr. at 181. She is board-certified in pathology, pediatrics, and pediatric pathology. Tr. at 182. It is her opinion that an overwhelming rapid sepsis caused Hannah's death. Tr. at 183. She had petechiae on her chest, neck, and shoulders. *Id.* She had leucocytosis and multiple viscera in her spleen, lungs, and liver. *Id.*

Dr. Anderson testified that Hannah did not have immunodeficiency disease. Tr. at 184. She would have had an abnormal thymus (atrophied due to depletion of T cells). *Id.* Her epithelial structures were present and her thymus was of normal weight. Tr. at 185. In immunodeficiency disease, the lymphoid follicles have a deranged pathology. Tr. at 186. Hannah had normal reactive follicles. *Id.* After a number of upper respiratory infections, it is common to have hyperplasia of lymphoepithelial structures. Tr. at 187-88. Hyperplasia indicates an intact immune system. Tr. at 188. Hannah had follicular hyperplasia in her gastrointestinal tract and upper airway. Tr. at 187.

Hannah was above two standard deviations for weight. Tr. at 188. Usually, a child with immunodeficiency has failure to thrive. *Id.* If she had severe immunodeficiency, there was a risk of measles after vaccination. Tr. at 189. Dr. Anderson has never seen a measles vaccine death on autopsy. Tr. at 190.

Hannah's autopsy was normal except for the petechiae. Tr. at 191. Petechiae are capillaries leaking (splinter hemorrhages). *Id.* It signals overwhelming sepsis. *Id.* There is no evidence of bleeding in Hannah. *Id.* There is no indication of the cause of her sepsis. Tr. at 192. Dr. Anderson did not understand Dr. Brenneman's description of the pathogenetic mechanism. *Id.*

The lymphoid cells in the epithelium in her respiratory tract were normal. Tr. at 193. She did not have oral thrush, a frequent sign of immune deficiency. *Id.* In Hannah's immune system, all the players were there and in proper proportion. Tr. at 195.

Dr. Anderson stated that her testimony applies to CVID. Tr. at 196. CVID is identified by aberrations of the immune system and an atrophic thymus. *Id.* The thymus instructs all the peripheral immune system: the gastrointestinal tract, the lymph nodes and the spleen. *Id.* CVID is more common in adults. Tr. at 197. Hannah's immune system at autopsy was robust. Tr. at 198. There is a relationship between structure and function. Tr. at 200. If someone has a poor immune system, he or she will have a poor structure. *Id.* Depletion of thymocytes is the first sign of poor immune function. Tr. at 201. Hannah had a beautiful collar of thymocytes in her spleen. Tr. at 202. She had a reactive follicle, which shows that her spleen functioned. *Id.*

Dr. Brenneman took the stand again and stated that he concurred with Dr. Wientzen that measles primarily occurs in the throat and rarely in the gastrointestinal tract. Tr. at 204. However, sepsis can be contracted from a measles infection in the throat. *Id.* He said one cannot determine function from structure. Tr. at 205.

Dr. Brenneman supplemented his testimony with literature that petitioners provided to the court. P. Ex. 18, Exs. A-KK. The first article⁽²⁾ finds a relationship between measles vaccine and death from viral infection primarily in individuals who are immunocompromised.

DISCUSSION

To satisfy their burden of proving causation in fact, petitioners must offer "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or

scientific explanation must support this logical sequence of cause and effect." <u>Grant v. Secretary, HHS</u>, 956 F.2d 1144, 1148 (Fed. Cir. 1992). <u>Agarwsal v. Secretary, HHS</u>, 33 Fed. Cl. 482, 487 (1995); see also <u>Knudsen v. Secretary, HHS</u>, 35 F.3d 543, 548 (Fed. Cir. 1994); <u>Daubert v. Merrell Dow Pharmaceuticals</u>, Inc., 509 U.S. 579 (1993).

"[E]vidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." <u>Grant, supra,</u> 956 F.2d at 1149.

Dr. Brenneman testified that all of Hannah's DPT vaccinations worsened her immunocompromised condition, but there is no evidence in the medical records to support his opinion. Moreover, Mrs. Schwarz's testimony does not indicate a worsening of Hannah's condition after each DPT, beyond a transient reaction. Since Mrs. Schwarz gave a history to St. Vincent Hospital stating that Hannah was ill with a runny nose and low-grade fever during the last several days before she died, the court must assume that the fourth DPT had nothing whatsoever to do with her final illness and death. The date of vaccination was October 15, 1993 while the date of death was ten days later, October 25, 1993. Several days could be four or five. That would indicate Hannah's illness began about October 20 or 21, 1993, off-Table from the DPT vaccine.

Dr. Brenneman's testimony would not support a conclusion that Hannah's fourth DPT caused her final illness and/or death. There were no symptoms attributable to DPT about which Dr. Brenneman testified. His theory was that DPT weakens the immune system, particularly in someone who is immunocompromised. However, there were no symptoms in Hannah's case to which the court could point in ascertaining that this worsening actually happened.

All the experts agreed that Hannah died from sepsis. The issue, however, is what caused the sepsis, the measles vaccine or an upper respiratory condition. (Respondent did not have any burden to prove that an upper respiratory infection caused the sepsis; the sole burden remained with petitioners to prove that measles vaccine caused the infection leading to sepsis.) Petitioners alleged that MMR caused Hannah to contract measles virus, which led to sepsis and her subsequent death. The battle of the experts (Brenneman versus Wientzen) devolved around the locus of the primary infection from sepsis.

Dr. Brenneman opined that Hannah's primary infection was in her gastrointestinal tract (inflamed intestinal mucosa). Hannah had a high lymphocyte count in her gastrointestinal mucosa. But, Dr. Wientzen testified (and Dr. Brenneman agreed later) that if the measles vaccine had indeed caused Hannah to contract measles, the locus of the primary infection from sepsis would have been her upper respiratory tract, not her gastrointestinal tract. Measles virus infection does not begin in the gastrointestinal tract.

This destroys Dr. Brenneman's basis for explaining how the measles vaccine could have caused sepsis in Hannah, leading to her death. Since the primary infection could have been only in the respiratory tract if derived from measles vaccine, but Hannah's primary infection was in her gastrointestinal tract, then measles vaccine could not have caused it. Hannah's lymphocyte count in her lungs was not overwhelming or fulminating compared to her gastrointestinal tract. Once her sepsis began, the infection overwhelmed her entire system and she died.

In light of the court's holding that Hannah's sepsis could not have come from a measles infection due to her measles vaccination because the source of the sepsis was not her upper respiratory tract, whether or not Hannah had immunodeficiency is moot. However, the court would note that it was highly impressed with Dr. Wientzen's testimony. He is board-certified in pediatric infectious diseases, while Dr. Brenneman is not board-certified in immunology. Less than ten percent of Dr. Brenneman's patients are

children, whereas Dr. Wientzen is also a board-certified pediatrician, associate professor of pediatrics and chief of pediatric infectious diseases at Georgetown University, Children's Medical Center, and teaches residents. Dr. Brenneman testified that Hannah had CVID, but also admitted that it usually occurs in the second decade. Hannah was less than two years old when she died. Dr. Wientzen testified that children with CVID typically fail to thrive, but Hannah was growing spectacularly well. Hannah had a number of allergies (e.g., to Bactrim, soy milk), but was not immunodeficient. If she had been immunodeficient, she would not have had a healthy summer in 1993.

Dr. Wientzen testified that healthy people contract sepsis. The most common reason is an upper respiratory infection which inflames the nose and back of the throat. Hannah had many upper respiratory infections in her twenty-two months of life. Dr. Wientzen testified that Hannah did not have measles infection in her inner organs. Contrary to Dr. Brenneman's thesis that DPT suppresses immunity, Dr. Wientzen testified that it boosts immunity, which is the purpose of administering the vaccine.

Exposure to day care is the most frequent cause of upper respiratory infection in children Hannah's age. Hannah was in day care while her parents practiced law. Besides many upper respiratory infections, Hannah had recurrent otitis media. She saw the doctor thirty-one times in her life. Dr. Wientzen testified that he sees children like Hannah all the time. The underlying cause of their infections is exposure and allergies, both of which Hannah had.

Confirming Dr. Wientzen's testimony was that of Dr. Virginia Anderson, also board-certified in pediatrics as well as in pediatric pathology and pathology. She agreed that sepsis caused Hannah's death. She also testified that Hannah did not have immunodeficiency disease, giving pathological reasons for her opinion. Petitioners never countered this testimony with their own pathological expert. The cause of Hannah's sepsis is not apparent pathologically. Her immune system, according to Dr. Anderson, was robust. The more persuasive evidence from Drs. Wientzen and Anderson is that Hannah was not immunocompromised.

The literature that petitioners submitted was unavailing either because Hannah did not fit into the immunocompromised category of those few articles describing death in a measles vaccine recipient or because the articles discussed a wide range of conditions and vaccinations which have no relevancy to the facts of this case. The court cautions counsel against inundation of the record with medical articles that seem inapplicable, particularly when petitioners' own expert does not specifically refer to them in his testimony.

Petitioners have not prevailed in proving an off-Table causation in fact injury and death from either the fourth DPT or measles vaccine. Moreover, they have not prevailed in proving a causation in fact significant aggravation of a purported immunocompromised state from either vaccine.

CONCLUSION

This case is dismissed with prejudice. In the absence of a motion for review filed pursuant to RCFC Appendix J, the clerk of the court is directed to enter judgment in accordance herewith.

IT IS SO ORDERED.	
DATE Laura D. Millman	

Special Master

- 1. The statutory provisions governing the Vaccine Act are found in 42 U.S.C.A. § 300aa-1 et seq. (West 1991). The National Vaccine Injury Compensation Program comprises Part 2 of the Vaccine Act. For convenience, further reference will be to the relevant subsection of 42 U.S.C. § 300aa.
- 2. Stratton, K.R., Howe, C.J., and Johnson, R.B., "Adverse Events Associated with Childhood Vaccines Other than Pertussis and Rubella. Summary of a Report from the Institute of Medicine," JAMA 271 (20):1602-05 (1994). P. Ex. A. Petitioners' Ex. D makes further reference in a general way to death from measles vaccine in patients with defective cell-mediated immunity. P. Ex. T is an abstract referring to a death six weeks post-measles vaccination in which the patient had severe, diffuse, giant cell pneumonia (which Hannah did not). P. Ex. U is similar without a mention of interval between vaccination and death. Some of the other exhibits have no specific relevance to the facts in this case: antinuclear autoantibodies in women with silicone breast implants (P. Ex. B); smallpox vaccination leading to lymphadenitis (P. Ex. C); DPT provoking polio during an outbreak in Oman (P. Ex. M); comparison of acellular DPT vaccine with whole cell (P. Exs. O, P, Q, W); an increase in deaths one to two years post-vaccination in those receiving high-titer measles vaccine versus standard-titer measles vaccine (P. Ex. S); MMR causing joint and limb symptoms (P. Ex. V); measles vaccine causing inguinal lymphadenopathy (P. Ex. E); MMR followed by acute thrombocytopenic purpura (P. Ex. X); articles on immunology, immunodeficiency, and HIV (P. Exs. Y, Z, AA-KK). P. Exs. H, I, J, K, L, R were deliberately left blank.