OFFICE OF THE SPECIAL MASTERS
April 21, 1998

No. 90-1344V

PETER REITZ and VICKIE REITZ, as Legal Representatives of DERRICK W. REITZ, a Minor,	*	
Petitioners,	*	**TO BE PUBLISHED**
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Boyd McDowell, III, Chicago, IL, for petitioners.

Elizabeth Kroop, Washington, DC, for respondent.

DECISION AND ORDER

MILLMAN, Special Master

On September 25, 1990, Peter and Vickie Reitz, on behalf of their son, Derrick W. Reitz (hereinafter "Derrick") filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986[(1)] (hereinafter the "Vaccine Act" or the "Act"). Petitioners have satisfied the requirements for a prima facie case pursuant to 42 U.S.C. § 300aa-11(c) by showing that: (1) they have not previously collected an award or settlement of a civil action for damages arising from the vaccine injury, (2) DPT vaccination was administered to Derrick in the United States, and, (3) they have incurred $1,000.00 in unreimbursable medical expenses prior to filing the petition.[(2)]

Petitioners allege that Derrick suffered an on-Table encephalopathy following DPT. 42 U.S.C. § 300aa-14(a)(I)(B). Respondent defends with the assertion that Derrick did not have encephalopathy.

The court held a hearing in this case on October 8, 1997. Testifying for petitioners were Vickie Reitz,

Peter G. Reitz, and Dr. James Valeriano. Testifying for respondent was Dr. Michael Kohrman.

FACTS

Derrick was born on April 13, 1982. Petition at Ex. 1, p. 1. On July 16, 1982, he received his first DPT vaccination at the age of three months. Med. recs. at Ex. 6, p. 1. He received his second DPT vaccination at the age of five months on September 28, 1982. Id. He received his third DPT vaccination at the age of eight months on Monday, December 20, 1982. Id. He received his fourth DPT vaccination at the age of twenty months on December 6, 1983. Med. recs. at Ex. 5, p. 2. On January 24, 1983, Derrick saw his pediatrician, who noted that the child had possible seizures. Med. recs. at Ex. 6, p. 3.

From January 29, 1983 to February 2, 1983, Derrick was at McKeesport Hospital for a seizure disorder of undetermined etiology and a viral illness. Med. recs. at Ex. 10, p. 2. The history given reflects that Derrick had received two DPT vaccinations[(3)] and had some mild viral illnesses; however, there was no evidence of any serious problems. Med. recs. at Ex. 10, p. 3. Over the past month, he had some episodes of crying and head banging, which were, until recently, believed to be behavioral. Id. On the day prior to admission, he had an episode of head banging during which he became limp and unresponsive, his eyes rolled back, and some mucous drooled from his mouth. Id. This episode lasted for two minutes. Id. He was brought to the emergency room and discharged. Med. recs. at Ex. 10, p. 3. He subsequently had two similar episodes, which lasted for approximately sixty to ninety seconds. Id. During these episodes, he was limp and unresponsive, becoming very sleepy thereafter. Id. Derrick was diagnosed as probably having some form of viral illness. Id.

A progress note from January 29, 1983, at 11:30 p.m., states that Derrick had his second[(4)] DPT vaccination on the Monday before Christmas. Med. recs. at Ex. 10, p. 22. For several days after the vaccination, he had a low-grade fever and diarrhea. Id. Thereafter, Mrs. Reitz noted that Derrick seemed to double up with cramps after eating. Id. She associated this movement with gas. Id. Derrick also began experiencing episodes during which he cried, and threw the upper part of his body and head against either the body of the person holding him or the high chair tray. Med. recs. at Ex. 10, p. 22. He would bang his head approximately six times and then return to normal. Id. These episodes had increased in frequency over the past week, recently occurring almost daily. Id. Since these episodes began, Derrick's activity level had decreased, and he was experiencing staring episodes. Id. On January 31, 1983, he had an EEG which was abnormal. Med. recs. at Ex. 10, p. 18.

From February 28, 1983 to March 8, 1983, Derrick was in Children's Hospital of Pittsburgh. Med. recs. at Ex. 7, p. 12. The history given by Mrs. Reitz notes that Derrick, at approximately eight months of age, began experiencing episodes of head bobbing where his arms would fly up. Id. These episodes were often associated with a sharp cry but no appreciation of a change in sensorium. Id. These episodes increased to two or three times per day. Id.

The record further reflects that, when Derrick was nine months old, he experienced an episode of head bobbing which was immediately followed by a 1 ½ - 2 minute period of limpness, drooling, and belabored breathing.[(5)] Med. recs. at Ex. 7, p. 12. Although his eyes were partially opened, he did not focus. Id. This occurred five days after his DPT vaccination. Id. Since the episodes began, Derrick was slower and less sociable. Id. Developmentally, Mrs. Reitz believed he had undergone a change. Med. recs. at Ex. 7, p. 12.

A medical record dated February 28, 1983 describes Derrick's development as slower than his brother's but the same as his sister's. Med. recs. at Ex. 7, p. 1. The history given reflects that Derrick received his third DPT vaccination on December 20, 1982 and developed fever and vomiting that night. Id. Later that week, Mrs. Reitz noticed that Derrick was experiencing episodes of head banging which occurred

several times per day and were accompanied by eye staring. Id.

In January, Derrick had a seizure. Id. His head bobbed approximately three to four times. Med. recs. at Ex. 7, p. 1. He continued to experience five to ten head bobs approximately four times per day. Med. recs. at Ex. 7, p. 2. Although his sleeping had not increased, his activity level had decreased. Id. His paternal half-uncle had a seizure disorder as a baby. Id. His paternal aunt's son had a seizure on his first day of life. Id.

On March 1, 1983, Derrick returned to Children's Hospital of Pittsburgh. Med. recs. at Ex. 5, p. 33. The history given reflects that his spells began in December 1982, with very brief, single head flexion episodes. Id. These episodes had expanded so that he was experiencing sudden head jerks during which his hands flew up. Id. Prior to these episodes, he was happy, active, and laughing. Id. However, his development had slowed down since the episodes began and his activity level had decreased, with his being active only for one hour per day. Med. recs. at Ex. 5, p. 33. Huntington's chorea runs in his father's family. Id. An EEG done on March 1, 1983 showed diffuse encephalopathy with an underlying seizure disorder. Med. recs. at Ex. 7, p. 7.

TESTIMONY

Mrs. Vickie Reitz testified first for petitioners. She has three children: Laurie, who is 24, Peter, who is 16, and Derrick, who is 15. Tr. at 6. Her husband has two nephews who were born with seizures. Tr. at 10. They were put on Phenobarbital and they are fine. Id. There is a grandmother and a few uncles with Huntington's chorea. Id.

As an infant, Derrick was very alert. Tr. at 14. In fact, he was nicknamed "Lookin' Rounds" because of his alertness. Tr. at 15. He ate and slept well and was able to coo and lift his head up. Id. He was on Similac with iron; however, this had to be discontinued because the iron caused fussiness.[(6)] Tr. at 16. Between one and two months of age, he slept through the night. Tr. at 20. At three months old, he was rolling over, smiling, and interested in his surroundings. Id. Mrs. Reitz thought he was more advanced than his siblings. Tr. at 21. At five months old, he was already sitting up and could say, "Hi," "Bye," and "Dada." Tr. at 24. He was crawling by eight months of age. Tr. at 27. His parents changed his nickname to "Lookin' Rounds Quarts and Pounds" because he was getting heavy and growing. Tr. at 27-28. He started to pull himself up and maneuvered a walker around. Tr. at 28. He also babbled. Tr. at 29. His siblings had not crawled or babbled until ten months of age. Id. By December 20, 1982, Derrick was eating three meals a day of baby food and his bottle plus an additional snack before bed with a bottle. Id. He normally slept from 9:00 p.m. to 7:00 a.m. Tr. at 30. He would nap early in the afternoon for sixty to ninety minutes. Id.

Derrick did not have a reaction to either his first or second DPT vaccinations. Tr. at 23, 25. He received his third DPT on December 20, 1982 at 4:00 or 4:15 p.m. Tr. at 31-32. Following vaccination, Derrick was very warm and Mrs. Reitz gave him Tylenol. Tr. at 32. Within ten minutes of returning home, he projectile vomited approximately two or three times.[(7)] Tr. at 32, 271-72. He had 103 degree fever and he was tired, sleepy, and groggy looking.[(8)] Tr. at 32-33. Mrs. Reitz laid him in his crib, where he slept from 5:00 p.m. until 9:00 a.m. the next morning. Id. Mrs. Reitz checked on him throughout the night. Id. Derrick did not move the entire night, remaining in the same fetal position. Tr. at 34. It was unusual for him not to move in his sleep. Id. The next morning, Mrs. Reitz went to wake Derrick because she was scared that he had been sleeping too long. Tr. at 36. She shook his arm. Id. He did not respond for five minutes. Id. Mrs. Reitz picked him up and he was groggy and sleepy. Id.

Concerned about the DPT, vomiting, high fever, and excessive sleep, Mrs. Reitz called Dr. Leslie J.

Silberman's office and spoke to his nurse.[(9)] Tr. at 37. The nurse said that these symptoms, including the vomiting, were normal reactions to DPT. Id. Mrs. Reitz did not speak to Dr. Silberman. Id.

On December 21, 1982, Mrs. Reitz testified that Derrick probably did not eat much. Tr. at 37. Although he was able to stay awake, he slept excessively. Tr. at 37-38. He would stay up for approximately thirty minutes and then sleep for a few hours. Tr. at 38. He did not have fever, vomiting, or diarrhea but he was whiny and cranky. Tr. at 40. Mrs. Reitz sat him up and he toppled over. Id. He was neither focusing nor alert. Tr. at 42. He could not crawl. Tr. at 42, 45.

For the next couple of days, Derrick was not himself. Tr. at 46. He was eating, but he would not sit up. Tr. at 47. He slept more than usual, napping a few times during the day. Id. He was not "with it." Id. He would neither crawl nor get in his walker. Id. Although his whining decreased, he was still whiny and grumpy. Tr. at 48. Derrick relearned to crawl and sit by the end of January 1983. Tr. at 49-50. However, Mrs. Reitz testified that he never returned to engaging in the normal activities that he did before the DPT. Tr. at 49.

On December 26, 1982, Mrs. Reitz picked up Derrick and he banged himself on her shoulder four to five times. Tr. at 50. Thereafter, he had episodes of head banging on a daily basis. Tr. at 51. On approximately January 23, 1983, Derrick was in his walker when he had an episode during which his head dropped onto the tray. Tr. at 52-53. His eyes were closed, he was breathing heavily, and foam came from his mouth. Tr. at 53. She took him to McKeesport Hospital emergency room (hereinafter "McKeesport"). Id. He came out of this episode while in transit to the hospital. Id. The emergency room personnel checked Derrick, but they did not believe Mrs. Reitz. Tr. at 53-54.

On January 24, 1983, Derrick saw Dr. Silberman. Tr. at 56. The doctor told Mrs. Reitz that Derrick was having temper tantrums. Id. On January 29, 1983, he experienced an episode of head bobbing while in his high chair. Tr. at 57. His head dropped onto the tray. Id. He was breathing heavily and foaming at the mouth. Id. She called Dr. Silberman. Id. He said it could possibly be a seizure and instructed Mrs. Reitz to call him if it happened again. Tr. at 57-58. If Derrick did not have any further episodes, Dr. Silberman advised Mrs. Reitz to bring Derrick to McKeesport the following Monday. Tr. at 57. A similar episode occurred that day and the Reitzes immediately took Derrick to McKeesport. Tr. at 58. He received a loading dose of Phenobarbital and was released after several days. Tr. at 61.

On February 28, 1983, Derrick was at Children's Hospital. Tr. at 68. He had regained skills but crawled with one leg extended. Tr. at 69. Dr. Silberman explained that Derrick was leveling out in skills because he had been so advanced at an early age. Tr. at 70. However, Dr. Ira Berman, a pediatric neurologist, diagnosed infantile spasms and prescribed ACTH. Tr. at 70-71. Derrick was on ACTH for one to one and one-half months. Tr. at 71. Although he remained seizure-free for eighteen months, his seizures returned slowly. Tr. at 73.

Derrick first visited Dr. Valeriano four or five years ago. Tr. at 90. In 1993, Dr. Valeriano told Mrs. Reitz that DPT caused Derrick's condition. Tr. at 91. Derrick currently has good and bad days. Tr. at 79. The week prior to trial, he had twenty-five seizures in an hour consisting of head drops. Tr. at 80-81. He goes to the local high school, where he is enrolled in a life skills support class. Tr. at 83. Derrick has the cognitive skills of a two or three year old, and improves slowly. Tr. at 84. Although he speaks, he cannot do so in complete sentences. Id. He has behavioral problems due to frustration. Tr. at 84-85. He receives behavioral therapy, occupational therapy, physical therapy, and speech therapy. Tr. at 85. He was fifteen months old when he first walked. Tr. at 86. He was never the same baby after the third DPT vaccination. Tr. at 87.

Dr. James Valeriano testified next for petitioners. He is a neurologist specializing in epilepsy. Tr. at 100. He is also a clinical neurophysiologist and, therefore, interprets EEGs. Tr. at 100-01. He is board-certified in neurology and neurophysiology. Tr. at 101. Five to ten percent of his practice deals with children. Id. He is Director of the Comprehensive Epilepsy Program and Assistant Professor of the Department of Neurology at Allegheny General Hospital. Id.

Derrick first saw Dr. Valeriano in 1993, with his last visit occurring in May 1996. Tr. at 103-04. Dr. Valeriano reviewed Derrick's post-DPT symptoms. Tr. at 105-09. He noted that Derrick was lethargic and had a fever of 103 degrees. Tr. at 105. Although he had normally been very active, he was extremely sleepy. Id. When Mrs. Reitz put him down for a nap, he slept from 5:00 p.m. to 9:00 a.m. Tr. at 106. He continued to be lethargic once awakened. Id. Episodes of head banging began five to six days after the vaccination. Id. He lost milestones and development. Id. He had changes in muscle tone. Tr. at 109. He could not sit up and lost head control. Id. An EEG conducted in January 1983 showed that he had infantile spasms. Tr. at 106-07.

With regard to the significance of the above symptoms, Dr. Valeriano testified that Derrick's 103 degree fever suggests an immune response to DPT, which is not uncommon. Tr. at 108. While projectile vomiting is nonspecific, it is more often related to a central nervous system problem rather than a gastrointestinal problem. Tr. at 107. Dr. Valeriano further stated that it was unusual for a baby not to move during sixteen hours of sleep. Tr. at 244-45. Babies tend to change position. Tr. at 245. To Dr. Valeriano, Derrick was in more than a deep sleep; he experienced an alteration in consciousness. Tr. at 245.

Dr. Valeriano's opinion is that Derrick had an on-Table encephalopathy and an off-Table seizure disorder, both of which were caused by the DPT.[(10)] Tr. at 111. The DPT caused a brain injury which essentially expressed itself in two forms. Tr. at 149. First, Derrick had an encephalopathy, which caused his initial lethargy. Id. Second, Derrick developed subsequently a seizure disorder, i.e., infantile spasms. Id. The seizure disorder then contributed to the encephalopathy, making it worse. Tr. at 149-50. Although Derrick had a mild to moderate encephalopathy after his DPT, he eventually developed a severe encephalopathy as his seizures worsened. Tr. at 200-02. In sum, DPT caused Derrick's brain injury, infantile spasms and final condition, all of which were affected by the severity of his seizures. Tr. at 191-92.

The basis for his opinion is that a post-vaccinal temperature will generally cause lethargy and irritability for about one day after vaccination. The fever then goes down and these symptoms revert to pre-immunization level. Tr. at 112. However, Derrick did not return to his pre-vaccination level. Id. He experienced a degree of lethargy which is severe for a fever-induced reaction. Id. Moreover, it is unusual for an eight-month-old child to sleep for sixteen hours following DPT. Id. He lost milestones and his muscle tone changed. Tr. at 112. His first EEG showed severe encephalopathy. Id. There was a clear decline in his activity level and mental status after the vaccination. Tr. at 113.

Dr. Valeriano further opined that Derrick's immune or allergic response to DPT caused his seizures. Id. The immune response first manifested itself with fever and encephalopathy, the latter of which subsequently resulted in a loss of cognitive skills. Id. He then developed seizures. Id. Dr. Valeriano explained this opinion in terms of four factors. Firstly, the time course of Derrick's symptomatology was suspicious. Tr. at 114. Derrick had encephalopathy, from which he never really recovered, on the day of the vaccination. Id. Thereafter, he began experiencing infantile spasms. Tr. at 114-15.

Secondly, Dr. Valeriano explained that infantile spasms can be either cryptogenic or symptomatic. Tr. 114-17. Children in the symptomatic category have a known precipitant for infantile spasms because

they are born with a neurological injury which causes abnormal development. Tr. at 114, 119. These children do not respond to ACTH and generally suffer from severe mental retardation and intractable seizure disorders. Id. Children in the cryptogenic category, however, appear normal, developing infantile spasms out of the blue. Tr. at 114-15, 119. These children have a good response to ACTH and can develop normally. Tr. at 114-15. When Derrick first developed seizures he seemed to be in the cryptogenic group; however, his long-term course is consistent with the symptomatic group, i.e., his seizures were caused by a brain injury. Tr. at 116.

Thirdly, although the epidemiologic evidence regarding the causal relationship between DPT and infantile spasms is controversial, other types of injections can cause seizure disorders and severe retardation. Tr. 117. Thus, Dr. Valeriano does not see why the causal relationship with DPT should be any different. Id.

Finally, Derrick was genetically predisposed to having seizures due to his family history. Tr. at 124. Dr. Valeriano believes that people who are predisposed to having seizures also have the highest risk of developing a vaccine-related injury. Tr. at 125.

Dr. Valeriano is suspicious that Derrick's head banging in December was a seizure.(11) Tr. at 151. When questioned about the five-day interlude between Derrick's vaccination and the December episode of head banging, Dr. Valeriano stated that such a time period is not unusual because the nature of a seizure is that it is an electrical disturbance in the brain. Tr. at 129. This disturbance is caused by abnormal electrical discharges which take a certain amount of time to develop before clinical symptoms are exhibited. Id. Regardless of whether his seizures began in December or January, Dr. Valeriano relates the DPT to the seizures because Derrick was continually having neurological problems after vaccination. Tr. at 160. He had a continual impairment of awareness and social interaction, and his motor skills failed to get better after the seizures began. Id. His course followed that of someone with a brain injury. Tr. at 161-62. In symptomatic infantile spasms, the individual often has an initial response to ACTH, similar to how Derrick was seizure-free for eighteen months; however, it is the poor long-term response to ACTH that essentially separates symptomatic children from cryptogenic children. Tr. at 162-63. In the long term, Derrick never bounced back after the vaccination. Tr. at 178.

On cross-examination, Dr. Valeriano admitted that none of his patients is under one year of age. Tr. at 137. Therefore, he does not diagnose infantile spasms when they first present. Id. However, he sees four to five children from five to nine years of age who have had some type of DPT reaction, either infantile spasms or Lennox Gastaut syndrome,(12) within close proximation to vaccination. Tr. at 208-09. Derrick has Lennox Gastaut syndrome because he experiences multiple kinds of seizures. Tr. at 213.

While Dr. Valeriano admitted that lethargy and sleepiness are not necessarily encephalopathic symptoms, he further testified that Derrick's sleeping for sixteen hours is a change in level of consciousness for more than six hours. Tr. at 184, 188. It would be difficult to attribute this amount of sleep to fever because the fever lasted for only a few hours. Tr. at 190. It is also difficult to attribute his sleeping, lethargy, and difficulty awakening to a non-specific viral illness. Id. Rather, these symptoms combined with his subsequent neurological decline, suggest the commencement of an encephalopathic process. Tr. at 190-91.

Dr. Valeriano explained the causal biologic mechanism as the introduction of a foreign substance into the body. Tr. at 215. The immune system is injured either centrally, or in some cases, peripherally, as in Guillain-Barre Syndrome. Id. Vaccines stimulate an immune response. Tr. at 219. Thus, people develop different types of immune-mediated encephalopathy and encephalitis. Tr. at 216. Although Derrick's cerebral spinal fluid was not checked when the encephalopathy first developed, there is evidence that

Derrick had an abnormal immune reaction. Tr. at 216, 220-21. He had an unusually high fever and his sleeping pattern was slightly abnormal. Tr. at 220-21. While fever can trigger infantile spasms in children, infantile spasms need not be accompanied by fever. Tr. at 130-31, 226. When they are, however, accompanied by fever, the fever can make the seizures worse. Tr. at 130-31.

Dr. Valeriano believes that Huntington's chorea played no part in Derrick's problems. Tr. at 109-10. Onset of that disease occurs in one's thirties or forties rather than in infancy. Tr. at 110. In addition, Derrick did not have onset of encephalopathy in utero because he had normal development as a neonate. Tr. at 227.

Dr. Michael Kohrman testified for respondent. He is board-certified in pediatrics and in neurology with an emphasis on child neurology. Tr. at 340. He sees 1500 outpatients under the age of sixteen. Id. He sees fifteen to twenty cases a year of infantile spasms. Tr. at 341. He also sees encephalopathic patients. Id.

His opinion is that Derrick did not have an on-Table encephalopathy or residual seizure disorder. Tr. at 342. The basis for his opinion is that development occurs in steps rather than as a continual process. Tr. at 343. It slows and picks up. Id. Derrick had no focal or diffuse neurologic signs. Tr. at 344. When he presented with seizures, his development was normal in that it was the same as his sister's. Tr. at 342-43. Although he stated that Derrick's mild or moderate encephalopathy was more likely caused by gastroenteritis, he further stated that Derrick did not have an encephalopathy as defined by the Act. Tr. at 365, 386.

Dr. Kohrman attributes Derrick's post-DPT symptoms, i.e., vomiting, diarrhea, and fever, to gastroenteritis because these symptoms are nonspecific to encephalopathy.[(13)] Tr. at 347, 360.

Furthermore, DPT reactions do not consist of vomiting and diarrhea. Tr. at 365-66. He stated that Derrick's stomach was not emptying properly prior to his DPT because he vomited food which he had consumed four hours earlier. Tr. at 366, 368. Thus, a process was occurring, i.e., gastroenteritis, before he received his vaccination, which, in turn, resulted in the above symptoms as well as mild encephalopathy. Tr. at 368. Although Derrick has encephalopathy today, he does not have a significant encephalopathy. Tr. at 369, 373-74.

He further remarked that Derrick's sleeping in a fetal position for sixteen hours was not evidence of a definite encephalopathy.[(14)] Tr. at 346. If he had been encephalopathic, he would have been sleeping flat on his back or front. Tr. at 347-48. When discussing a change in consciousness in terms of encephalopathy, one usually refers to the waking state. Tr. at 348. While being irritable for one week would not imply a change in consciousness, Dr. Kohrman stated that being overall groggy or sleepy for one week would imply an alteration in one's level of consciousness. Tr. at 349.

Although encephalopathy is a nonspecific term for a brain injury, it can be described as a marked change in responsiveness which is characterized by no interaction or smiling, and alterations in motor skills. Tr. at 352, 362. The severity of these symptoms is dependent on the severity of the encephalopathy. Tr. at 352. Although Derrick's illness was consistent with encephalopathy, it was not diagnostic of it, meaning that systemic illness, i.e., gastroenteritis, could produce the symptoms that Derrick had while not causing a central nervous system injury. Tr. at 357. For Derrick's illness to be diagnostic of encephalopathy, either a doctor should have diagnosed it or an EEG should have confirmed it. Tr. at 357-58.

Dr. Kohrman stated that one pathologic process caused Derrick's infantile spasms, but he does not know

what it is. Tr. at 371-72. DPT, however, does not cause infantile spasms. Tr. at 372. Infantile spasms interfered with Derrick's ability to function.[(15)] Tr. at 372-73. Thus, his deficits are due to infantile spasms. Tr. at 373. Dr. Kohrman further stated that Derrick has Lennox Gastaut syndrome, which is a natural sequela of infantile spasms. Tr. at 374.

Derrick was at greater risk for having seizures due to his family history. Tr. at 375. Dr. Kohrman would not put Derrick in the symptomatic group because he does not know the cause of his seizures. Tr. at 377. In cryptogenic infantile spasms, one assumes the cause to be genetic, metabolic, or structural. Tr. at 378. We do not understand all the causes of infantile spasms. Tr. at 382. Epidemiologic analysis, however, suggests that there is no causation between DPT and infantile spasms. Id. In addition, Dr. Kohrman noted that head banging (parasomnia) is not uncommon in young children. Tr. at 364. However, head dropping is more typical of seizures. Tr. at 364.

Derrick did not have birth trauma or other trauma. Id. The onset of his injury was in utero. Tr. at 382-83. Although he believes that gastroenteritis caused the encephalopathy, it is difficult to ascribe causation of the infantile spasms to the encephalopathy because of the short interval of time between the encephalopathy and the onset of infantile spasms if onset occurred December 26th. Tr. at 383-84. In Dr. Kohrman's opinion, Derrick's transient encephalopathy had no neurological consequences. Tr. at 387-88.

On cross-examination, Dr. Kohrman admitted that projectile vomiting can be a sign of increased intracranial pressure. Tr. at 398. Gastroenteritis does not normally include projectile vomiting. Tr. at 400. Derrick's first EEG on January 31, 1983 showed multifocal sharp waves and slow waves, which are typical of hypsarrhythmia, a hallmark of encephalopathy and infantile spasms. Tr. at 401, 405. Loss of milestones does not necessarily mean that a person has a focal neurological disease. Tr. at 407. It could be a focal sign, however, if a child ceases to engage in activities such as crawling or pulling himself up. Tr. at 408. The more activities which stop, the more likely that the child has a neurological injury. Tr. at 408-09. Finally, Dr. Kohrman stated Derrick has a chronic, static encephalopathy secondary to his seizure disorder. Tr. at 413.

DISCUSSION

Petitioners allege that Derrick suffered an on-Table encephalopathy as a result of his DPT vaccination. To determine whether petitioners have proven this allegation, the court must address three questions. Firstly, the court must determine whether petitioners, through affirmative evidence, have proven that Derrick suffered an encephalopathy as defined by the Act within the time limits prescribed by the Act. Upon meeting this burden, petitioners are afforded a presumption of causation. Secondly, the court must determine if Derrick's seizure disorder, i.e., infantile spasms, is a sequela of his encephalopathy. Thirdly, if the court finds that petitioners have proven a Table injury, the court must then analyze whether respondent has rebutted the presumption by proving that a known factor unrelated caused Derrick's encephalopathy.

1. On-Table Encephalopathy

The Vaccine Act defines encephalopathy under a section entitled "Qualifications and aids to interpretation." 42 U.S.C. § 300aa-14(b)(3)(A). Subsection (3)(A) states:

The term "encephalopathy" means any significant acquired abnormality of, or injury to, or impairment of function of the brain. Among the frequent manifestations of encephalopathy are focal and diffuse neurologic signs, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness, with or without convulsions. The neurological signs and symptoms of encephalopathy may be temporary with complete recovery,[(16)] or may result in various degrees of permanent

impairment. Signs and symptoms such as high pitched and unusual screaming, persistent unconsolable [sic] crying, and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of encephalopathy. Encephalopathy usually can be documented by slow wave activity on an electroencephalogram.

While neither medical expert disputes that Derrick had encephalopathy after his DPT, they disagree as to the severity, consequences, and cause of the injury. Dr. Valeriano testifies that Derrick's encephalopathy, which was caused by the DPT, began as mild to moderate, eventually becoming significant due to his seizures. However, Dr. Kohrman testified that the encephalopathy, which was caused by gastroenteritis, was mild. While Dr. Valeriano believes that the encephalopathy led to a loss in milestones, excessive sleeping, and alteration in consciousness and tone, Dr. Kohrman thinks that it had no neurological consequences. Thus, the court must determine whether Derrick experienced an encephalopathy as described by Dr. Valeriano or as described by Dr. Kohrman. While the former allows the court to find that an on-Table injury occurred, the latter fails to meet the criterion dictated by the Act.

The court finds Dr. Valeriano's testimony to be more credible. Firstly, he was Derrick's treating neurologist prior to the commencement of this litigation. Secondly, Dr. Kohrman's opinion failed to explain the fact that Derrick lost milestones. The medical records reflect that Derrick could no longer sit up, crawl, or pull himself to a stand after his DPT. Dr. Kohrman attempted to explain this by opining that a child's development occurs in a stepwise fashion rather than a smooth procession. However, a stepwise increase in attaining milestones is certainly not equivalent to losing completely the milestones that one already had. Thirdly, Derrick experienced projectile vomiting immediately after his DPT. While gastroenteritis does not normally result in projectile vomiting, both neurologists testified that it can indicate central nervous system disturbances.

The court further holds that Derrick's sixteen hours of sleep is certainly an alteration of consciousness beyond the six hours required by the Act. In Riggs v. Secretary, HHS, No. 95-295V, 1998 WL 64115, at *7 (Fed. Cl. 1998), a recent case interpreting the regulations[(17)] changing the definition of encephalopathy, the Honorable James Merow held that a child who slept almost continuously for sixty hours met the regulatory requirement of twenty-four hours of alteration of consciousness for an on-Table encephalopathy. In Riggs, aside from experiencing excessive sleeping, the child fed less than usual, was irritable, and sometimes appeared disengaged . Id. at 2-3. In the instant case, aside from sleeping excessively, Derrick was similarly whiny, irritable, less alert, and fed less than usual. Based on the foregoing, the court finds that Derrick had an on-Table encephalopathy.

2. Sequelae

While the court is convinced that Derrick's encephalopathy meets the statutory definition of encephalopathy, the issue of whether or not a causative link exists between his encephalopathy and seizure disorder remains. It is difficult to pinpoint an exact date for the onset of Derrick's first seizure because the doctors disagreed as to whether or not the head banging of December 26, 1982 was a seizure. However, it is undisputed that Derrick experienced infantile spasms in January 1983. That Mrs. Reitz took Derrick to her pediatrician on January 24, 1983, and to McKeesport Hospital emergency room on January 29, 1983 clearly evidences that his symptoms had worsened since December. In addition, an EEG conducted on January 31, 1983 confirmed the diagnosis of infantile spasms.

The court finds portions of Dr. Kohrman's testimony highly credible. Dr. Kohrman opined that Derrick's entire illness must be attributed to one cause. This makes sense to the court. Therefore, the court finds that all of Derrick's neurological maladies, including his infantile spasms, stem from the same cause of

his encephalopathy, which, with the statutory presumption, is the DPT. Dr. Kohrman further testified that, for a causative relationship to exist between the DPT-encephalopathy and infantile spasms, one must have an onset interval of more than six days, assuming, for the point of his statement, that the December 26th head banging was the onset of the infantile spasms.

But, Dr. Kohrman doubted that the head banging would ever be called neuropathic, and thus, to him, they were not seizures. Both Dr. Valeriano and the records are unclear as to the onset of the infantile spasms until January 1983, which permits the appropriately longer interval between the immunologic insult and onset of spasms to satisfy Dr. Kohrman's views. Therefore, based on Dr. Kohrman's opinion, the court finds that Derrick's seizure disorder was a sequela of his on-Table encephalopathy.

3. Factor Unrelated

Respondent has failed to prove that a known factor unrelated,(18) i.e., gastroenteritis, caused Derrick's encephalopathy. While gastroenteritis is not normally manifested by projectile vomiting, it is accepted as a symptom of a central nervous system problem such as encephalopathy.(19) The court now looks at Derrick's other post-DPT symptoms, analyzing whether or not these symptoms are more likely caused by gastroenteritis or a neurological injury. Although the medical histories that Mrs. Reitz gave to McKeesport and Children's Hospital reflect that Derrick had diarrhea, she denied that he had this. While Dr. Valeriano stated that diarrhea would be an uncommon reaction to vaccination, diarrhea, itself, is a nonspecific symptom. According to Dr. Valeriano, if Derrick had an intercurrent viral illness while he was suffering a vaccine reaction, the intercurrent illness was mild. Certainly, the court cannot attribute Derrick's overwhelming neurological manifestations to a mild gastroenteritis accompanied by transient fever. The presence or absence of diarrhea is, therefore, insignificant to Derrick's neurologic presentation, which manifested itself by projectile vomiting, sleeping sixteen hours, difficulty in arousal, lessened eating, lessened alertness, loss of muscle tone, failure to sit up unassisted, and failure to crawl or climb.

Furthermore, it seems fortuitous that Derrick would have 103 degree fever after his DPT as a result of gastroenteritis rather than as a result of his vaccination. Derrick's other symptoms, i.e., projectile vomiting, sleeping for sixteen hours, and grogginess, are not descriptive of gastroenteritis. Unable to explain this symptomatology, Dr. Kohrman opted for diagnosing an encephalopathy due to the gastroenteritis. This is, frankly, too pat an explanation. Dr. Valeriano's opinion that the fever was an immunologic reaction to the vaccination is more credible than Dr. Kohrman's opinion that it was due to gastroenteritis.

Dr. Kohrman admitted that Derrick's symptomatology was consistent with, but not diagnostic of, encephalopathy. He stated that a doctor's contemporaneous diagnosis as well as confirmation by EEG would be necessary to diagnose Derrick's symptoms as encephalopathy. However, the fact that neither of these objective tests was performed within three days of his DPT should not preclude a finding of on-Table encephalopathy.(20)

The court has the overall impression that Dr. Kohrman's aim was to defeat petitioners' case, regardless of whether his testimony contradicted itself, by opining both for and against a diagnosis of on-Table encephalopathy. While Dr. Kohrman originally opined that Derrick did not suffer an on-Table encephalopathy, he later contradicted himself by stating that Derrick did have an encephalopathy, albeit mild with no neurologic consequences, which was caused by gastroenteritis. As a result, the court is unable to credit that portion of Dr. Kohrman's testimony pertaining to a known factor unrelated.(21)

Petitioners have satisfied their burden of proving that Derrick had an on-Table acute encephalopathy

following his third DPT vaccination, with the sequelae of a seizure disorder arising weeks later, and his current condition of a static, chronic encephalopathy.

CONCLUSION

Petitioners are entitled to a program award. The court hopes that the parties will be able to settle the damages portion of this case and will schedule a status conference in aid of determining damages or encouraging settlement.

IT IS SO ORDERED.

DATE _____ _____

Laura D. Millman

Special Master

1. [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. Respondent objected to petitioners' having satisfied the $1,000.00 requirement four hours into the trial on the merits, even though she failed to raise this issue in any of the eight status conferences the undersigned held with counsel before the hearing.

The court objected to respondent's untimely introduction of this threshold issue, which, if true, would have obviated the expense of a trial on the merits. Respondent replied to the court's objection by pointing to her pretrial memorandum and her initial report in which she included "boilerplate" language of petitioners' burden to prove the $1,000.00 requirement as if that alerted both petitioners' counsel and the court that this was a pending issue. The boilerplate did not so alert either petitioners' counsel or the court. In fact, petitioners' counsel had previously submitted evidence of the $1,000.00 requirement without specific objection from respondent's counsel.

Although respondent's raising the $1,000.00 issue was unjustifiably tardy, the court ordered petitioners' counsel to provide additional evidence after the trial, which he did. The court then issued an Order to respondent's counsel that if the subsequent evidence of $1,000.00 were inadequate, she would file her objections by January 9, 1998 or the court would consider her objections waived. Respondent never filed any objections by January 9, 1998. During summations on January 22, 1998, respondent's counsel again raised objections to petitioners' meeting the $1,000.00 requirement. Pursuant to this court's Order, the court holds that respondent has waived the issue.

3. This is erroneous since he had three DPT vaccinations before admission.

4. This should state "third."

5. The record also noted that the day after his vaccination, he experienced vomiting and fever, which was followed by diarrhea. Med. recs. at Ex. 7, p. 12.

6. Although Mrs. Reitz remembers that there was a period of fussiness due to the Similac and a diaper rash, she does not recall Derrick having crying spells as a baby. Tr. at 252-53.

7. This was the first time he had ever vomited. Tr. at 36.

8. Mrs. Reitz was questioned about some of the histories in the medical records, which include post-DPT symptoms such as fever, constipation and diarrhea. Tr. at 54. She testified that Derrick did not have diarrhea after DPT. Id. She also testified that she believed Derrick was experiencing constipation when he started to pull his knees to his chest on approximately December 26, 1982. Tr. at 54-55.

9. Dr. Silberman was Derrick's pediatrician during this time. Tr. at 37.

10. Although Dr. Valeriano had written a letter to petitioners' counsel stating that Derrick had leukoencephalopathy, he testified that he believes the more accurate diagnosis is that Derrick had an encephalopathy because Derrick's CT scan and MRIs were normal. Tr. at 146-47. Leukoencephalopathy is a disease of the white matter in the brain. Tr. at 146.

11. Regardless of whether his head banging was behavioral or a seizure, Dr. Valeriano believes that it was an expression of a brain injury. Tr. at 236.

12. Lennox Gastaut syndrome is a variant of infantile spasms occurring in children over one year of age. Tr. at 209.

13. The symptoms of gastroenteritis last three to ten days depending on the individual. Tr. at 359.

14. On cross-examination, he stated that it was not physically possible for a child to be motionless for sixteen hours without being comatose. Tr. at 422-23.

15. When these seizures are controlled, one's function returns. Tr. at 372-73.

16. As described under Section 14, one would presume that an encephalopathy, which is temporary with complete recovery, would not be compensable pursuant to the Act in contradistinction to an encephalopathy which results in permanent impairment.

17. 42 C.F.R. §100.3 (1995), particularly §100.3(b)(2)(I)(A).

18. 42 U.S.C. §300aa-13(a)(1)(B), and (2).

19. Respondent's expert also stated that the cause of Derrick's infantile spasms occurred in utero. This, however, was pure supposition on Dr. Kohrman's part. In testifying further, he could not give a cause of Derrick's infantile spasms, putting them in the cryptogenic group.

20. In addition, Dr. Kohrman testified that Derrick was more susceptible to having a seizure disorder because of his family background. This fact is further confirmation of the linkage between the DPT-induced encephalopathy and the onset of infantile spasms weeks later.

21. However, as discussed supra, the court finds him credible on the community standard of finding one cause for a neuropathy, and on the necessity of having an interval of weeks, rather than days, between the insult and the onset of infantile spasms in order to make a causative link.