OFFICE OF THE SPECIAL MASTERS
February 2, 1998

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FRANK and LISA O'CONNELL as legal	*	
representatives of their daughter,	*	
KELLI-ANN O'CONNELL,	*	
	*	
Petitioners,	*	
	*	
vs.	*	No. 96-63V
	*	PUBLISHED
SECRETARY OF THE DEPARTMENT	*	
OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
* *	*	

Brian A. O'Connell, Wellesley, MA, for petitioners.

Kate Adam Coleman, Washington, DC, for respondent.

DECISION AND ORDER

MILLMAN, Special Master

On February 5, 1996, Frank and Lisa O'Connell, on behalf of their daughter, Kelli-Ann O'Connell (hereinafter "Kelli-Ann"), filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986[(1)] (hereinafter the "Vaccine Act" or the "Act"). Pursuant to 42 U.S.C. § 300aa-11(c), petitioners have satisfied the requirements for a prima facie case 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) the DPT vaccination was administered to Kelli-Ann in the United States and, (3) they have incurred $1,000.00 in unreimbursable medical expenses prior to filing the petition.

Petitioners allege a causation-in-fact seizure disorder and encephalopathy following DPT. 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I).[(2)] Respondent denies that DPT caused in fact Kelli-Ann's onset of seizures, seizure disorder, or encephalopathy.

The court held a hearing in this case on July 24, 1997. Testifying for petitioners were Lisa O'Connell and Dr. Marcel Kinsbourne. Testifying for respondent was Dr. Gerald M. Fenichel.

FACTS

Kelli-Ann was born on October 10, 1992. Petition at p.1. She received her first DPT vaccination on December 10, 1992 when she was two months old. Med. recs. at Ex. 7, p.1. She received her second DPT vaccination on February 9, 1993 when she was four months old. Id.

On February 10, 1993, Kelli-Ann visited her pediatrician, Dr. Rekha Bains, with a complaint of decreased appetite, and brief, involuntary shaking of her left arm and right leg, amounting to twelve to thirty twitches. Med. recs. at Ex. 7, p. 4.

Subsequent to this visit, she was taken to Lowell General Hospital with a similar complaint. Med. recs. at Ex. 1, p. 4. A history taken at the hospital reflects that Kelli-Ann had twitching of her arms and legs since approximately 12:30 p.m on February 10, 1993. Med. recs. at Ex. 1, p. 4. The history further noted that she experienced mild twitching in her left arm and right leg two to three times on the day before she received her DPT.[(3)] Id. There was no record of fever. Id. She fed well in the morning of February 10, 1993; however, she was irritable and did not eat well since noon. Id. She experienced involuntary shaking, akin to tremors, which affected all four limbs, particularly her left arm and right leg. Med. recs. at Ex. 1, p. 4. On the way home from her visit with Dr. Bains, she again experienced jerking movements which were accompanied by mild movements of the jaw. Id. During these episodes, her eyes did not roll up nor did she have staring spells. Id. She did not vomit. Id.

A physical examination described Kelli-Ann as a playful, active child who appeared bright and alert. Id. She had normal tone and posture but was irritable. Med. recs. at Ex. 1, p. 4. She had mild nasal congestion, and her tympanic membranes were inflamed. Id. A nursing note reflects that she was alert, happy, and awake with a temperature of 100 degrees. Med. recs. at Ex. 1, p. 22.

A pediatric nursing assessment, recorded on February 10, 1993, stated that Kelli-Ann was alert, happy, and pale, with a good grasp and flat fontanelle. Med. recs. at Ex. 1, p. 20. At 6:00 p.m., she was playful, smiling, and fed well. Med. recs. at Ex. 1, p. 8. She was described as a well-looking baby. Id. However, at 7:30 p.m., Kelli-Ann was fussy and flushed, with a temperature of 101.4 degrees. Med. recs. at Ex. 1, p. 22. At 7:45 p.m., she experienced jerking of the right arm and leg, which lasted for two seconds. Id. She did not change color or have respiratory distress. Med. recs. at Ex. 1, p. 22. After this jerking episode, she started to fall asleep. Id. At 10:30 p.m., Kelli-Ann had jerking movements again. Med. recs. at Ex. 1, p. 8. Her temperature was 101.5 degrees, but she was still bright-eyed and playful. Id.

On February 11, 1993, Kelli-Ann's left arm was tremulous and she had a glassy look momentarily with pallor. Med. recs. at Ex. 1, p. 8. There was no jerking. Id. On examination, she was playful. Id. A sleep EEG was normal. Med. recs. at Ex. 1, p. 11. She was discharged home with fever control to be performed with Tylenol and Amoxicillin for a possible urinary tract infection. Med. recs. at Ex. 1, p. 8. In view of a strong family history of febrile convulsions, she was to be put on Tylenol. Id.

Kelli-Ann returned to the Lowell General Hospital Emergency Room (ER) on February 13, 1993 with a diaper rash. Med. recs. at Ex. 1, p. 25. She had been on Amoxicillin for several days, and she had received intramuscular antibiotics earlier that week for a febrile seizure. Id.

On February 17, 1993, Kelli-Ann returned to the Lowell General Hospital ER with a complaint of a generalized seizure. Med. recs. at Ex. 1, p. 30. She had a minor seizure involving her right arm and right leg that morning. Id. She had had a temperature of 100.3 degrees and a decreased appetite. Id. In the past two days, she had been very cranky and her spitting up had increased. Med. recs. at Ex. 1, p. 30. She had been unwell since the prior week when she experienced tremors in her left arm and right leg. Id. The history given further noted that her cousin had been on Phenobarbital for seizures and she had a paternal grandfather with febrile seizures. Id. Although her urinalysis showed an increase in white blood cells, no

abnormality was found when she was examined in the office. Id.

While in the ER, Kelli-Ann had a generalized tonic-clonic convulsion during which her eyes rolled up and her pupils dilated. Id. Her temperature was 100.5 degrees and her vital signs were stable. Id. She had a whitish nasal discharge and noisy respiration. Id. Her seizure stopped spontaneously. Id. The doctor's impression was a prolonged generalized seizure lasting one hour and ten minutes. Id. It was noted that Kelli-Ann's mother had had two generalized seizures of unknown etiology. Med. recs. at Ex. 1, p. 34.

On February 17, 1993, Kelli-Ann was also taken to Massachusetts General Hospital. Med. recs. at Ex. 3, p. 1. The medical records indicate that Kelli-Ann was easily aroused from sleep and had good tone. Med. recs. at Ex. 3, p. 7. She had had explosive diarrheal stools six or seven times. Med. recs. at Ex. 3, p. 20. The impression was that her seizures were probably related to uremia.[(4)] Id. The history given by Mrs. O'Connell reveals that she had had two seizures in her teens. Med. recs. at Ex. 3, p. 4. In addition, Kelli-Ann's first cousin was treated with Phenobarbital for febrile seizures while her paternal grandfather had a seizure disorder during childhood. Id. A maternal grandmother had a benign brain tumor. Id.

On February 28, 1993, Kelli-Ann returned to the Lowell General Hospital ER with a complaint of approximately ten brief, two, three, and twenty second seizures. Med. recs. at Ex. 1, p. 36. Upon admittance to the hospital, she was active, playful, smiling, afebrile, and moving all extremities. Id.

On March 4, 1993, she was taken to the Lowell General Hospital ER to have her Phenobarbital level checked. Med. recs. at Ex. 1, p. 40. She returned the next day due to tonsillitis. Med. recs. at Ex. 1, p. 43. On March 9, 1993, she returned because of a seizure. Med. recs. at Ex. 1, p. 45. However, she was without distress, appeared well, and smiled during this visit. Id.

From March 10 to 11, 1993, Kelli-Ann was in Lowell General Hospital because of seizure activity. Med. recs. at Ex. 1, p. 50. Upon admittance, her fontanelle was flat, her color pink, and she was alert, happy, and smiling. Med. recs. at Ex. 1, p. 64. The history given reflects that she had an increase in seizure activity on May 9, 1993. Med. recs. at Ex. 1, p. 53. She was also agitated and irritable. Id. Her seizures consisted of a sudden jerking of her arms and legs as well as a sudden darting of her eyes. Id. She remained awake through these episodes. Id. Before the seizures began, she would become irritable, and jerk and arch her back. Id. The medical records describe her as afebrile, alert, hyperactive, and babbling loudly. Id. She had increased flailing of her arms. Med. recs. at Ex. 1, p. 55. Five days prior to this hospitalization, she was seen in the office because of a mild fever, and ulcerative pharyngitis. Id. A throat culture showed streptococcus pneumonia. Id. Two EEGs were normal. Id. A family history of febrile seizures in a first cousin was again given. Id.

On March 24, 1993, Kelli-Ann returned to Lowell General Hospital for seizures. Med. recs. at Ex. 1, p. 71. She went back five days later to have her Depakote level checked. Med. recs. at Ex. 1, p. 77. She returned on April 1, 7, 23 and May 2, 1993 for seizures. Med. recs. at Ex. 1, pp. 80, 83, 86, & 91.

On May 6, 1993, she saw Dr. Elizabeth C. Dooling, a pediatric neurologist at Massachusetts General Hospital, who diagnosed benign myoclonic seizures of infancy. Med. recs. at Ex. 5, p. 3.

On August 2, 1993, Kelli-Ann saw Dr. James J. Riviello, Jr., a neurologist with the Childhood Epilepsy Program at Children's Hospital. Med. recs. at Ex. 2, p. 75. The history given to Dr. Riviello reflects that Kelli-Ann had her first seizure the day after receiving her DPT. Id. This seizure was accompanied by a slight temperature of 100-101 degrees. Id. She experienced several other generalized seizures throughout the next twenty-four hours. Id. She had a normal EEG, and a normal head ultrasound. Id. One week

later, she had a ninety-minute generalized, tonic-clonic seizure with a 100.5 degree fever. Id. Although she did not experience alteration of awareness during this seizure, she did get quiet after the event. Med. recs. at Ex. 2, p. 76. There has not been any regression in her intellectual or motor milestones with the exception of a slight regression when she began taking Phenobarbital. Id. On physical examination, she had a sloping forehead, protruding left ear, and hypertelorism.(5) Med. recs. at Ex. 2, p. 77. On neurological examination, she was alert, responsive, and social. Id.

On August 6, 1993, Kelli-Ann went to the Clinical Neurophysiology Lab to have her median nerve somatosensory evoked potential tested. Med. recs. at Ex. 2, p. 106. She had dysfunction in the cortical portion of the median nerve somatosensory pathway bilaterally. Id. On August 10, 1993, Kelli-Ann underwent an MRI, which showed that her left temporal lobe appeared smaller than her right, and her myelinization(6) was borderline normal. Med. recs. at Ex. 2, p. 85.

On August 11, 1993, Kelli-Ann saw Drs. Uri Kramer and Gregory Holmes, who noted that the ninety-minute seizure was the only one that she had during which she was unconscious. Med. recs. at Ex. 2, p. 107. Two EEGs revealed right posterior slowing. Med. recs. at Ex. 2, pp. 107-08. Her development was normal. Med. recs. at Ex. 2, p. 109. Drs. Kramer and Holmes diagnosed Kelli-Ann as having benign myoclonic epilepsy of infancy. Med. recs. at Ex. 2, pp. 108-09.

From November 18-23, 1993, Kelli-Ann was at Children's Hospital due to increasing seizures. Med. recs. at Ex. 2, p. 138. Dr. Riviello wrote that she had a normal level of alertness. Med. recs. at Ex. 2, p. 139. He believed that she still had benign myoclonic epilepsy of infancy. Med. recs. at Ex. 2, p. 140. Although Mrs. O'Connell questioned whether there was a regression in speech, Dr. Riviello noted that Kelli-Ann continued to gain motor milestones and her physical exam revealed an alert, responsive and social child. Med. recs. at Ex. 2, p. 277.

On April 15, 1994, Kelli-Ann saw Dr. Mark Korson at Children's Hospital metabolism service. Med. recs. at Ex. 7, p. 79. In a letter dated April 18, 1994, he opined that she had a possible metabolic disorder, suggesting that testing be conducted to determine whether such was mitochondrial. Med. recs. at Ex. 7, pp. 79, 83.

On July 13, 1994, Kelli-Ann saw Dr. Frederick Andermann, a pediatric neurologist at McGill University, who noted that it was difficult to be certain whether Kelli-Ann's condition was related to DPT. Med. recs. at Ex. 4, p. 2. He diagnosed myoclonic epilepsy. Med. recs. at Ex. 4, p. 1.

TESTIMONY

Mrs. Lisa O'Connell testified first for petitioners. Kelli-Ann received her first DPT vaccination on December 10, 1992. Tr. at 10. She did not experience any problems after the vaccination; however, in December 1992, she did suffer from an ear infection, which was accompanied by a 100 degree fever.(7) Tr. at 9-10.

Kelli-Ann received her second DPT at approximately noon on February 9, 1993. Tr. at 10. On February 10, 1993, between 10:00 a.m. and 11:00 a.m., her arm jerked. Tr. at 10-11. At approximately 12:30 p.m., this jerking recurred; however, this time it included both arms and legs. Tr. at 11. These jerking motions lasted from seconds to over one-half hour. Id. During the half-hour seizure, Mrs. O'Connell could not rouse Kelli-Ann. Tr. at 13. She seemed asleep. Id. Subsequent seizures occurred at 4:00 p.m. and 8:00 p.m. Tr. at 11-12. During the 8:00 p.m. seizure, which was the last episode of that day, Kelli-Ann had a fever of 101 degrees. Tr. at 11-12, 15. Mrs. O'Connell did not, however, remember if Kelli-Ann was warm during the earlier episodes. Tr. at 15-16. Her whole body jerked that night. Tr. at 17. Kelli-Ann never received her third DPT. Tr. at 19.

Mrs. O'Connell further testified that there was a family history of seizure activity. Tr. at 19-21. Kelli-Ann's cousin had had a febrile seizure while Mrs. O'Connell, herself, had two grand mal, afebrile seizures while in high school, which caused her to be on Dilantin for one week. Id. In addition, a maternal second cousin had seizures as a child and a paternal cousin suffered from febrile seizures. Tr. at 20. Kelli-Ann's paternal grandfather also had seizures as a child. Id.

On February 17, 1993, Kelli-Ann had numerous brief seizures. Tr. at 21. She had one ninety minute seizure during which she was unconscious. Tr. at 22-23. In early March 1993, seizures became a daily event, with the majority taking the form of myoclonic jerks. Tr. at 26. Kelli-Ann's development seemed fine for a year after her seizures began. Tr. at 31. However, between January and February 1994, Kelli-Ann's seizures increased and she experienced real regression. Id. She regains the skills that she loses but continues to progress very slowly. Id. Although she first walked at three years of age, she cannot presently climb stairs or run. Tr. at 32-33. Her language skills improved after her first Early Intervention at eight months. Tr. at 32. However, rather than using sentences, she babbles. Tr. at 32-33. She is not toilet-trained. Tr. at 34. She attends preschool and is a very social and happy child. Id.

Although Kelli-Ann has experienced both afebrile and febrile seizures, she has not had infantile spasms. Id. She has also had seizures where her head drops and she bends at the waist. Tr. at 33. No etiology for her seizures has ever been given. Tr. at 38.

Dr. Marcel Kinsbourne, a pediatric neurologist, testified next for petitioners. He diagnosed Kelli-Ann as having a severe myoclonic seizure disorder, a degree of developmental delay, and encephalopathy. Tr. at 63. These conditions were caused in fact by her second DPT. Id. The onset of her encephalopathy occurred on February 10, 1993 and was reflected by the extended, repeated seizures that she experienced. Id. Thus, for Dr. Kinsbourne, the onset of seizures was the same time as the onset of encephalopathy. Tr. at 63-64, 66.

Dr. Kinsbourne stated that Kelli-Ann had three generalized seizures in twenty-four hours. Tr. at 64. During generalized seizures, patients are always unconscious. Id. He further opined that Kelli-Ann had status epilepticus within twenty-four hours of her DPT. Tr. at 68. Dr. Kinsbourne defined status epilepticus as either a seizure which lasts for more than one-half hour or multiple, repeated seizure episodes which occur over brief periods of time. Id.

The basis of his opinion rested on the fact that Kelli-Ann was a totally normal child who was in an ominous seizure state within twenty-four hours of receiving DPT. Tr. at 69. This toxic occurrence caused Kelli-Ann to become a totally different child from what she was prior to the DPT. Id.

Dr. Kinsbourne testified that it is normally conceded that DPT can cause generalized convulsions, and an acute encephalopathy. Tr. at 70-71. The fact that DPT can cause these conditions, thus, implies that a mechanism is at work. Tr. at 71. According to Dr. Kinsbourne, the National Childhood Encephalopathy Study (NCES)[(8)] discussed the biological plausibility of the causal link between DPT and seizures and encephalopathy. Id.

Dr. Kinsbourne favors a particular mechanism of causation. Id. Pertussis vaccine contains pertussis toxin (exotoxin) and endotoxin[(9)]. Tr. at 71-72. The pertussis toxin and the endotoxin are both absorbed into the blood stream after vaccination. Tr. at 73. The endotoxin can have multiple effects, such as an increase in the permeability of the small blood vessels[(10)] and, in rare cases, an increase in the permeability of the blood-brain barrier. Id. Pertussis toxin also has potent effects on the functioning of neurons. Tr. at 74. The G proteins instruct the neurons in intercellular and intracellular functioning. Id. Pertussis toxin blocks the activity of the G proteins. Id. As such, the neurons either fire in excess or not

at all. Id. Inhibitory neurons stop functioning, leaving other neurons to function excessively. Tr. at 74-75.

Dr. Kinsbourne testified that only non-specific clinical symptoms, such as seizures or change in level of consciousness, manifest while these processes occur. Tr. at 75-76. By merely describing these symptoms, one could not deduce the cause of such symptoms from the symptoms themselves. Tr. at 76. Furthermore, these processes could occur without the presence of symptoms, like inconsolable screaming and fever. Tr. at 77. Dr. Kinsbourne does not emphasize screaming or fever in his diagnosis of the neurological effects of DPT because the vaccine, itself, is painful and hurts the child. Id. Oftentimes, the vaccine site is red and swollen. Id. As such, the common screaming which results due to this pain cannot be distinguished from the less common encephalopathic screaming. Id. The same reasoning applies to fever. Id. Since fever is a common reaction to vaccination, it, alone, does not indicate neurological damage. Id. Thus, Dr. Kinsbourne found the fact that Kelli-Ann was afebrile during her first seizure to be irrelevant. Tr. at 69-70.

Seizure disorders in infancy have many causes, one of which is DPT. Tr. at 118. Dr. Kinsbourne diagnosed Kelli-Ann as having severe myoclonic epilepsy, opining that her seizure disorder began explosively with multiple seizures, and myoclonus.[(11)] Tr. at 78, 83-84. He has not, however, seen any progression of encephalopathy in Kelli-Ann. Tr. at 119. Although the mechanism of damage from seizures is unknown, they are regularly associated with flattening out of development. Tr. at 82. Kelli-Ann took one year to show substantial developmental delay. Tr. at 81-82. While the rate at which she acquired skills was flattened, it was also punctuated with actual, temporary loss of skills when her seizures increased. Tr. at 82. A lot of seizure activity disturbs computation of the brain while anti-convulsants depress mental function. Id. The large amount of seizure activity as well as the use of anti-convulsants can explain Kelli-Ann's loss and retention of skills; however, Dr. Kinsbourne stated that her developmental delay is due primarily to her seizures. Tr. at 82-83.

Dr. Kinsbourne thought that Kelli-Ann's family history of seizures was irrelevant. Tr. at 86. The family's history of grand mal seizures is different than the type of seizures she experiences. Id. Kelli-Ann's seizures are predominantly myoclonic. Id. Dr. Kinsbourne also found fever to be irrelevant in Kelli-Ann's case because she did not present with convulsions.[(12)] Tr. at 86-87. Rather, she presented with myoclonus, which is epilepsy with or without fever. Id. She had an absolutely focal onset. Tr. at 89.

Dr. Kinsbourne noted that the fact that Kelli-Ann suffered status epilepticus the day after her DPT was significant in that it reflected the seriousness of her condition, and allowed her to meet the criteria of the NCES. Tr. at 95-96. He further testified that Kelli-Ann satisfies the NCES criteria because: (1) she had more than one seizure, (2) the seizure was longer than one-half hour and, (3) the seizures were focal. Tr. at 133. She had a spectrum of seizures in the first twenty-four hours which included jerks affecting one limb for a short period, jerks affecting limbs on the same side, jerks affecting opposite limbs, jerks affecting all four extremities, and an episode of glazed, staring eyes. Tr. at 134.

On cross-examination, Dr. Kinsbourne admitted that his basis for concluding that DPT caused Kelli-Ann's seizures and encephalopathy is not solely the breach of the blood-brain barrier. Tr. at 124. Dr. Kinsbourne testified that he did not know of any literature which discusses this theory. Tr. at 126. Although he is uncertain whether the blood-brain barrier theory is the mechanism which causes neurological events after vaccination, he stated that it is a biologically plausible theory. Id. However, there is no clinical way to determine if the blood-brain barrier is breached. Tr. at 131.

When challenged to find the one-half hour seizure in the records, Dr. Kinsbourne stated that it did not matter whether such seizure was generalized. Tr. at 136-38. He opined that having as many seizures

over twenty-four hours as Kelli-Ann experienced constitutes status epilepticus, which is serious, neurological illness. Tr. at 139. He found no significance in the fact that Kelli-Ann's tympanic membranes were inflamed, stating that such diagnosis was subjective. Tr. at 141. He further noted that a child with a serious, acute neurological illness can still be alert, and have a normal EEG. Id. Even if one is suffering from a toxic insult, which causes a neurological illness, the EEG can be normal depending on what part of the brain is damaged. Tr. at 141-42. Although exactly what portion of Kelli-Ann's brain is damaged is unknown, Dr. Kinsbourne testified that she experienced myoclonus, which arose from somewhere deep in her brain. Tr. at 142-43.

In Dr. Kinsbourne's opinion, timing is critical to his opinion on causation. Tr. at 146. Acute neurological damage from pertussis occurs within seventy-two hours. Tr. at 147. The largest number of reactions occurs within twenty-four hours of vaccination. Id. He admitted that there is no medical literature that associates DPT and myoclonic seizures. Tr. at 150.

Dr. Gerald Fenichel, a pediatric neurologist, testified for respondent. His opinion is that DPT did not cause Kelli-Ann's seizures. Tr. at 154. Rather, Kelli-Ann has progressive myoclonic epilepsy. Tr. at 156. Although she did not have a serious, acute encephalopathy the day after she received DPT, he does not know if she has a progressive encephalopathy.[(13)] Tr. at 154-55. Her seizure disorder progressed, during which time her seizures caused her brain to become worse. Tr. at 155.

The cause of most myoclonic encephalopathies as well as the mechanism for how DPT can produce encephalopathy is unknown. Id. at 156-58. Even without understanding the mechanism, Dr. Fenichel can accept causation when a child receives a DPT, develops a serious, acute neurological disorder within three days, and then is left with a chronic neurological disorder. Tr. at 158, 184. DPT can cause acute, serious neurological illness; however, not all acute, serious neurological illnesses are encephalopathy. Tr. at 188-89. Because Kelli-Ann was awake, alert, playful, and had a normal EEG, Dr. Fenichel found it incomprehensible for her to have had an acute, serious neurological disorder the day after the DPT vaccination. Tr. at 158-59. Moreover, she would not have been included in the NCES because she was discharged from the hospital the next day, and no one in the NCES was discharged after one day. Tr. at 159.

Dr. Fenichel defined "myoclonus" as a sudden, jerking movement that results: (1) from a seizure, (2) during sleep, or (3) from a movement disorder which is not a seizure. Id. Regardless of the cause, these jerks look the same. Tr. at 160. He defined status epilepticus as either twenty to thirty minutes of continuous seizure or repeated seizures that occur without recovery to normal function between each episode. Tr. at 165. The medical records are devoid of evidence that Kelli-Ann had status epilepticus. Tr. at 166. Dr. Fenichel noted that she could not have been awake when she reached the hospital if she had had twenty minutes of generalized tonic-clonic convulsions in the car. Id. Moreover, having multi-focal seizures while being bright and alert is inconsistent with status epilepticus. Tr. at 168. Finally, while most status epilepticus has a known cause, Dr. Fenichel does not know the cause of Kelli-Ann's seizure disorder. Tr. at 161-63.

Dr. Fenichel testified that his opinion would not change regardless of the fact the Dr. Bains' record incorrectly stated that Kelli-Ann experienced twitching prior to her DPT.[(14)] Tr. at 172. Kelli-Ann had twitching or myoclonic seizures on February 10 and 11, 1993. Tr. at 173. The hospital did not diagnose her as having epilepsy at the time of admission. Tr. at 174-75. Her family has a genetic, underlying benign epilepsy which is temporary. Tr. at 175.

Dr. Fenichel admitted that Kelli-Ann has a seizure disorder. Tr. at 176. While he would not use the term encephalopathy to describe her condition, he admits that something is wrong with her brain. Id. DPT

does not cause chronic encephalopathy; however, DPT may cause acute encephalopathy, followed by a chronic course. Tr. at 177. Although Kelli-Ann developed a very serious neurological illness, the onset did not occur on the same day as her seizures. Tr. at 178. She did not have a seizure lasting thirty minutes on the day following her DPT. Id. Rather, she had migrating multi-focal seizures which came and went during the twenty-four hours after her DPT. Tr. at 178-79. Dr. Fenichel noted that Kelli-Ann did not have a febrile seizure. Tr. at 181. However, he has never seen migratory multi-focal, myoclonic seizures with fever and finds the presence of fever to be irrelevant to his opinion.[(15)] Tr. at 182, 193.

With regard to Mrs. O'Connell's recitation of the factual events involved in this case, Dr. Fenichel stated that most parents are disturbed when their children have seizures and their recollections are not always perfect. Tr. at 180. Records created closer in time to the incident are generally more accurate than those created later in time. Tr. at 180-81.

DISCUSSION

A. Encephalopathy

Petitioners allege that Kelli-Ann suffered an acute encephalopathy which was caused in fact by her DPT vaccination. 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." See Grant v. Secretary, HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992); Agarwsal v. Secretary, HHS, 33 Fed. Cl. 482, 487 (1995); see also Knudsen v. Secretary, HHS, 35 F.3d 543, 548 (Fed. Cir. 1994); Daubert v. Merrell Dow Pharmaceuticals, 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." Grant, supra, 956 F.2d at 1149.

Mrs. O'Connell testified that Kelli-Ann had a seizure which lasted for one-half hour on February 10, 1993 during which she was unconscious; however, this testimony is totally unsubstantiated by the multiple histories she gave to doctors on that day and during later visits. Well-established case law holds that information in contemporary medical records is more believable than that produced years later at trial. United States v. United States Gypsum Co., 333 U.S. 364, 396 (1948); Burns v. Secretary, HHS, 3 F.3d 415 (Fed. Cir. 1993); Ware v. Secretary, HHS, 28 Fed. Cl. 716, 719 (1993); Estate of Arrowood v. Secretary, HHS, 28 Fed. Cl. 453 (1993); Murphy v. Secretary, HHS, 23 Cl. Ct. 726, 733 (1991), aff'd, 968 F.2d 1226 (Fed. Cir.), cert. denied sub nom. Murphy v. Sullivan, 113 S. Ct. 263 (1992); Montgomery Coca-Cola Bottling Co. v. United States, 615 F.2d 1318, 1328 (1980). Contemporaneous medical records are considered trustworthy because they contain information necessary to make diagnoses and determine appropriate treatment. Cucuras v. Secretary, HHS, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.

Id.

A review of the histories that Mrs. O'Connell gave reflects the following. On February 10, 1993, the day the seizures began, Mrs. O'Connell told Dr. Bains that Kelli-Ann had had twelve to thirty twitches, i.e., brief, involuntary shaking. Med. recs. at Ex. 7, p. 4. However, a medical record from Lowell General Hospital, also recorded on February 10, 1993, notes that Kelli-Ann experienced brief seizures. Med.

recs. at Ex. 1, p. 4. One week later, the Lowell General Hospital ER Record reflects that Kelli-Ann had a one hour and ten minute seizure. Med. recs. at Ex. 1, p. 30. On August 2, 1993, Mrs. O'Connell told Dr. Riviello that Kelli-Ann had a ninety-minute seizure one week after her DPT. Med. recs. at Ex. 2, p. 75. On August 11, 1993, she told Drs. Kramer and Holmes that the ninety-minute seizure was the only seizure during which Kelli-Ann lost consciousness. Med. recs. at Ex. 2, p. 107.

While these histories describe a variety of events during the twenty-four hours after Kelli-Ann's DPT, there is no mention of the thirty-minute seizure about which Mrs. O'Connell testified. The court must conclude that Kelli-Ann did not suffer a seizure of thirty minutes or longer or lose consciousness during the twenty-four hours after her DPT. Accordingly, the court further finds that she did not have status epilepticus during this time. Based on these histories, the court does, however, conclude that Kelli-Ann experienced multiple, short jerks and twitches after her DPT.

Without an alteration in consciousness, Kelli-Ann's encephalopathy, as defined by Dr. Kinsbourne, means merely that her brain is abnormal. Otherwise, it is difficult to see why anyone would diagnose a smiling, alert, happy, playful, and responsive child as encephalopathic. But, it is unreasonable to believe that the doctors who treated Kelli-Ann somehow missed diagnosing her as having encephalopathy. They did not make this diagnosis because she did not have encephalopathic symptoms. Dr. Kinsbourne's diagnosis of encephalopathy is unpersuasive to the court because it rests on events that the court finds did not occur (seizing for more than thirty minutes and losing consciousness within twenty-four hours of DPT) and extends the meaning of encephalopathy so generally (an abnormal brain) as to be meaningless.

The court does not accept Dr. Kinsbourne's thesis that anyone who seizes has an encephalopathy or, at least, an acute encephalopathy. Certainly, there would be ample medical justification for supposing that someone born with a chronic encephalopathy could begin seizing at any time. This, however, is not petitioners' allegation. Rather, they allege, inter alia, that Kelli-Ann had an acute encephalopathy one day after her DPT at the same time she began seizing.

Based on the foregoing, petitioners have not satisfied their burden of proving that Kelli-Ann had an acute encephalopathy within seventy-two hours of her receipt of DPT. Since seventy-two hours is the outer limit to which Dr. Kinsbourne will go in diagnosing a DPT-induced acute encephalopathy, petitioners have failed to satisfy their burden of proving that DPT caused Kelli-Ann to have encephalopathy.[(16)]

B. Seizure Disorder

Petitioners have also alleged that Kelli-Ann's DPT vaccination was the cause in fact of her seizure disorder.

This court has previously held that DPT vaccine can cause a fever which in turn causes the onset of a seizure disorder. McMurry v. Secretary, HHS, No. 95-682V, 1997 WL 402407 (Fed. Cl. Spec. Mstr. July 27, 1997). In McMurry, petitioners similarly alleged a causation in fact seizure disorder.[(17)] Id. at *1. In that case, the child had a high fever and seized for fifty or more minutes following her DPT. Id. at *1-2. In addition, she was unresponsive and in status epilepticus. Id. Based on the occurrence of the fever as well as the onset of severe seizures, the court held for petitioners. McMurry, supra, at *8-9.

McMurry and this case are easily distinguished based on the vaccinees' symptomatology. In this case, Kelli-Ann did not have a fever during her initial seizures. Rather, she had a fever only after she had been brought to the hospital. Moreover, the court does not believe that she had status epilepticus during the

twenty-four hours after her DPT. Her seizures were twitches and she never lost conciousness. Based on this lack of severity of symptoms, petitioners in the instant action clearly have a more difficult causation in fact case to prove than did the petitioners in McMurry.[(18)]

Dr. Kinsbourne posited a logical sequence of cause and effect, which relied partly on timing, and partly on a biologically plausible theory, ie., the breaching of the blood-brain barrier.[(19)] While he opined that there would be no clinical symptoms of such an immunological affront to the system, the court has previously held that post-DPT symptoms of extreme irritability, anorexia, and insomnia, followed by lethargy and death, are evidence of a DPT toxic effect on a vaccinee. Misenko v. Secretary, HHS, No. 92-0013V, 1995 WL 761436, at *14-15 (Fed. Cl. Spec. Mstr. Dec. 7, 1995). However, Kelli-Ann did not experience any of these symptoms. Although the initial seizures eventually followed a path of intractability and developmental delay, a happy, functional, responsive, playful, and alert child is simply not experiencing a serious, acute neurological illness.

The court's recent Omnibus decision in Barnes v. Secretary, HHS, et al., No. 92-0032V, 1997 WL 620115 (Fed. Cl. Spec. Mstr. Sept. 15, 1997), which essentially addresses respondent's burden of proof with respect to a factor unrelated defense in a signifigant aggravation context, is also helpful in analyzing whether petitioners herein have met their causation in fact burden. Petitioners in Barnes did not have the burden of proving that DPT caused their children's onset of seizures since these were Table injuries. Id. at *33. Respondent had the burden of proving that a factor unrelated, tuberous sclerosis (TS), caused in fact petitioners' onset of afebrile seizures. Where there were no symptoms except the seizures themselves, and there was overwhelming proof that TS's common symptomatology was afebrile seizures, the court held that respondent met its burden of proof that a known factor unrelated (TS) caused the onset and that DPT did not significantly aggravate their TS. Id. at *34.

The instant action is analogous to the aforementioned cases because petitioners have the burden, post-1995 regulations, of proving that DPT caused Kelli-Ann's seizures. Thus, the fact that Kelli-Ann did not have any post-DPT symptoms, such as fever, anorexia, screaming, crying, insomnia, loss of affect, lethargy, unresponsiveness, etc., has some bearing on the causative relationship vel non of DPT and the onset of Kelli-Ann's seizures, particularly in light of the biologically plausible scenario that underlies Dr. Kinsbourne's opinion of causation. In the instant case, the only manifestation that Kelli-Ann had was twitching. Kelli-Ann was hospitalized for one day. No one diagnosed status epilepticus. The hospital would certainly have kept her longer if her medical condition warranted concern at that time. Her seizures appeared so mild that the initial diagnosis of even her pediatric neurologists was benign myoclonic epilepsy of infancy. The court must assume that the onset of the twitching was purely coincidental to the administration of DPT the previous day.

Petitioners have not satisfied their burden of proving that DPT caused Kelli-Ann's seizure disorder.

Respondent has pressed periodically for the court to hold that petitioners must precisely describe a causative mechanism in order to satisfy their burden of causation of fact. However, in Knudsen v. Secretary, HHS, 35 F.3d 543, 549 (Fed. Cir. 1994), the Federal Circuit stated that "to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program." Moreover, herein, respondent's expert, Dr. Fenichel, admitted that DPT can cause serious, acute neurological illness, yet no one knows how. In DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis (1994), the Institute of Medicine (IOM) noted, upon considering all of the pertinent medical literature available, that DPT can cause serious, acute neurological illness, which is followed by chronic nervous system dysfunction. Id. at 12. Yet, the IOM did not describe an exact mechanism underlying its conclusion. Respondent's demand for precise proof as to a causative mechanism is certainly not warranted either in law (Knudsen) or in medicine

(IOM).

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. [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. [2] Under a change in the regulations, effective March 10, 1995, residual seizure disorder is no longer considered a Table injury. See 42 C.F.R. §100.1-100.3. In addition, the definition of encephalopathy as a Table injury changed in such a way that Kelli-Ann's symptomatology would not satisfy the new regulations. Id. Thus, since petitioners filed their petition after the effective date of the regulations, they proceeded under a theory of causation in fact with respect to both the seizure disorder and encephalopathy.

3. In a signed statement obtained by respondent, dated July 23, 1997, Dr. Bains stated that this history is incorrect. "It is an error in dictation. There is no history of twitching or jerking before Kelli-Ann received her immunization for which she was seen in my office on 2/9/93. It should read - the child was given 1 dose of Tylenol and was keeping well through the night but the mother notes the baby to have mild twitching [in] left arm, right leg 2-3 times before being seen TODAY." R. Ex. J (unpaginated). Dr. Bains also stated that Kelli-Ann was afebrile during her office visit on February 10, 1993. Id.

4. Uremia is "an excess in the blood of urea, creatinine, and other nitrogenous end products of protein and amino acid metabolism...." Dorland's Illustrated Medical Dictionary 1790 (27th ed. 1988).

5. Hypertelorism is an "abnormally increased distance between two organs or parts." Id. at 799.

6. Myelin is "the substance of the cell membrane of Schwann's cells that coils to form the myelin sheath....; it has a high proportion of lipid to protein and serves as an electrical insulator...." Id. at 1086.

7. Mrs. O'Connell testified that the fever was over 100 degrees; however, she further admitted that she, herself, did not take her daughter's temperature.

8. See Alderslade, R., et al., "The National Childhood Encephalopathy Study, Whooping Cough: Reports from the Committee on Safety of Medicines and the Joint Committee on Vaccination and Immunisation," 79-184 (London 1981).

[T]he relative rarity of acute encephalopathic disorders in children, the diversity of potential aetiological

agents, the large proportion of affected children in whom no

cause for the illness can be established, and the similarity of the clinical features associated with different aetiologies, all conspire to create special difficulties in any attempt to demonstrate that pertussis vaccine rather than some other agent causes

these conditions in some cases.

Id. at p. 96.

9. All DPT vials contain different amounts of endotoxin. Tr. at 94.

10. This effect has been shown in animal experimentation. Tr. at 73.

11. Myoclonus is a brief, shock-like contraction of the muscle groups. Tr. at 78.

12. Dr. Kinsbourne noted that the only relevancy fever has is in relation to benign febrile convulsions.

13. Dr. Fenichel noted that Kelli-Ann does not have a progressive encephalopathy in the sense that she has a degenerative disease of the nervous system; however, she does have a progressive brain disorder. Tr. at 155.

14. See R. Ex. J (unpaginated).

15. In addition, there is no significance in Kelli-Ann's nasal congestion or inflamed tympanic membrane. Tr. at 165.

16. This does not mean that at some point during her seizure disorder, Kelli-Ann did not manifest symptoms of chronic encephalopathy.

17. Unlike the instant action, petitioners in McMurry did not allege encephalopathy.

18. The court recognizes that both medical experts herein thought that the presence or absence of fever was irrelevant to their opinions; however, both Drs. Kinsbourne and Fenichel testified in McMurry that fever triggers seizures. Dr. Fenichel had no problem stating that the fever Rebecca McMurry had prompted her seizures, and the DPT caused her fever.

19. This theory suggests that pertussis toxin and endotoxin, which are both present in DPT, breach the blood-brain barrier, permitting interference with the firing of neutrons.