OFFICE OF THE SPECIAL MASTERS

(No. 90-3705V)
(Filed March 30, 1998)

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HAROLD BERGER and ETTY BERGER,	*	
as Legal Representatives of SARA BERGER,	*	
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Petitioners,	*	
	*	Publish
v.	*	
	*	
SECRETARY OF THE DEPARTMENT OF	*	
HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
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* *	*	

E. Drew Britcher, Morristown, NJ, for petitioners.

Gabrielle Manganiello, Washington, DC, for respondent.

DECISION AND ORDER

MILLMAN, Special Master

On October 1, 1990, Harold and Etty Berger, on behalf of their daughter Sara Berger (hereinafter "Sara"), 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) the DPT vaccination was administered to Sara in the United States, and, (3) they have incurred $1,000.00 in unreimbursable medical expenses prior to filing the petition.

Petitioners proceeded originally under two theories, alleging that Sara suffered both on-Table residual seizure disorder (hereinafter "RSD") and hypotensive-hyporesponsive shock collapse (hereinafter "HHE") following her first DPT vaccination. 42 U.S.C. §§300aa-11(c)(1)(C)(I); 14(a)(I)(C) and (D). Subsequently, petitioners dropped the allegation of HHE, proceeding sole under a claim of RSD. In addition to this claim, the court considered the question of on-Table significant aggravation because there was a possibility that Sarah had seizures prior to the administration of her vaccination.

Respondent denied that the onset of Sara's seizures occurred within Table time of her DPT vaccination.

Alternatively, if the court found Sara's post-vaccination seizures to be on-Table, respondent further argued that DPT did not significantly aggravate her preexisting condition.

The court held a hearing in this case on May 29, 1997, June 2, 1997, and June 9, 1997, with closing arguments on December 22, 1997. Testifying for petitioners were Harold Berger, Regina (Etty) Berger, William Berger, Dr. Marcel Kinsbourne, and Dr. Gerald Schulman. Testifying for respondent were Dr. Aaron G. Meislin, Dr. Edwin H. Kolodny, Dr. Irving Fish, Dr. Isabelle Rapin, and Dr. M. Harold Fogelson.

FACTS

Sara was born on March 8, 1988. Med. recs. at Ex. 1 (Vol. II)(unpaginated). On May 24, 1988, she saw Dr. Aaron G. Meislin. R. Ex. D, p. 1. The medical record from this visit notes that she had episodes of random movements of her arms and legs. Id. At the time of the visit, he believed that these movements were isolated incidents. Therefore, he did not find them abnormal or recommend further specific evaluation. Med. recs. at Ex. 2, p. 1 (Vol. V). In retrospect, however, he believes that these episodes were probably seizures and the onset of abnormal motor activity. R. Ex. D, p. 2.

Sara received her first DPT vaccination on June 14, 1988 at the age of three months. Med. recs. at Ex. 5, p. 1 (Vol. II). A record from her three-month exam notes that she had fever and was cranky. Med. recs. at Ex. 1, p. 5 (Vol. I). She also had slight congestion and a cough. Id.

On June 18, 1988, Sara saw Dr. Max A. Bulmash, a pediatrician. Med. recs. at Ex. 3, p. 1 (Vol. I). In his record from this visit, he questions whether Sara was having seizures and a reaction to her DPT vaccination. Id. Although she was afebrile, she looked blank and was not alert. Id. She had diminished tone and poor reflexes. Id. During this visit, Dr. Bulmash recommended that Sara see a neurologist; however, the Bergers wished to decide when and where to go for a neurologic consultation. Med. recs. at Ex. 3, p. 1 (Vol. I).

On June 20 or 29, 1988, Sara saw Dr. Gerald Schulman, a pediatrician. Med. recs. at Ex. 1, p. 6 (Vol. I); R. Ex. C (unpaginated). He noted that Sara was three and one-half months old and had been irritable for two days. Id. There was no change in her feeding pattern and she did not have a fever or cough. Id. She was neurologically intact with good tone. Id. She was generally alert and playful, and she was not irritable upon examination. Med. recs. at Ex. 1, p. 6 (Vol. I); R. Ex. C. Dr. Schulman noted that Sara was healthy with periods of irritability, resulting in an overall impression of colic. Id. He also noted that Mrs. Berger appeared anxious about the family's upcoming vacation. Med. recs. at Ex. 1, p. 6 (Vol. I).

On July 25, 1988, Sara saw Dr. Irving Fish, a neurologist. Med. recs. at Ex. 4, p. 27. (Vol. I). The record from this visit reflects that Sara could smile, follow, hear, and lift her head. Id. The record further notes that at five weeks of age Sara experienced episodes where her eyes would shift to the side or up, and she would stiffen and tremble. Id. These episodes lasted for approximately twenty seconds and would occur several times a day. Id. She was very cranky between each episode. Med. recs. at Ex. 4, p. 27 (Vol. I). The episodes gradually tapered off, disappearing at about three months of age. Id. Her crankiness improved and she smiled more. Id.

On July 15, 1988, Sara had an episode consisting of staring, tightening up, and crying. Id. Episodes of this nature continued to increase in frequency. Med. recs. at Ex. 4, p. 27 (Vol. I). Dr. Fish noted the possibility of infantile spasms because her head may have dipped and her arms flew out. Id. A visit to the pediatrician three days prior revealed blood in her stool. Id. Lately, she was not nursing well. Id. On examination, she was extremely irritable. Med. recs. at Ex. 4, p. 27 (Vol. I).

On July 26, 1988, Dr. Fish conducted an EEG which showed bursts of multifocal spikes and irregular high voltage slow waves. Med. recs. at Ex. 4, p. 28 (Vol. I). At times, the bursts seemed centrencephalic. Id. His conclusion was that she had a severely abnormal EEG with hypsarrhythmia. Id.

From July 27-29, 1988, Sara was at New York University Medical Center. Med. recs. at Ex. 5, p. 1 (Vol. I). Dr. Meislin noted that she had been developing seizures over the past two months, which had become more frequent over the past two weeks. Med. recs. at Ex. 5, p. 10 (Vol. I). These episodes lasted for approximately five minutes and repeated themselves every 30 to 40 seconds. Id She appeared to be in pain during them. Id.

On July 27, 1988, Mrs. Berger gave a history that Sara's seizures had begun ten days earlier.[(2)] Med. recs. at Ex. 5, p. 27 (Vol. I). During these episodes, her extremities stiffened and she would cry when her extremities relaxed. Id. In addition, her eyes rolled up into her head. Id. The seizures lasted for about five minutes and were cyclical. Id. The record further reflects that Sara's parents were angry and anxious, saying, "My child doesn't belong here. She was a normal baby." Med. recs. at Ex. 5, p. 28 (Vol. I).

At 6:30 p.m. on July 27, 1988, a patient care note states that Sara was alert and awake. Med. recs. at Ex. 5, p. 31 (Vol. I). She continued to be both awake and alert at 9:00 p.m. that evening. Id. Her breathing was easy and unlabored. Id.

On August 23, 1988, Sara saw Dr. Omar Patxot, a pediatric neurologist. Med. recs. at Ex. 6, pp. 3-7 (Vol. I). The history taken reflects that Sara appeared normal as a baby, except for frequent crying, disturbed sleep, and what was described as colic. Med. recs. at Ex. 6, p. 3 (Vol. I). At six weeks of age, she had episodes where her eyes would turn to the side or upward, and she would briefly stiffen and tremble. Id. These episodes lasted for approximately twenty seconds and would occur several times per day. Id. During these episodes, she was very cranky and irritable. Id. These episodes gradually decreased in frequency, completely disappearing at three months of age. Med. recs. at Ex. 6, p. 3 (Vol. I). At four months of age, episodes of stiffening and eye rolling resumed. Id. During these episodes, she also shook her extremities, moved her arms outward, and bobbed her head. Id. She was not feeding well and was irritable. Id.

A developmental history taken during her visit with Dr. Patxot reflects that she smiled normally and laughed at one and one-half months. Med. recs. at Ex. 6, p. 4 (Vol. I). Although the Bergers were not good historians, the records indicate that she was smiling and following objects with good head movements at four months of age. Id. On physical examination, her head circumference was in the 40th percentile. Id. Dr. Patxot found Sara to be alert, awake, and attentive. Med. recs. at Ex. 6, p. 5 (Vol. I). She was cooperative and not self-abusive and she cooed intermittently. Id. Although she was five and one-half months of age at this visit, she was functioning at the level of three to four months of age. Id. She could focus on the doctor's face and her optic discs were normal. Id. Dr. Patxot thought that Sara had a slowly progressive, neurological degenerative condition. Med. recs. at Ex. 6, p. 6 (Vol. I).

On October 31, 1988, Sara saw Dr. Steven Pavlakis, a pediatric neurologist. Med. recs. at Ex. 7, p. 1 (Vol. I). A history taken during this visit reveals that Sara occasionally jerked at six weeks of age and had continuous myoclonic seizures at three and one-half months of age. Id. She was irritable and did not visually follow or track. Id. Her head circumference was in the 25th to 30th percentile. Id. Optic disc examination showed significant optic pallor. Med. recs. at Ex. 7, p. 2 (Vol. I). She had diffuse hypotonia. Id. She did not lift her head off the bed. Id. There was no clear cut evidence of a progressive disease; however, his opinion was that encephalopathy was a direct result of whatever was causing her seizures. Id.

Upon completion of his evaluation of Sara, Dr. Patxot wrote Dr. Irving Fish.[(3)] Med. recs. at Ex. 6, pp. 1-2 (Vol. I). In a letter dated January 4, 1989, Dr. Patxot noted that he saw Sara on September 6, 1988 and on October 25, 1988. Med. recs. at Ex. 6, p. 1 (Vol. I). An EEG performed on October 25, 1988 revealed that her condition had worsened since her initial EEG and she was severely abnormal. Id. The letter further stated that Dr. Pavlakis saw Sara on November 1, 1988. Id. Dr. Pavlakis noted that he observed optic disc pallor, diffuse hypotonia, and bilateral upgoing plantar responses which had not been present previously. Id. This suggested to Dr. Patxot that Sara had a progressive degenerative disease of the central nervous system (CNS), involving the optic disc and the white and grey matter. Med. recs. at Ex. 6, p. 1 (Vol. I).

A January 19, 1989 medical record contains a history that Sara was a slow feeder and very cranky. Med. recs. at Ex. 4, p. 15 (Vol. I). Eventually, she was put on Prosobee. Id. At six weeks of age, she experienced tremors for several weeks; however, they seemed to improve gradually. Id. At four months of age, she began having multiple seizures of different types. Id. Genetic and metabolic tests proved normal. Med. recs. at Ex. 4, p. 15. On March 16, 1989, Sara had an MRI which showed an enlarged basilar artery (1.2 cm.), and mild enlargement of the ventricles/sulci. Med. recs. at Ex. 4, p. 12 (Vol. I).

From May 15 to 19, 1989, Sara was at New York University Medical Center. Med. recs. at Ex. 9, p. 1 (Vol. I). A history given at this time revealed that Sara was well until she was five weeks old at which time she began having generalized twitches and seizures. Med. recs. at Ex. 9, p. 7 (Vol. I). She had about two to three episodes per day. Id. These seizures slowly became better without any treatment. Id. At three months of age, she was no longer having seizures and she received her first DPT vaccination. Id. Thereafter, she began having recurrent seizures, approximately five to six per day. Med. recs. at Ex. 9, p. 7 (Vol. I). These seizures were generalized without fever or focality. Id. She had grossly delayed motor development. Med. recs. at Ex. 9, p. 8 (Vol. I). She was to receive ACTH therapy. Med. recs. at Ex. 9, p. 7 (Vol. I). On examination, she had flat affect. Med. recs. at Ex. 9, p. 9 (Vol. I). She did not have any response to auditory or visual stimuli and she was unaware of her surroundings. Id.

On August 14, 1989, Sara saw Dr. Isabelle Rapin, a pediatric neurologist. Med. recs. at Ex. 10, p. 1 (Vol. I). Dr. Rapin took a history which reflects that Sara had been a colicky baby. Id. She seemed to be developing well and she smiled at nine weeks. Id. However, she had some tremors of her hands and feet at five weeks of age. Id. These tremors did not impress her pediatrician and later subsided. Med. recs. at Ex. 10, p. 1 (Vol. I). She followed visually and appeared alert. Id. In June, Sara received her DPT vaccination without particular reaction. Id. In late July, however, she had infantile spasms with a hypsarrhythmic EEG. Id. Subsequently, Sara lost most of her developmental milestones. Med. recs. at Ex. 10, p. 1 (Vol. I). On examination, Dr. Rapin noted that Sara was irritable and crying. Med. recs. at Ex. 10, p. 2 (Vol. I). She had neither a social smile nor visual fixation. Id. She was extraordinarily floppy and had no head control. Id. She had no skills and was unresponsive. Id.

On July 5, 1990, Sara saw Dr. Edwin Kolodny at Harvard Medical School, Massachusetts General, Eunice Kennedy Shriver Center. Med. recs. at Ex. 7, pp. 1-3 (Vol. II); R. Ex. F (unpaginated). He diagnosed her as having West's Syndrome. Med. recs. at Ex. 7, p. 2 (Vol. II). Dr. Kolodny's records reflect that Sara had bilateral tremors of her hands and feet at five weeks. Med. recs. at Ex. 7, p. 1; R. Ex. F. Her pediatrician was apparently unconcerned by these episodes and her pediatric workup was normal. Med. recs. at Ex. 7, p. 1; R. Ex. F. She was a cranky baby and she cried constantly. Id. At three months of age, she had her first DPT vaccination without particular reaction. Med. recs. at Ex. 7, p. 1.

Dr. Kolodny's records further reflect that Sara had her first strong seizure a few weeks after her DPT. R. Ex. F. It was akin to a salaam seizure, with her hands and feet moving. Id. For more than five days, her seizures increased daily. Id. She saw Dr. Fish and an EEG showed hypsarrhythmia. Id. ACTH was

originally recommended as treatment, but the Bergers refused. R. Ex. F. She had no response to Klonopin. Id. Her MRI was normal. Id. She was having approximately thirty to forty seizures per day and had been on ACTH for one year with good response. Id. She has myoclonic movements all the time. R. Ex. F. Her development was nil and she was hypotonic without any reflexes. Id.

An MRI conducted in March 1989 showed some enlargement of the ventricles and widening of the sulci as compared to her prior MRI. Med. recs. at Ex. 7, p. 1 (Vol. II). Sara's head circumference was in the 3rd percentile for her age (28 months) and in the 50th percentile for one year of age. Med. recs. at Ex. 7, p. 2 (Vol. II). Her weight was in the 3rd percentile for her age. Id. The optic discs appeared normal. Id. Sara was sleepy and poorly responsive during examination. Id. She did not respond, follow, or fixate. Med. recs. at Ex. 7, p. 2.

Dr. Alex Tenenbaum also saw Sara when she visited Dr. Kolodny. Dr. Tenenbaum's records reflect that Sara was following objects at three weeks of age. R. Ex. F (unpaginated). At five weeks, she had twitching in her hands and feet for a few seconds, but the pediatrician found her normal. Id. She could not turn over but she shook a lot. Id. She cried constantly and was a very cranky baby. Id. She received her DPT at three months of age and experienced her first strong seizure in July. R. Ex. F. She saw Dr. Fish five days after this episode. Id. The seizures have increased in number. Id. She is constantly moving when awake and her only functions are crying, eating, sleeping, and defecating. Id.

Sara saw Dr. Patxot on February 7, 1991. Med. recs. at Ex. 2, p. 3 (Vol. III). She was profoundly developmentally delayed, unresponsive, and functioning at a level of a one month old child. Med. recs. at Ex. 2, p. 4 (Vol. III). Her head circumference was at the 5th percentile, having decreased from the 30th percentile. Id. She was awake but did not focus. Id. She seemed unaware of her surroundings and had recurrent eye rolling as well as fine jerky movements of the extremities. Id. Occasionally, Sara "jackknifed," which is consistent with infantile spasms. Med. recs. at Ex. 2, p. 4 (Vol. III). She had between seven and ten episodes during the examination. Id. She had profound hypotonia with poor head control. Id. Muscle strength was markedly decreased. Id. Dr. Patxot concluded that her disease had progressed since her initial examination. Med. recs. at Ex. 2, p. 5 (Vol. III).

TESTIMONY

Harold Berger testified first for petitioners. He stated that there was no history of mental retardation or seizure disorder in his family. Tr. at 5. He has a total six children, with Sara being the second oldest child[(4)]. Tr. at 6. Sara received her first DPT on June 14, 1988. Tr. at 19. During the evening of June 14, 1988, she was cranky, irritable, and feverish. Tr. at 19-20. She cried the entire night and she did not eat. Tr. at 21. In the morning of June 15, 1988, she was still cranky. Tr. at 22. In late afternoon, her eyes, feet, and hands went up for 15 to 20 seconds. Tr. at 22-23. After this episode, she relaxed and went to sleep. Tr. at 23. She had a similar episode a couple of hours later. Tr. at 24. The Bergers did not call the doctor because they thought Sara was having stomach problems since she had not eaten. Id.

On June 15, 1988, she had two or three episodes within a couple of hours. Tr. at 25. There were no episodes on June 16, 1988. Id. On Friday, June 17, 1988, she did not experience any episodes until late evening. Tr. at 26. At 10:00 p.m. that evening, she had a more intense episode which lasted 15 to 20 seconds. Tr. at 29. Within an hour, she had two episodes. Id. They called Dr. Bulmash and he returned their call at midnight. Tr. at 30-31.

On June 18, 1988, at 9:00 a.m., Sara saw Dr. Bulmash. Tr. at 32. Dr. Bulmash stated that the episodes could have been caused by her DPT vaccination. Id. Although Dr. Bulmash mentioned seizures, which alarmed Mr. Berger, Sara was not immediately taken to a pediatric neurologist.[(5)] Id.

In the beginning of July 1988, the family went to the Catskill Mountains. Tr. at 37. While on this trip, Sara had frequent episodes which could not be linked to anything. Tr. at 38-39. She fell asleep after these episodes. Tr. at 39.

Mr. Berger testified that Sara smiled, looked at people, and kicked her feet prior to her DPT. Tr. at 33-34. However, she was not a happy child after the DPT. Id. Today, Sara is devastated. Tr. at 48. She has no head control, does not sit or stand, cannot talk, and is on medication. Tr. at 48. She still has seizures. Tr. at 48-49. She is on Medicaid and SSI and has a home attendant. Tr. at 49. The Bergers want to keep her at home. Tr. at 50.

Regina (Etty) Berger testified next for petitioners. She does not have mental retardation or seizure disorder in her family history. Tr. at 110. Sara was a cranky baby, who had difficulty breast feeding. Tr. at 120. Gradually, she quieted down and her feeding improved. Tr. at 120. Although Sara began twitching at five weeks of age, Mrs. Berger noticed nothing unusual about her eyes during these episodes. Tr. at 121-22.

On May 24, 1988, Sara visited Dr. Meislin. Tr. at 122. He said that twitching was very common in babies and he was not alarmed. Id. This reassured Mrs. Berger. Tr. at 123. Sara's twitching improved and she was more content, relaxed, and happy. Id. By eight weeks, Sara was smiling, kicking her feet, and looking at people. Tr. at 125. She was gaining weight and she had head control. Tr. at 125, 127. Today, her head is floppy, like dead weight. Id.

On June 14, 1988, Sara had her first DPT vaccination at Bedford Medical Center. Tr. at 128-29. During that evening, she was cranky and had a fever, perhaps 101 or 102 degrees. Tr. at 131. Sara cried the entire night and she would not eat although Mrs. Berger tried to feed her. Tr. at 131-32.

On June 15, 1988 at 5:00 p.m., Sara started to tense. Tr. at 133. She got red in the face, her eyes rolled up, and her feet rose. Tr. at 133; 136-37. This lasted for approximately 20-30 seconds. Tr. at 134. After this episode, she fell asleep. Id. She had two or three episodes that evening. Id. Mrs. Berger thought it was stomach cramps or colic. Tr. at 135.

On June 17, 1988 at 10:00 p.m., the episodes resumed. Tr. at 138. They were more intense and frequent, lasting 20 to 30 seconds. Tr. at 138-39. Her father-in-law became scared and the Bergers called Dr. Bulmash. Tr. at 139. At 9:00 a.m. the next day, Sara was taken to Dr. Bulmash's office. Tr. at 140.

Although the episodes stopped for a short period, they resumed in July while the family was vacationing in the Catskills. Tr. at 141-42. The episodes occurred every five minutes and she was not sucking. Tr. at 142. The family immediately left the Catskills because of Sara's condition. Id.

William Berger, Sara's paternal grandfather, testified next for petitioners. He stated that Sara was a normal child before her DPT. Tr. at 210. On the evening of June 17, 1988, he saw Sara with her arms bent in, her legs up, her head to one side, and her eyes up. Tr. at 211. This episode lasted for approximately 30 to 60 seconds. Id. One-half hour later, a similar episode occurred. Tr. at 212. She was crying and fell asleep. Tr. at 214. He testified that she smiled and focused prior to her DPT; however, she lost this after her vaccination. Id.

Dr. Aaron Meislin, Sara's pediatrician, testified for respondent. He is board-certified in pediatrics. Tr. at 224. Although Dr. Meislin did not note any abnormality until July 1988, in retrospect, the episodes which Sara experienced at five weeks of age could have possible medical significance. Tr. at 225. At the time of the May 24, 1988 visit, he was neither concerned by Mrs. Berger's descriptions nor did he

believe that Sara had a neurological illness. Tr. at 225-26. Dr. Meislin saw Sara again on July 25, 1988. Tr. at 226. The record from this visit notes that Sara was cranky, stopped feeding, raised her eyes, and cried. Id. Her height, weight, and head circumference were normal. Id. On examination, she was vigorous and in good color. Id.

Dr. Meislin saw Sara at the New York University Medical Center on July 27, 1988. Tr. at 227. A history from this visit reflects that her seizures had been developing for two months. Tr. at 229. Dr. Meislin testified that such history makes it more likely that the random movements she experienced at five weeks were related to her disease process.[(6)] Id.

However, he further noted that the July 1988 convulsive movements were very different from the random movements she experienced at five weeks of age, with the former being consistent with her EEG. Tr. at 238. In addition, her head circumference was normal on both April 12, 1988 and May 24, 1988. Tr. at 235-37.

Dr. Edwin H. Kolodny testified next for respondent. He is chairman of the Department of Neurology at New York University. Tr. at 242. He is board-certified in adult neurology but half of his patients are children. Id. He examined Sara only on July 5, 1990. Tr. at 243. He somewhat remembers this visit, having taken a history from her father and grandfather. Tr. at 243-44. They told him that Sara had a DPT vaccination without particular reaction. Id. Dr. Kolodny testified that when he asks parents about vaccine reactions he generally asks open-ended questions so as not to elicit or suggest answers. Tr. at 245. He also does not mention time frames with regard to the occurrence of symptoms. Id. He noted that the first clear-cut seizure in the records occurred a few weeks after DPT. Tr. at 246. This was a salaam seizure which caused her to lose motor tone. Id. Dr. Kolodny's record further notes that the twitching she experienced at five weeks of age seemed normal to her neonatalogist. Tr. at 246-47.

On cross-examination, Dr. Kolodny stated that West's syndrome has no specific cause.[(7)] Tr. at 252. When he referred to Sara's "first strong seizure" in his notes, he testified that he was recognizing the fact that she had previously experienced twitching at five weeks of age. Tr. at 253. Retrospectively, without the aid of an EEG, it is difficult to determine whether her twitching was neurological. Tr. at 253-54. However, he further noted that Sara had some sort of seizure disorder at five weeks of age which then progressed. Tr. at 254. In addition, she had no history of fever with the seizures. Tr. at 256. Finally, Dr. Kolodny stated that the course of infantile spasms varies in children. Tr. at 257. While few children recover spontaneously, other children either respond to medication or get worse. Id.

Dr. Irving Fish testified next for respondent. He has been a pediatric neurologist since 1964. Tr. at 260. He currently treats Sara, having first seen her on July 25, 1988. Id. Although he has no independent recollection of the first visit, a history taken during that visit reflects that, at five weeks of age, Sara experienced episodes where her eyes would stare to the side or up, and she would stiffen and tremble. Tr. at 260-61. This occurred several times a day and disappeared at three months of age. Tr. at 261. At two months of age, she could smile, follow, hear, and lift her head. Tr. at 263. On July 15, 1988, she had an episode during which her eyes stared, she tightened and cried, her head dropped, and her arms went out. Tr. at 261. He thought the episodes which occurred at five months could be neurological; however, he could not say with probability that these episodes were seizures. Tr. at 264.

On cross-examination, Dr. Fish said he would tend to relate the June seizures to the July seizures. Tr. at 268-70. However, on redirect, he stated that he was uncertain whether the May seizures were related to June and July seizures. Tr. at 270. He also agreed that random movements of arms and legs are not seizure activity. Tr. at 271-73.

Dr. Isabelle Rapin, a pediatric neurologist, testified next for respondent. Tr. at 274. She took a history which notes that Sara received DPT without any particular reaction. Tr. at 275-77. When inquiring as to whether a child experienced a vaccine reaction, Dr. Rapin asks about fever, convulsions, and loss of consciousness. Tr. at 278.

Dr. Marcel Kinsbourne, a pediatric neurologist, testified for petitioners. Tr. at 281. His opinion is that Sara had an on-Table RSD, consisting of infantile spasms, which led to a loss of psychomotor skills. Tr. at 282-83. Her current condition is a consequence of those seizures. Tr. at 283. He does not believe that the episodes she experienced at five weeks of age were seizures. Tr. at 283. He bases his opinion on the parents' descriptions of these occurrences as well as the fact that trembling and shaking are simply not the same as myoclonic seizures. Id. In bilateral motor jerking, the individual is momentarily unconscious. Id. However, Sara cried through the episodes which occurred at five weeks, causing him to believe that she was experiencing colic, rather than seizures. Tr. at 283-84. Finally, although infantile spasms can cause encephalopathy, Dr. Kinsbourne did not believe that Sara had an encephalopathy in the "classic neurological sense."[(8)] Tr. at 292; 296.

Although doctors vary in how comprehensively they examine children, the differential diagnosis for colic and infantile spasms is very difficult. Tr. at 287-89. While both colic and infantile spasms cause stiffening of the body, colic does not result in the eye deviation and the child cries throughout the event. Tr. at 289. Conversely, during infantile spasms, the child is momentarily unconscious and the eyes roll up, the head moves forward or back, and the arms and legs jackknife. Tr. at 290, 324-25. This lasts a few seconds. Tr. at 325. Staring, alone, however, is insufficient for a diagnosis of infantile spasms. Tr. at 324.

Dr. Kinsbourne opined that the infantile spasms which occurred within three days of Sara's DPT and the infantile spasms which occurred on July 15, 1988 were the same condition. Tr. at 313. Both sets of seizures are descriptive of infantile spasms, and Sara experienced a continual loss of reactivity and mental skills after DPT. Tr. at 284. Infantile spasms are commonly associated with mental regression. Id. Although it is uncharacteristic for infantile spasms to appear and disappear, therefore making their one-month absence surprising to Dr. Kinsbourne, it is possible for such seizures to continue subtly, making them difficult to detect. Tr. at 305. However, the disappearance of the seizures is inconsequential to his opinion because Sara continued to lose milestones during the hiatus. Id.

When comparing the pre- and post-DPT episodes, Dr. Kinsbourne found the Bergers' description of Sara's post-DPT behavior to be reflective of infantile spasms. Tr. at 293. The motor events prior to DPT are harder to characterize, however, since they disappeared and she continued to develop normally. Tr. at 293-94.

Dr. Kinsbourne further distinguished Sara's pre- and post-DPT episodes by noting that she went into a postictal state after her post-vaccination seizures while being alert and crying throughout the pre-DPT seizures. Tr. at 298. Dr. Kinsbourne also found significant the fact that Sara continued to develop normally following her pre-DPT episodes. Tr. at 300. Conversely, her mental skills were lost after her post-DPT episodes. Tr. at 295-96. She was not alert, had diminished tone, and appeared blank. Id. If both the pre- and post-DPT episodes were governed by the same process, it is less likely that Sara would have continued to develop normally after her pre-DPT episode at five weeks. Id.

On cross-examination, Dr. Kinsbourne admitted that it is possible that the pre-DPT movements were seizures; however, they remitted and Sara's development continued. Tr. at 301. Furthermore, random movements of arms and legs have no neurological significance. Tr. at 303. He admitted that it is more likely that her pre-DPT movements are seizures if Dr. Fish's notation referring to pre-DPT eye deviation

is correct. Tr. at 306.

Dr. Kinsbourne admitted that Dr. Bulmash's June 18, 1988 record, which questions seizures, could have been referring to any form of seizure. Tr. at 308, 310. For instance, seizures such as benign myoclonic epilepsy get better and disappear. Tr. at 311. But, these seizures do not cause diminished tone and alertness as Sara had as noted on June 18, 1988. Id. Infantile spasms, however, will result in such symptoms. Id.

With regard to significant aggravation, Dr. Kinsbourne admitted that if Sara had infantile spasms at the age of five or six weeks, DPT did not significantly aggravate them. Tr. at 317-18. He further stated that if the pre-vaccination episodes were neurological but not infantile spasms, her DPT did significantly aggravate them. Tr. at 338-39. However, random movements are non-specific and shaking is common in infancy. Tr. at 320. To Dr. Kinsbourne, neither random movements nor shaking is necessarily neurological. Id.

Dr. Gerald Schulman testified for respondent. He is the board-certified pediatrician who saw Sara once at the end of June 1988 at the Bedford Clinic. Tr. at 346-48. Sara seemed to be a well baby who had colic. Tr. at 354-55. Nursing may have caused some irritability. Tr. at 356. She had good tone. Id. He stated that it is difficult to diagnose infantile spasms because it is an episodic event, and the baby may appear be completely normal between episodes. Tr. at 358. He conducted a neurological exam because Mrs. Berger complained that Sara was irritable. Tr. at 361. On examination, she did not have any focal deficits, low tone, or weakness. Id.

Dr. M. Harold Fogelson, a pediatric neurologist, testified as an expert for respondent. His opinion was that Sara had difficulties from birth. Tr. at 393. For instance, she had difficulty breast feeding and she was born with a cephalohematoma. Tr. 393-94. She also had petechiae in her armpits. Id. Though these are not neurologic findings, they indicate that she was not completely normal at birth. Tr. at 394-95.

Although Sara's early episodes cannot be classified as infantile spasms, Dr. Fogelson believes that these episodes were seizures.[(9)] Tr. at 399. Her episodes began at five weeks of age and then disappeared at approximately three months. Tr. at 397-98. She had stiffening at thirteen weeks. Tr. at 397-98. Unlike Sara's course, infantile spasms do not remit and later worsen. Id. Although she was damaged prior to her DPT, her infantile spasms did not occur until one month after her DPT on July 15, 1988. Tr. at 399-400. He further believes that Sara's pre-DPT episodes were partial or generalized seizures. Tr. at 399. He referred to these episodes as "stuttering" seizures because they developed and later got better. Tr. at 400. With regard to significant aggravation, Dr. Fogelson stated that DPT did not worsen her seizures because she got better after the administration of the vaccine. Tr. at 399. In essence, Dr. Fogelson believes that DPT had no effect on Sara. Tr. at 416-17. Even if she had not received DPT, her course would have resulted in infantile spasms and severe mental retardation. Tr. at 417. He opines that her current condition is due to her pre-existing seizure disorder whose cause is unknown. Tr. at 417-18.

Dr. Fogelson testified that Sara's disorder was progressive, proceeding from partial seizures to infantile spasms, finally culminating in loss of her abilities. Tr. at 407. While she is chronologically nine years old, she is functionally less than six weeks of age. Id. Dr. Fogelson could not explain Dr. Bulmash's description of Sara as having a blank look on June 18, 1988 compared to Dr. Schulman's description of her as alert and playful at the end of the same month. Tr. at 409. If, however, Sara had infantile spasms, her course would have been progressive, resulting in a continual lapses in alertness. Id.

Dr. Fogelson noted that the discrepancies in the records further support the fact that Sara's infantile spasms began in July, rather than June. Tr. at 412. For instance, he did not believe that Sara's seizures

remitted and she did not lose alertness until July 1988. Id. In June, her feeding pattern remained unchanged; however, her feeding pattern decreased in July. Id. Finally, she was neurologically intact to Dr. Schulman in late June. Tr. at 413. In Dr. Fogelson's opinion, Sara's symptoms post- DPT were transient. Id. She had neither an increase in frequency nor duration of seizures after the DPT vaccination. Id.

Dr. Fogelson said that it is not unusual to have generalized or partial seizures before three months, followed by infantile spasms thereafter. Tr. at 413-14. Infantile spasms occur between three or four and eight months of age. Tr. at 414. The consensus in the medical community is that DPT does not provoke infantile spasms. Id. In addition, infantile spasms do not immediately follow DPT vaccinations unless there is an underlying pathology. Tr. at 414-15. The causes of infantile spasms can be malformation, hypoxia, trauma, and neurocutaneous illness. Tr. at 415. Unless the patient has a prompt response to ACTH, the prognosis in West's syndrome is grim. Tr. at 416.

On cross-examination, Dr. Fogelson admitted that he relied on Dr. Fish's and Dr. Patxot's descriptions of Sara's movements in May 1988, rather than Dr. Meislin's description, which was the only contemporaneous record. Tr. at 419. He stated that Dr. Meislin's description would not be diagnostic of either seizure or colic. Tr. at 420. A child with seizures can still be neurologically intact. Tr. at 420. Dr. Fogelson acknowledged that Sara passed into sleep after her post-DPT episodes although this did not occur after her earlier episodes. Tr. at 427-28. However, he further stated that this could be consistent with either the postictal state or her being tired. Id.

DISCUSSION

Petitioners allege that Sara had an on-Table RSD. The Vaccine Act defines RSD in 42 U.S.C. § 300aa-14(b)(2):

A petitioner may be considered to have suffered

a residual seizure disorder if the petitioner did

not suffer a seizure or convulsion unaccompanied

by fever or accompanied by a fever of less than

102 degrees Fahrenheit before the first seizure

or convulsion after the administration of the

vaccine involved and if--

(B) in the case of any other vaccine

[than measles, mumps, or rubella], the

first seizure or convulsion occurred

within 3 days after administration of

the vaccine and 2 or more seizures or

convulsions occurred within 1 year

after the administration of the vaccine

which were unaccompanied by fever or

accompanied by a fever of less than 102

degrees Fahrenheit.

The seminal focus of the court's analysis, therefore, rests on determining whether the onset of Sara's seizure disorder occurred either at five weeks of age when she experienced random movements or in June 1988 when she experienced seizure-like episodes after her DPT. To reach this conclusion, the court must first examine the course that Sara's illness took as provided by the medical records and witness' testimony.

Sara's course can best be described as waxing and waning. Prior to DPT, her development clearly progressed as she was able to smile, raise her head, and feed. What is most notable about this time period, however, is that Sara experienced episodes of twitching, screaming, and crankiness when she was approximately five weeks of age. Yet, medical histories taken subsequently reflect that these twitches eventually disappeared.

Sara then received her DPT on June 14, 1988. Her post-DPT course similarly waxed and waned. She experienced seizure-like episodes on June 15 and 17, 1988. These episodes were clearly noted in Dr. Bulmash's June 18, 1988 record where he describes Sara as having diminished tone and reflexes, lack of alertness, and a blank look. This visit caused Dr. Bulmash to query further whether Sara was experiencing seizures and a reaction to DPT.

However, these episodes similarly disappeared. Sara seemingly recovered her ability to respond and smile. Mrs. Berger did not take Sara to see another doctor until the end of June. When she saw Dr. Schulman at the end of June, it was to allay her fears about taking Sara on the family's upcoming vacation. The record from this visit reflects that Sara was normal and alert. She did not have encephalopathy and she was neurologically intact. She had not lost milestones. Obviously, the dullness she manifested after the DPT vaccination was gone. There seemed to be no deleterious vestige of her vaccine reaction.

In July 1988, however, episodes of stiffening, crying, and eye deviation resumed, causing Dr. Fish to raise the possibility of infantile spasms. These episodes continually increased in frequency and intensity. At the end of July, her EEG showed severe abnormality and hypsarrhythmia. From this point, Sara's course was completely downhill.

Were it not for Dr. Bulmash's June 1988 record and the obvious occurrence of infantile spasms in July 1988, the court would conclude that the onset of Sara's seizure disorder occurred off-Table. However, the court cannot reach this conclusion based on the evidence before it.

First, random movements of the arms and legs, such as Sara experienced at five weeks of age, are not descriptive of infantile spasms. Although Sara's pre-DPT movements are difficult to diagnose, Dr. Fish would not opine that such events were seizures. Moreover, Dr. Meislin was not alarmed when Mrs. Berger told him about them during Sara's May visit. His description of the child at that time is totally different than Dr. Bulmash's June 18, 1988 description.

Second, the court was impressed with the testimony of Mr. William Berger, Sara's paternal grandfather. It was his alarm at Sara's movements on June 17, 1988 that compelled the Bergers to contact Dr. Bulmash on the Sabbath. The movements witnessed by Mr. Berger on June 17, 1988 were the same as those described by Sara's parents as occurring on June 15, 1988. It was this history combined with Dr. Bulmash's own observation of Sara, i.e., lack of alertness, diminished tone and reflexes, and blank affect, that caused Dr. Bulmash to consider whether Sara were having seizures and a reaction to her DPT vaccination.

Diagnosis of the June seizures is problematic because Sara then had a one-month hiatus from seizure activity during which she appeared to be "normal." Dr. Kinsbourne cannot explain this apparent normalcy if the seizures that she experienced in June were infantile spasms because infantile spasms do not disappear. He thought perhaps that they were too subtle for the parents to notice. In Dr. Schulman's view, however, a child can look normal between episodes of infantile spasms.

Nevertheless, the type of seizures Sara manifested in June is legally irrelevant if petitioners prove that they occurred on-Table, followed by two or more afebrile seizures within a year of vaccination, and their sequelae lasted more than six months. Drs. Fish and Kinsbourne opined that the June seizures were related to the July seizures. Neither Dr. Fish nor Dr. Kolodny could state with probability that the May movements were seizures. This is significant to the undersigned since these latter doctors were Sara's treating pediatric neurologists.

That the Bergers told Drs. Kolodny and Rapin that Sara did not have any particular reaction to DPT does not undercut their allegations.[(10)] First, as Dr. Patxot stated in his records, they are not generally good historians. Second, they were not experienced enough to recognize them as a reaction. Additionally, Sara did not have a fever after her DPT. Fever is the one symptom about which doctors universally warn their patients' parents. Due to the absence of this symptom, there was no reason for the Bergers to suspect that Sara was experiencing an adverse reaction to her vaccination. That they did not connect her movements with a reaction to DPT, or even identify them as convulsions, is not dispositive to the court concerning whether or not she had on-Table seizures.

Respondent's defense is that Sara's onset of seizures occurred pre-DPT at five weeks of age, manifesting itself as generalized or partial seizures upon which DPT had no effect. Dr. Fogelson does not diagnose the post-DPT June 15 and 17, 1988 movements and cannot explain why Dr. Bulmash found Sara to have a blank look, poor tone, decreased alertness, and lessened reflexes on June 18, 1988. Dr. Fogelson does opine that the onset of Sara's infantile spasms occurred in July 1988. Unlike Sara's treating pediatric neurologists, however, he does not link the on-Table movements and the July infantile spasms, except to say they are all part of a pre-existing seizure disorder which began at five weeks.

Importantly, the fact that Dr. Schulman found Sara to be neurologically intact, alert, playful, and with good tone in late June 1988 does not mean she was neurologically normal to Dr. Fogelson. He believes that she was neurologically ill at five weeks. Conversely, Drs. Kinsbourne, Fish, and Kolodny think she became neurologically ill after the DPT vaccination. Regardless, both petitioners' and respondent's medical experts testified that a normal neurological examination is not dispositive of whether or not the vaccinee is actually normal.

Taking the record in its entirety, the court is left with two alternatives pertaining to the onset of Sara's seizure disorder: it (1) occurred at five weeks or (2) on-Table after DPT. Because the treating pediatric neurologists would not opine with probability that Sara's pre-DPT movements were seizures, the court must opt for petitioners' view that Sara's seizures began on-Table. Dr. Schulman's examination results are a red herring since neither party would say she was normal neurologically at the end of June 1988.

Since the court does not find the evidence to support a holding that Sara's pre-DPT movements were seizures, this case does not require a significant aggravation analysis.[(11)] Petitioners have prevailed in proving on-Table RSD. Sara had post-DPT seizures whose onset was within three days of vaccination, followed by two or more afebrile seizures within one year of vaccination.

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. The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C.A. §300aa-1 et seq. (West 1991), as amended by Title II of the Health Information, Health Promotion, and Vaccine Injury Compensation Amendments of November 26, 1991 (105 Stat. 1102). For convenience, further references will be to the relevant subsection of 42 U.S.C.A. § 300aa.

2. A record dated July 28, 1988, however, stated that Sara had the onset of her seizure activity at six weeks of age. Med. recs. at Ex. 5, p. 8 (Vol. I).

3. This letter is dated "January 4, 1988" on page one while being dated "January 4, 1989" on page 2. The latter date is correct.

4. None of Sara's younger siblings has received DPT vaccinations. Tr. at 112-13.

5. Sara was, however, taken to a pediatric neurologist in July 1988 because the episodes had increased in frequency. Tr. at 33.

6. Dr. Meislin never actually witnessed these random movements. Tr. at 230.

7. For the purpose of clarity, it should be noted that the transcript contains an error, referring to "West's syndrome" as "breast" syndrome.

8. However, Dr. Kinsbourne later testified that Sara's infantile spasms, which began on June 15, 1988, resulted in an encephalopathic process by June 18, 1988. Tr. at 297. As such, he was surprised by the fact that she was alert and playful on June 29,1988. Id.

9. He admitted, however, that Sara did not experience seizures at five weeks if she cried during such episodes. Tr. at 429.

10. The Bergers initially thought she was having stomach trouble or colic because she refused to eat.

11. The court does, however, find it necessary to comment on Dr. Fogelson's opinion with regard to significant aggravation. Dr. Fogelson believes that DPT did not significantly aggravate Sara's pre-existing seizure disorder because she got better. This position is untenable. Assuming that Sara's June seizures were not infantile spasms, it is impossible to consider her as being "better" when she developed infantile spasms in July. Moreover, the symptoms she experienced in June, i.e., blankness, lack of tone, lessened alertness and reduced reflexes, are surely worse than the prior random movements and crying she experienced in May.