

OFFICE OF THE SPECIAL MASTERS

No. 95-191V

(Filed on: August 18, 1998)

FRANK and LAURA GALLAGHER, *
Parents and Next Friends of *
COURTNEY LEIGH GALLAGHER, *

Petitioners, * **TO BE PUBLISHED**

v. *

SECRETARY OF HEALTH AND *
HUMAN SERVICES, *

Respondent. *

Robert T. Moxley, Cheyenne, WY, for petitioners.

Karen P. Hewitt, Washington, DC, for respondent.

DECISION AND ORDER

MILLMAN, Special Master.

Statement of the Case

The above-captioned matter was part of the cases pending during the undersigned's Omnibus TS hearing dated October 8-11, 1996 and June 3-4, 1997. Subsequent to my decision in the Omnibus case, dated September 15, 1997, ⁽¹⁾ the court determined what course to follow in this individual case.

Respondent challenges whether Courtney Leigh Gallagher (hereinafter "Courtney") experienced the onset of her seizures within Table time of her DPT vaccination. The court held a hearing on March 3, 1998 to determine this issue. Testifying for petitioners were Frank Gallagher and Laura Gallagher. Respondent did not call any witnesses.

Facts

Courtney was born on November 22, 1992. Med. recs. at Ex. 1, p. 1. She received her first DPT vaccination at the age of two months on January 27, 1993. Id. She received her second DPT vaccination at the age of four months on March 31, 1993. Id.

During an April 19, 1993 visit, Courtney's pediatrician, Dr. Luis Fernandez, noted that she had been crying constantly for the past three days. Med. recs. at Ex. 1, p. 2. She seemed to be in pain after she ate. Id. She was afebrile and she did not appear ill. Id. Physical examination of Courtney's head, ears, eyes, nose, and throat was negative. Id. Courtney received her third DPT vaccination in June 1993 at the age of six months. Med. recs. at Ex. 1, p. 3.

A medical record dated September 2, 1993 reflects that, since Courtney was four months old, she had periods of stiffness during which her eyes rolled. Id. That day, she had had two episodes and, for the past two days, she experienced severe shaking. Id. She was unable to sit up by herself. Id. She no longer smiled or was happy. Id. Her appetite had not changed. Id. During this visit, the doctor could not get her to track or focus on an object. Id.

This record also contains a history given by the Gallaghers which reiterates that Courtney had been

experiencing stiffening of her extremities for several months. Id. Her eyes would roll into the back of her head and her left arm and face would twitch. Id. The Gallaghers attributed these episodes, which subsequently increased in frequency, to formula intolerance. Id.

Courtney was admitted to Morristown Memorial Hospital from September 2 to 9, 1993. Med. recs. at Ex. 5, p. 2. The history given reveals that she had been experiencing periods of stiffness of her arms and legs for approximately four months. Med. recs. at Ex. 5, p. 4. The history further reflects that three days prior to admission, the Gallaghers noticed that Courtney was having involuntary movements of her left arm and face. Med. recs. at Ex. 5, p. 2. These movements progressed to generalized stiffening of her entire body. Id. A consultation report dated September 8, 1993 notes that, at approximately four months of age, Courtney experienced "cramps," which were described as tightening of her arms and legs. Med. recs. at Ex. 5, p. 6. These cramps were believed to be constipation. Id.

On November 3, 1994, Courtney saw Dr. David E. Mandelbaum, a pediatric neurologist at the New Jersey University of the Health Sciences. Med. recs. at Ex. 8, p. 51. The record from this visit includes a history that Courtney received a DPT vaccination when she was four and one-half months of age. Id. During the evening of her vaccination, she was irritable and she had a low temperature. Id. The day after the vaccination, she had the onset of salaam-type jerking movements. Id. These episodes, which were comprised of one to two jerks, occurred twice that day. Id. The record further notes that Courtney had become quite cranky and irritable. Id. Her smiling decreased. Id. She also became less interactive and playful. Id. Courtney continued to have one to two episodes of seizures per day; however, the seizures were now comprised of ten jerking movements per episode. Id. She had a generalized convulsion in September 1993. Id.

Testimony

Laura Gallagher testified first for petitioners. She has three children of whom Courtney is the youngest. Tr. at 22.

Mrs. Gallagher testified that Courtney did not have a reaction to her first DPT vaccination on January 27, 1993. Tr. at 29. Between two and four months of age, Courtney's development was normal. Id. She smiled, cooed, and babbled. Id.

Courtney received her second DPT on Wednesday, March 31, 1993. Tr. at 30. During the evening of the vaccination, Courtney was a little cranky and had a low fever. Id. Mrs. Gallagher gave her Tylenol. Id. The vaccine site was slightly red. Id. That evening, Courtney went to sleep earlier than normal. Tr. at 31.

On April 1, 1993, the day after vaccination, Courtney was half-awake from a morning nap when Mrs. Gallagher saw her make a funny movement. ⁽²⁾ Tr. at 34. Courtney drew her knees up to her chest and her upper body stiffened. Id. Mrs. Gallagher thought her daughter was constipated. Id. That evening, this movement repeated itself, lasting for a few seconds. Tr. at 35. Courtney's eyes twitched and rolled back. Id. After the episode, Courtney looked dazed and she had a blank stare. Tr. at 36. Thereafter, she was cranky, irritable, and whiny. Tr. at 37. She seemed uncomfortable. Id. She had a fever of 100 degrees Fahrenheit. Id. She did not have normal bowel movements that day. Id.

On Friday, April 2, 1993, Courtney had a large bowel movement. Tr. at 38. One to two weeks later, Courtney began waking up in the middle of the night for periods of approximately twenty minutes. Tr. at 39-40. Her appetite seemed to have disappeared and her desire to suck had diminished. Tr. at 40. She lost some weight; however, Mrs. Gallagher was not concerned by this. Tr. at 41. Courtney's overall affect had also changed. Id. She no longer smiled or cooed. Id. Her muscle tone was gone and she would not sit up. Id.

Courtney continued to have two to three seizures per day. Tr. at 49. By August 1993, she had three to four seizures per day and her bowel movements were poor. Tr. at 50-52. She was irritable. Tr. at 53. She stopped crawling and she had no upper arm strength. Tr. at 54. Although she could turn over and support her head, she could not support the rest of her body. Tr. at 55. Her vocalization did not progress. Tr. at 56.

By September 1993, Courtney's seizure episodes had become more intense. Tr. at 43. Her body would shake and twitch and her eyes would roll back until the color of her eyes was no longer visible. ⁽³⁾ Id. She was put on ACTH from September to November or December 1993. Tr. at 66. In September 1993, these episodes were diagnosed as infantile spasms. Tr. at 43.

Currently, Courtney smiles, laughs, and giggles. Tr. at 69. She goes to a regional day school for the disabled. Id. She has physical therapy, occupational therapy, speech therapy, music therapy, and computer therapy. Tr. at 69. She is still on Depakote and Klonapin. Tr. at 70. Her seizures have resurged. Tr. at 71. She has daily seizures which usually last for a few seconds and consist of one head drop. Tr. at 71-72. Once the seizure ends, Courtney immediately returns to the activity in which she was engaged. Id. Thus far, Courtney has not undergone any IQ tests. Tr. at 73.

Frank Gallagher testified next for petitioners. On April 4, 1993, he first saw Courtney seize. ⁽⁴⁾ Tr. at 115. He saw her knees draw up to her chest. Id. He stated that she looked as if she were trying to defecate or had the hiccups. Id. At the time, he believed the episodes might be related to digestion. Tr. at 116.

Mr. Gallagher noticed a gradual change in Courtney after these episodes began. Tr. at 118. She would not smile or maintain eye contact. Id. Her personality seemed to fade away. Id.

Courtney's seizures became more frequent and violent. Id. She developed a definite arm twitch which was not present previously. Id. In July 1993, Mr. Gallagher called Dr. Fernandez regarding these episodes. Id. However, Dr. Fernandez said that Mr. Gallagher was overreacting. Id. The Gallaghers called Dr. Fernandez five to six times throughout the summer. Tr. at 120.

Today, Courtney is happy and she is able to smile; however, she cannot speak. Tr. at 149. She seldom cries. Id. She has difficulty with balance and she is not yet toilet-trained. Id. Courtney continues to have seizures. Tr. at 150. She has a mixed seizure disorder with myoclonic and aclonic⁽⁵⁾ seizures. Id. Courtney's progress is affected by her seizures. Tr. at 151. The less seizures that she has, the more she is able to do. Id. As part of treatment, Courtney's seizure medication has been decreased so that her level of awareness can be maintained while her seizures are controlled. Id.

Discussion

If the onset of Courtney's infantile spasms occurred within Table time of her second DPT, petitioners benefit from the statutory presumption that DPT caused the seizures. It does not, however, automatically prove that petitioners prevail on a theory of on-Table significant aggravation.

Based on the medical records and the testimony of Mr. and Mrs. Gallagher, the court holds that Courtney's first seizure occurred within Table time of her second DPT vaccination. The medical records are consistent with an onset at approximately four months of age which is when her vaccination was administered.

As the court held in its Omnibus TS Decision, if a vaccinee with TS has a seizure as his or her sole symptom following DPT vaccination, without any indicia of a vaccine reaction, e.g., fever, screaming, inconsolable crying, altered affect, insomnia, anorexia, or excessive irritability, the court will hold that: (1) TS is the factor unrelated to the vaccination that caused his seizures, and (2) petitioners do not prevail on a theory that DPT significantly aggravated the vaccinee's TS. See Barnes et al., *supra*, at *32-33.

The scenario discussed in the holding of the Omnibus TS Decision seems to be illustrated by the instant case. After DPT, Courtney cried, had a low fever, and was irritable and a little cranky. The court needs expert medical reports to determine the significance vel non of these symptoms.

Conclusion

The court shall hold a telephonic status conference with the parties to determine the timing of their filing of expert medical

reports. Respondent shall contact the court no later than Friday, August 28, 1998 to schedule this conference.

IT IS SO ORDERED.

DATED: Laura D. Millman

Special Master

1. Barnes et al. v. Secretary, HHS, 1997 WL 620115 (Fed. Cl. Spec. Mstr. Sept. 15, 1997). The holding of the Barnes decision is discussed infra.

2. Mrs. Gallagher testified that Courtney routinely took a mid-morning nap. Tr. at 42. However, on this day, Mrs. Gallagher noticed that Courtney was not as alert or attentive as she normally was before her nap. Tr. at 42-43.
3. For instance, Mrs. Gallagher testified that on September 2, 1993, Courtney had an episode during which her body shook, her eyes rolled back, and she was very lethargic. Tr. at 57.
4. However, on April 2, 1993, Mrs. Gallagher told Mr. Gallagher that Courtney was having episodes during which she looked like she was constipated. Tr. at 115.
5. These seizures are referred to as "atonic" in the transcript.