

**OFFICE OF THE SPECIAL MASTERS**  
**No. 97-0692V**  
**(Filed on June 18, 1998)**

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KIMBERLY M. LAGRAN, as Personal \*  
Representative of the Estate of \*  
HAYLEY NICOLE LAGRAN, \*

Petitioners, \* **TO BE PUBLISHED**

v. \*

SECRETARY OF HEALTH AND \*  
HUMAN SERVICES, \*

Respondent. \*

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E. Paul Gibson, North Charleston, SC, for petitioner.

David L. Terzian, Washington, DC, for respondent.

**DECISION AND ORDER**

**MILLMAN, Special Master**

On October 14, 1997, Kimberly M. Lagrand, on behalf of her daughter, Hayley Nicole Lagrand (hereinafter "Hayley"), filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986<sup>(1)</sup> (hereinafter the "Vaccine Act" or the "Act"). Petitioner has satisfied the requirements for a prima facie case pursuant to 42 U.S.C. § 300aa-11(c) by showing that: (1) she has not previously collected an award or settlement of a civil action for damages arising from the vaccine injury, and (2) DPT vaccinations were administered to Hayley in the United States.

Petitioner alleges that DPT was the cause-in-fact of Hayley's seizures which, in turn, resulted in her death at fifteen months of age. 42 U.S.C. §§300aa-11(c)(1)(C)(ii)(I). Respondent defends by arguing that DPT did not cause Hayley's seizures.

At petitioner's counsel's request, the court rules on the records.

**FACTS**

Hayley was born on September 1, 1995. Med. recs. at Ex. 1. She received her first DPT vaccination on October 27, 1995 when she was two months old. Med. recs. at Ex. 4, p. 1. She received her second DPT vaccination on January 5, 1996 when she was four months old. Med. recs. at Ex. 9, p. 1.

On January 12, 1996, Hayley saw Dr. Mark J. McCall, a pediatrician, because she was occasionally experiencing jerky motions. Med. recs. at Ex. 9, p. 4. The record from this visit further reflects that Hayley had an episode, lasting for one-half hour, where her arm drew up and her hand turned blue. Id.

On January 12, 1996, Hayley also saw Dr. Ernest Barbosa, a pediatric neurologist. Med. recs. at Ex. 10, pp. 1-2. A medical history given by Mrs. Lagrand reflects that Hayley had a two-month history of isolated myoclonic jerks of her arms and legs without any specific pattern. Med. recs. at Ex. 10, p. 1. These episodes occurred sporadically while she was awake without any alteration in mental status. Id. The history further reflects that, in the morning of January 12, 1996, Mr. Lagrand witnessed a tonic flexing of Hayley's left upper extremity during which she stared and clenched her fists. Id. This episode lasted for approximately two to three minutes with significant postictal paralysis of the left upper extremity. Id. She was afebrile. Med. recs. at Ex. 10, p. 1. The medical record further notes that Hayley had not had any recent illnesses and her immunizations were up to date. Id. An EEG performed on January 12, 1996 was unremarkable without any focal or generalized discharge. Med. recs. at Ex. 26, p. 1.

On January 22, 1996, Hayley underwent an MRI which was abnormal, showing left temporal lobe atrophy with increased prominence of the temporal sulci. Med. recs. at Ex. 27, p. 1. While there was no size or signal asymmetry, both hippocampal formations were somewhat small in their mid-portions though symmetrically so. Id.

Hayley returned to Dr. Barbosa on February 12, 1996. Med. recs. at Ex. 10, p. 3. A history taken at this visit reflects that Hayley's first seizure occurred during the first week of January. Id. This seizure consisted of tonic flexing of her left arm for approximately one to two minutes. Id. She had no alteration of consciousness. Id. The record continues to note that Hayley had a second seizure, consisting of tonic flexing of the right arm, which lasted for more than five minutes. Med. recs. at Ex. 10, p. 3. She remained conscious during this episode as well. Id. In addition to these seizures, Hayley also had a history of occasional leg-jerking on either side which generally lasted for a few seconds. Id. Although Hayley's MRI showed left temporal lobe atrophy, an EEG conducted on January 23, 1996 was normal. Med. recs. at Ex. 10, p. 3. Dr. Barbosa's impression was an isolated seizure event. Id.

Hayley saw Dr. McCall, her pediatrician, on March 13, 1996 with a history of grand mal seizures. Med. recs. at Ex. 10, p. 5. The record from this visit notes that she had a low-grade fever the prior evening. Id. Her appetite had decreased and she had a cough and runny nose. Id. It was noted that she was allergic to pertussis and was on Phenobarbital. Id.

Haley returned to Dr. McCall on March 15, 1996. Med. recs. at Ex. 9, p. 6. During this visit, Dr. McCall notes that Hayley was getting better. Id. Hayley returned to Dr. McCall on March 20, 1996 at which time he recorded that she was "okay." Med. recs. at Ex. 9, p. 7. However, he questioned whether she had roseola. Id.

A March 22, 1996 medical record, prepared by Dr. Barbosa, reflects that Hayley underwent a video-EEG on March 6, 1996. Med. recs. at Ex. 10, p. 7. The EEG was abnormal, showing that Hayley had nineteen seizure episodes over six hours. Id. During these episodes, she bent forward slightly and appeared dazed. Id. The episodes were followed by brief clonic activity on her left side. Id. The record further reflects that Hayley was brought to the emergency room in status epilepticus on the evening of

March 6, 1996. Med. recs. at Ex. 10, p. 7. It took hospital personnel one and one-quarter hours to control her seizures. Id. After discharge from the hospital, Hayley had a low-grade fever which her pediatrician diagnosed as roseola. Id. She had a rash on her face and body which had since resolved. Med. recs. at Ex. 10, p. 7. Dr. Barbosa's impression was complex partial seizures. Id.

On May 10, 1996, Hayley returned to Dr. Barbosa. Med. recs. at Ex. 12, p. 12. He noted that, since her March visit, she had two focal left lower limb seizures, lasting for three to five minutes. Id. On May 9, 1996, she had a generalized grand mal seizure which lasted for thirty minutes during which her temperature was normal. Id. Dr. Barbosa noted that Hayley's development continued to be at or above her age level since her last visit. Id. His impression was complex partial seizures with secondary generalization. Id.

From June 8 to 10, 1996, Hayley was at the Medical University of South Carolina. Med. recs. at Ex. 29, p. 5. A medical record prepared by Dr. J. Roult Reigart, a pediatrician, reflects that Hayley presented to the emergency room in status epilepticus for twenty to thirty minutes. Id. She continued to seize there for another twenty minutes. Id. She was initially afebrile but was later found to have a 101 degree temperature. Id. Dr. Reigart diagnosed a urinary tract infection and a seizure disorder. Med. recs. at Ex. 29, p. 6.

In a medical record dated August 23, 1996, Dr. Barbosa stated that Hayley had had one grand mal seizure per month since her last visit. Med. recs. at Ex. 11, p. 1. Her last grand mal seizure, which lasted for one hour, occurred on July 5, 1996. Id. Mrs. Lagrand was concerned about new eye movements that Hayley was experiencing. Id. Hayley's eyes would roll back into her head multiple times throughout the day. Id. A medical history taken from both Mrs. Lagrand and prior medical records reflect that Hayley's arm-twitching began within two to three days of her first DPT. Med. recs. at Ex. 11, p. 2. After her second DPT, she experienced increased twitching of her limbs. Id. Her first generalized seizure occurred shortly thereafter. Id. During this visit, the Lagrands stated that they believed that Hayley's seizure condition was "coincident" to her first DPT and subsequently worsened by her second DPT. Id. Dr. Barbosa stated that "[s]ince we can find no other reason for her seizures, the relationship that the seizures are related to the vaccine probably exists." Med. recs. at Ex. 11, p. 2.

A video-EEG performed on October 14, 1996 was abnormal with frequent brief episodes of upward eye deviation associated with epileptic discharges arising from the right central-parietal area. Med. recs. at Ex. 32, p. 1.

On October 15, 1996, Hayley went to the Medical University of South Carolina. Med. recs. at Ex. 33, p. 4. The medical record from this visit reflects that Hayley experienced her first seizures at approximately two months of age after her first DPT. Id. These seizures were focal left-sided. Id. Hayley again experienced seizures at four months of age after her second DPT. Id. Her seizures continued over the following nine months. Med. recs. at Ex. 33, p. 4.

On December 10, 1996, Mrs. Lagrand found Hayley dead at 7:11 a.m. Med. recs. at Ex. 40, pp. 3, 6. Mrs. Lagrand told the coroner that Hayley seemed to have had a cold the evening before her death. Med. recs. at Ex. 40, p. 4. When found by her parents, Hayley's feet were icy cold. Med. recs. at Ex. 40, p. 7. Her entire body was stiff but her neck was quite loose and flopped back when her body was lifted. Id. The looseness in her neck surprised the coroner since the rest of her body was in rigor mortis. Id. The only sign on autopsy was slight pulmonary edema. Med. recs. at Ex. 40, p. 13.

The coroner contacted Dr. McCall who stated that Hayley had a history of seizures of unknown etiology. Med. recs. at Ex. 40, p. 5. The onset of these seizures occurred very shortly after her first DPT. Id. Aside

from this condition, Dr. McCall stated that Hayley had always been healthy. Id.

The death certificate, dated December 13, 1996, recorded the cause of death as sudden unexplained death in epilepsy.<sup>(2)</sup> Med. recs. at Ex. 41, p. 1. The autopsy showed cerebral and pulmonary edema. Med. recs. at Ex. 42, p. 1. Hayley's brain weighed 1030 grams and the gyri appeared slightly flattened. Med. recs. at Ex. 42, p. 3. She had moderate pulmonary edema with a small amount of white foamy material within the larger airways. Med. recs. at Ex. 42, p. 7. Microscopic sections confirmed pulmonary edema and moderate congestion. Id. She had a mild amount of cerebral edema without any evidence of herniation. Id. The pathologist concluded that Hayley suffered a sudden unexplained death in epilepsy which occurs in 1 out of 260 patients per year. Med. recs. at Ex. 42, p. 8.

A Vaccine Adverse Event Reporting System (VAERS) form was completed on January 30, 1997. Med. recs. at Ex. 39, p. 1. The VAERS form indicated that Hayley received a DPT vaccination on January 6, 1996 and the onset of the adverse event was January 12, 1996. Id.

### **AFFIDAVITS**

Mrs. Kimberly M. Lagrand filed an affidavit, dated September 11, 1997, stating that Hayley received her first DPT on October 27, 1995. Ex. 5, p. 1. On either October 28, 1995 or October 29, 1995, Hayley developed unusual twitching activity. Ex. 5, p. 2. Prior to this, she was in good health. Ex. 5, p. 1.

On January 5, 1996, Hayley received her second DPT. Ex. 5, p. 2. Within twenty-four hours of vaccination, Hayley had unusual twitching activity<sup>(3)</sup> which subsequently increased in severity over the next two months. Id. In addition to twitching, Hayley also experienced "limb jumping." Id. Mrs. Lagrand stated that Hayley's arms and legs seemed to jump several times consecutively for no apparent reason. Ex. 5, p. 2. During these episodes, she would have an odd look on her face. Id. Mrs. Lagrand attested that she told Dr. McCall about these episodes at Hayley's four-month check-up. Id. Dr. McCall stated that it was not unusual for babies to have poor muscle control. Id. He then administered Hayley's second DPT. Id.

The affidavit further notes that, on January 12, 1996, Hayley had an episode during which she got an odd look on her face, her right leg jumped several times, her right arm seized up to her chest, and her hand curled into a tight fist. Id. Her arm was paralyzed for about thirty minutes. Ex. 5, p. 2. After this episode, Mrs. Lagrand took Hayley to see Dr. McCall who immediately referred her to Dr. Barbosa. Id. Hayley was diagnosed as having a complex partial seizure with Todd's paralysis. Id. On nine occasions prior to Hayley's death, she experienced respiratory arrest as a result of treatment for her seizures. Ex. 5, p. 3.

Mr. Dean Lagrand, Hayley's father, submitted an affidavit, dated September 9, 1997, which was identical to his wife's affidavit. Ex. 6, pp. 1-3.

Ms. Michelle DeBate, Hayley's babysitter, also submitted an affidavit dated September 9, 1997. Ex. 7, pp. 1-2. Ms. DeBate's affidavit states that Hayley started twitching within a day or two of her first DPT vaccination. Ex. 7, p. 1. Within twenty-four hours of her second DPT, Hayley's twitching increased in severity. Ex. 7, p. 2. During these episodes, Hayley had an odd look on her face and limb jumping. Id. She further noted that Hayley continued to have seizures until her death. Id.

Ms. Elizabeth Coker, Ms. DeBate's mother, submitted an affidavit, dated September 11, 1997, which is identical to her daughter's affidavit. Ex. 8, pp. 1-2.

On April 6, 1998, Dr. Barbosa submitted a letter to petitioner's counsel which opined that DPT caused

Hayley's seizure disorder and resulted in her subsequent death on December 10, 1996. P. Filing, p. 1 (filed April 17, 1998). He bases this opinion on the initial history that Mrs. Lagrand gave which reflects that Hayley had seizure-type activity within seventy-two hours of her DPT. Id. Although Dr. Barbosa did not know the "exact link" between DPT and residual seizure disorder, he stated that it is "known that a certain small percentage of children will develop seizure disorders within seventy-two hours after the administration of the DPT vaccine." Id. Dr. Barbosa further noted that Hayley's seizures were unusual because they were resistant to multiple anticonvulsants. P. Filing, p. 2 (filed April 17, 1998). She had status epilepticus several times. Id. In Dr. Barbosa's opinion, Hayley's death was caused by her seizure disorder. Id.

Respondent submitted two expert reports, from Dr. Yuval Shafir, a pediatric neurologist, and Dr. Virginia M. Anderson, a pediatric pathologist. R. Exs. A & C.

Dr. Shafir stated that Hayley had seizures following her DPT vaccinations; however, she did not have encephalopathy since there was no any alteration in her mental status. R. Ex. A, p. 1. He comments that Dr. Barbosa's April 6, 1998 letter is completely contrary to his initial evaluation on January 12, 1996. R. Ex. A, pp. 1-2. Dr. Shafir further noted that infantile seizure disorders typically begin within the first six months of life during which time infants also receive DPT vaccinations. R. Ex. A, p. 3. However, a link between these disorders and DPT has not been established. Id.

Dr. Anderson stated that Mrs. Lagrand signed Hayley out of the hospital on December 6, 1996 against medical advice. R. Ex. C, p. 1. Hayley had presented to the hospital gasping in a postictal state with questionable mental status. Id. Four days later, Hayley was found dead. Id. On autopsy, mild pulmonary and cerebral edema was found. Id. Her death was attributed to respiratory arrest following a seizure. Id. Dr. Anderson noted that children with seizure disorders do not typically exhibit specific morphologic changes. R. Ex. C, p. 1. Dr. Anderson found no cause of death on autopsy. Id.

## DISCUSSION

The Vaccine Act affords petitioners three distinct theories of recovery, thereby allowing causation to be proven by showing that: (1) a Table-injury occurred as a result of the vaccine, (2) a pre-existing condition was significantly aggravated by the vaccine, or (3) the vaccine was the cause-in-fact of the injury. Section 14(a) contains the Vaccine Injury Table (hereinafter the "Table").<sup>(4)</sup> If the any of the various injuries in this Table occur within the statutorily defined time period, a rebuttable presumption of causation has been proven. To rebut this presumption, respondent must provide affirmative evidence demonstrating that a known factor unrelated was the cause-in-fact of the petitioner's condition.<sup>(5)</sup>

Since the Act's promulgation, changes in the regulations have altered the Table, eliminating residual seizure disorder (hereinafter "RSD") as a Table injury after DPT vaccine.<sup>(6)</sup> Thus, petitioner herein cannot benefit from the statutory presumption that DPT caused Hayley's seizure disorder. Since petitioner can no longer assert an on-Table RSD, her burden is one of causation-in-fact.

To prove that DPT was the cause-in-fact of her seizure disorder, petitioner 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." Grant v.

Secretary, HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Agarwal 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.

In light of the aforementioned change in the regulations, onset of Hayley's seizures is not critical to her claim. However, the onset of Hayley's seizures does warrant limited discussion because it bears on whether she has satisfied her causation-in-fact burden. Clearly, without demonstrating onset, it is indeed more difficult for petitioner to prove causation-in-fact. A review of the medical records implies that Hayley did not suffer her first seizure within the first few days, i.e., Table-time, of her DPT.

The medical records reflect that Mrs. Lagrand did not give a history of onset within a few days of Hayley's DPT vaccinations to either Dr. McCall, her pediatrician, or to Dr. Barbosa, her pediatric neurologist, when she initially saw them on January 12, 1996. Dr. Barbosa and Mrs. Lagrand apparently discussed Hayley's immunizations on January 12, 1996 because the record from this visit notes that her immunizations were up to date. If Hayley's twitching had in fact begun within a few days of her first DPT and subsequently worsened after her second DPT, it would have been natural for her to discuss this with Dr. Barbosa on January 12, 1996. However, this is not mentioned in the medical record. Rather, Mrs. Lagrand told Dr. Barbosa that Hayley had had a two-month history of isolated myoclonic jerks, indicating that onset occurred during the second week of November 1995 instead of within a day or two of her October 27, 1995 vaccination. Mrs. Lagrand also saw Dr. McCall on January 12, 1996 at which time she told him that Hayley occasionally experienced jerky motions. According to Dr. McCall's records, however, Mrs. Lagrand did not link the onset of these episodes with a particular event or time. It was not until Mrs. Lagrand saw Dr. Barbosa on February 12, 1996 that she informed him that Hayley first seized during the first week of January.<sup>(7)</sup>

The court must assume that Mrs. Lagrand and her husband are both responsible and loving parents. Thus, if Hayley's first seizure actually occurred during the first week of January, Mrs. Lagrand would have brought her to a doctor at that time or at least given histories reflecting such an event at the January 12, 1996 visits. Based on the medical records, the undersigned is unsure Hayley suffered a seizure within the first few days of her first vaccination or experienced a worsening of her condition directly after her second vaccination.

Regardless of the question of onset, however, the court must determine whether petitioner has proven that DPT was the cause-in-fact of Hayley's seizures. Turning to the expert reports submitted in the case, the court does not find that petitioner has met her burden. When Dr. Barbosa initially saw Hayley on January 12, 1996, Mrs. Lagrand did not give a history of seizure onset within days of vaccination. When Dr. Barbosa subsequently saw Hayley on February 12, 1996, Mrs. Lagrand told him that Hayley's first seizure occurred during the first week of January 1996. In a visit to Dr. Barbosa on August 23, 1996, Mrs. Lagrand stated that Hayley began arm-twitching within two to three days of her first DPT in October 1995. The history given at this time further notes that these episodes consequently increased after her second DPT.

It was not until this last (August 23, 1996) visit that Dr. Barbosa rendered the opinion that DPT probably caused Hayley's seizures because he could find no other cause for her disorder. Pursuant to Grant, supra, this is legally insufficient to prove affirmatively that DPT caused Hayley's seizure disorder. Petitioner cannot satisfy her burden simply by showing that no other cause for the injury is known.

In addition, Dr. Barbosa's April 6, 1998 opinion letter is unpersuasive on two grounds. First, this letter assumes information that Mrs. Lagrand purportedly conveyed to him on January 12, 1996 which is not

only absent from that record but also contrary to the history that he did record. Thus, there is no credible factual basis for the opinion he rendered in his letter. Second, Dr. Barbosa concludes that, although he does not know "the exact link" between DPT and seizure onset, a certain small percentage of children will develop seizures within seventy-two hours of vaccination. This opinion relies solely on a temporal relationship as the basis for causation. It is well-settled that temporality is legally insufficient to prove that DPT was the cause-in-fact of a seizure disorder. Strother v. Secretary, HHS, 950 F.2d 731 (Fed. Cir. 1991). That B follows A simply does not prove by that fact alone that A caused B.

Dr. Shafrir, respondent's expert, stated that the incidence of severe infantile seizure syndromes occurs during the same time period when children receive DPT vaccinations. This seems to be the more persuasive explanation for Hayley's condition. Even if the undersigned were to assume that the onset and exacerbation of Hayley's seizures occurred within a few days of her vaccinations, their occurrence seems coincidental without any other evidence.

According to Dr. Anderson, the autopsy does not provide a cause of death, which is not surprising in a seizure-related death. The court does not doubt, however, that Hayley died from a seizure since she experienced nine episodes of respiratory arrest resulting from seizures prior to her death. What is not apparent to the court, however, is the cause of Hayley's seizure disorder. Accordingly, petitioner has not satisfied her burden of proving that DPT caused in fact Hayley's seizure disorder. Although Hayley's course of illness and subsequent death is indeed tragic, the court cannot credit the medical records or Dr. Barbosa's letter with providing persuasive evidence of a "logical sequence of cause and effect" between her DPT vaccinations and her seizures. Grant, supra, at 1148.

#### **CONCLUSION**

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

**IT IS SO ORDERED.**

DATE: \_\_\_\_\_

Laura D. Millman

Special Master

1. The 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. This was confirmed by an addendum to the coroner's report. Med. recs. at Ex. 40, p. 16.
3. The affidavit also reflects that Hayley's babysitter mentioned to Mrs. Lagrand that Hayley's twitching seemed to increase on the day of her second vaccination. Ex. 5, p. 2
4. 42 U.S.C. § 300aa-14(a).
5. 42 U.S.C § 13(a)(1)(B).
6. 42 C.F.R. § 100.1-100.3.
7. While this history does in effect put Hayley's RSD within a few days of her second DPT, it is contrary to the history given on January 12, 1996 that her husband saw Hayley have her first seizure that morning.