OFFICE OF SPECIAL MASTERS

September 23, 2003

GABRIELLE NANEZ and SERGIO NANEZ, Individually and on Behalf of Their Minor Child, KARINA ISABEL NANEZ,	*	
	*	No. 02-1261V
	*	PUBLISHED
Petitioners,	*	
v.	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Evelina Ortega, El Paso, TX, for petitioners.
Julia W. McInerny, Washington, DC, for respondent.

DECISION

MILLMAN, Special Master

Petitioners filed a petition on September 25, 2002 under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10 et seq., alleging that their daughter Karina Nanez (hereinafter, "Karina") suffered an on-Table residual seizure disorder (RSD) after receipt of her second DPaT vaccination. Because RSD is no longer a Table injury after March 10, 1995 (60 Fed. Reg. 7694, Feb. 8, 1995), petitioners allege that DPaT (acellular pertussis) vaccine caused in fact Karina's seizures.

Because the undersigned considers the evidence petitioners have filed in support of their allegations not credible, the undersigned did not hold a hearing. Holding a hearing is within the undersigned's discretion. 42 U.S.C. § 300aa-12(d)(3)(B)(v).

This case is dismissed for failure to present a credible prima facie case.

FACTS

Karina was born on July 6, 1999. Med. recs. at Ex. 1. She received her first set of vaccinations, including pertussis, at the age of two months on September 1, 1999. Med. recs. at Ex. 5. She received her second DPaT, HiB, and inactive polio vaccines at the age of four months on November 3, 1999. Id. She was taken to Columbia Medical Center West on November 4, 1999 with a history that at 4:00 a.m. that day, she had awakened with a painful cry. Her eyes rolled up and her upper extremities stiffened. The episodes lasted one to two seconds and occurred every three minutes. In the ER, she had three or four episodes. She was afebrile. Her EEG and CT scans were normal. She did well without any change in her mental status or any difficulty feeding. Med. recs. at Ex. 4, p. 3.

On November 4, 1999, at 5:30 a.m., she returned to Columbia Medical Center ER. Her eyes had twitched, her back arched, and her eyes rolled back. She presented to the ER awake and smiling. Med. recs. at Ex. 10, p. 11. On November 4, 1999, her EEG was again normal. Med. recs. at Ex. 4, p. 21. Dr. Alan Carpenter, on November 4, 1999, wrote that Karin did not have any fevers through the night, never lost consciousness, did not have cyanosis, inconsolable distress, vomiting, diarrhea, or coughing. Her temperature was 97.9°. Her general appearance was healthy. She was in no visible distress. Her color was normal. She was not perspiring. She was fully relaxed, fully

alert, adapting well, smiling frequently, and cooing loudly to her mother and father. Except for seizures, her examination was normal. Med. recs. at Ex. 10, pp. 15, 16.

On November 4, 1999, Dr. Mary Carrizal Brown noted that Karina was alert, active, pleasant, smiling, and clinging. Her episode lasted one and one-half to three seconds. She returned to her normal pre-event status. Her anterior fontanelle was open, soft, and flat. It was non-bulging and non-pulsatile. Med. recs. at Ex. 10, p. 9.

On November 4, 1999, Dr. Brower wrote to Dr. Rodolfo Fierro-Stevens that he doubted Karina's seizures were related to her pertussis vaccination because she did not have encephalopathy. Med. recs. at Ex. 10, p. 20.

On November 4, 1999, Dr. Fierro-Stevens wrote that at about 4:30 a.m., Karina cried as if hurt. Her eyes closed when her mother picked her up. In a few minutes, she had unusual activity: her eyes rolled back, she made a gagging noise, and she had a startle response with extension of her arms and legs with her arms abducted, which she sustained for a few seconds and which was associated with some distal tremor, lasting a few seconds. She regained consciousness although she was somewhat quiet for a few seconds. Then, Karina became active again. The episodes recurred every few minutes from 4:30 a.m. to about 6:45 a.m. when she arrived at the ER where she was found to be stable, afebrile, and tolerating feedings well. She had no further spells throughout the day and remained in stable condition. She has a maternal cousin with epilepsy that began at 5 or 6 years of age. Med. recs. at Ex. 10, p. 21.

On physical examination, Karina was alert, cooperative, pleasant, and smiled at the examiner. She followed objects 180°, was able to roll over, and had normal motor tone, posture, and bulk. The impression was recurrent episodes of bilateral tonic activity with abduction of the arms as well as

a fixed stare with upward eye rolling and some eyelid flickering lasting a few seconds after which she was normal. This occurred every five minutes for a long period of time, but had not recurred since 7:00 a.m. The doctor wrote in the medical records, "I have discussed with the parents, the questions about the DPT immunization, having something to do with the current episode, but this is unlikely since the patient is not encephalopathic, and had only these transient episodes of what appeared to have been seizures." Med. recs. at Ex. 10, p. 22.

On July 6, 2000, her EEG was mildly abnormal. Med. recs. at Ex. 4, p. 18.

On June 26, 2001, Dr. Edna Larrinua-Avila took a family history that Karina had a maternal cousin with seizures since he was a baby who died in his 20's after a prolonged generalized seizure. Med. recs. at Ex. 8, p. 1.

Other Submissions

Dr. Larrinua-Avila provided an affidavit dated August 21, 2002 in which she states that DPT caused Karina's epilepsy, but does not give a basis for her opinion. Med. recs. at Ex. 6. In a letter dated January 14, 2002, she states the same and gives as a basis that there is no other cause. Med. recs. at Ex. 6, Ex. B.

Petitioners filed Ex. 13, an affidavit and report dated February 28, 2003 from Dr. Arie Ashkenasi, a pediatric neurologist. His affidavit states that Karina's epilepsy is more likely the result of and was caused by her DPaT, without giving a basis. In his report, Dr. Ashkenasi states, relying on an attached text from Oski's Pediatrics. Principles and Practice (1999), that the rate of convulsions is 1 in 1,750 cases, and about half of these seizures are not associated with fever. However, Oski's text at 992 states that about half of children receiving DPT (not DPaT) vaccine have fever, not that half of children seizing after DPT have fever. Furthermore, the rate of 1 out of

every 1,750 DPT vaccinations applies to febrile, not afebrile, convulsions, according to Oski's text at 992. Dr. Ashkenasi's conflating the 50% figure applying to fever alone after DPT with a figure that refers to febrile, not afebrile, convulsions in 1 out of 1,750 immunizations is a misrepresentation of the text.

Petitioners filed Exhibit 14, a supplemental expert report from Dr. Ashkenasi, dated April 20, 2003. Relying on a different attachment,[1] Dr. Ashkenasi states that about 10 percent of children who seize within 48 hours of receiving DPT do not have fever. However, the Blumberg article upon which he relies does not state this. Blumberg et al. state, at 1159, that seizures were associated with fever in 90% of the episodes when they documented temperature. It does not state that the 10% of cases in which fever was not documented were afebrile. It also does not state that DPT caused seizures in the 10% of cases in which fever was not documented. The issue in this case is whether Karina's acellular DPT caused her afebrile seizures, and the Blumberg article is silent as to that issue.

Respondent filed the report of Dr. Bennett Lavenstein on August 25, 2003. R. Ex. A. Dr. Lavenstein, a pediatric neurologist, wrote that Karina's acellular pertussis vaccine is unrelated to her afebrile seizures because she did not have an encephalopathy, her EEG was normal until June 2000, and there is no evidence that DPaT causes afebrile seizures. There also is "no evidence of associated developmental delay, neurologic regression, or concordant neurologic picture secondary to immunization." R. Ex. A, p. 2.

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[1] "Severe Reactions Associated with Diphtheria-Tetanus-Pertussis Vaccine: Detailed Study of Children with Seizures, Hypotonic-Hyporesponsive Episodes, High Fevers, and Persistent Crying," by D.A. Blumberg, et al., 91 *Ped* 1158-65 (1993).

DISCUSSION

Petitioners have two options under the Vaccine Program: (1) to proceed under a theory of a Table injury or (2) to proceed on a causation in fact theory. Because RSD is no longer a Table injury, petitioners must proceed under a causation in fact theory.

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." 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).

Without more, "evidence 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. Mere temporal association is not sufficient to prove causation in fact. Hasler v. US, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984).

Petitioners must not only show that but for the DPaT vaccine, Karina would not have had the injury, but also that the vaccine was a substantial factor in bringing about her injury. Shyface v. Secretary, HHS, 165 F.3d 1344 (Fed. Cir. 1999).

Dr. Larrinua-Avila gives no basis for her opinion of causation except there is no cause other than the vaccine. This is legally insufficient. See Grant, supra.

Dr. Ashkenasi gives as his basis for causation two references to medical literature. The first, Oski's text, he misinterprets. The second, Blumberg's article, does not lead to the conclusion that DPT (not DPaT which is not discussed) causes afebrile seizures. Without encephalopathy or any

medical abnormality except seizures, petitioners have not presented any logical sequence of cause and effect to show that Karina's DPaT caused her seizures except temporality and that is not legally sufficient to prove causation. See Hasler, supra.

The undersigned has held repeatedly in other cases that DPT (much less DPaT) does not cause afebrile seizures, based on the National Childhood Encephalopathy Study,[2] the Institute of Medicine (IOM), and other literature. See Borin v. Secretary of HHS, No. 99-491V, 2003 WL 21439673, *11 (Fed. Cl. Spec. Mstr. May 29, 2003); Bruesewitz v. Secretary of HHS, No. 95-0266V, 2002 WL 31965744 (Fed. Cl. Spec. Mstr. Dec. 20, 2002); Clements v. Secretary of HHS, No. 95-484V, 1998 WL 481881 (Fed. Cl. Spec. Mstr. July 30, 1998); O'Connell v. Secretary of HHS, No. 96-63V, 1998 WL 64185 (Fed. Cl. Spec. Mstr. Feb. 2, 1998), aff'd, 40 Fed. Cl. 891 (1998), aff'd by unpub. opinion, No. 98-5134 (Fed. Cir., Nov. 1, 1999); and Haim v. Secretary of HHS, No. 90-1031V, 1993 WL 346392 (Fed. Cl. Spec. Mstr. Aug. 27, 1993).

The IOM also concluded that DPT does not cause afebrile seizures. Adverse Effects of Pertussis and Rubella Vaccines (1991). The IOM did a meta-analysis of febrile and afebrile seizures and concluded that "even pooling available data provides no evidence of a statistically significant increase in the risk of afebrile seizures following DPT vaccination." Id. at 115.

Petitioners have not presented a credible prima facie case that DPaT caused Karina's afebrile seizures.

CONCLUSION

[2] *Whooping Cough: Reports from the Committee on Safety of Medicine and the Joint Committee on Vaccination and Immunization*, R. Alderslade, et al. (Department of Health and Social Security, London: Her Majesty's Stationery Office, 1981), pp. 79-183.

Petitioners' petition is dismissed with prejudice. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment in accordance herewith.[3]

IT IS SO ORDERED.

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DATE Laura D. Millman
Special Master

[3] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party's filing a notice renouncing the right to seek review.