IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS
02-1491V
January 31, 2007
Not for Publication

KALEIGH BRIELE GRIMES, a minor, by her mother and natural guardian, MICHELLE HOWIE,	*	
Petitioner,	*	Hepatitis B vaccine; Causation; Decision on the record;
v.	*	Seizure disorder
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

David Terzian, Esq., Rawls & McNelis, P.C., Richmond, VA, for petitioner.
Julia McInerny, Esq., U.S. Department of Justice, Washington DC, for respondent.

VOWELL, Special Master

DECISION[1]

On November 1, 2002, Michelle Howie ["Ms. Howie"] timely filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq*.[2] [the "Vaccine Act" or "Program"] on behalf of her minor daughter, petitioner Kaleigh Briele Grimes ["Kaleigh"], alleging that the hepatitis B vaccination

[1] Because this unpublished decision contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to delete medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will delete such material from public access.

[2] Hereinafter, for ease of citation, all "§" references to the Vaccine Injury Compensation Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2000 ed.).

Kaleigh received on March 7, 2000 caused her "developmental problems and seizures." Petition, ¶ 7-8.

None of the statutorily required supporting documentation accompanied the petition.[3] Five and a half months later, on April 18, 2003, petitioner filed seven exhibits containing records from various health care providers. Additional exhibits containing medical records were filed on August 22, 2003 and June 10, 2004. Thereafter, it appears that the case was informally stayed, along with many other cases alleging injury from hepatitis B vaccines, pending completion of discovery in the Autism Omnibus Proceedings.

The case was reassigned to me on February 8, 2006. On March 27, 2006, I conducted a joint recorded status conference in this and several other stayed cases, all filed by the same petitioner's counsel. Petitioner's counsel represented that he intended to transfer this case to another attorney, who was also present at this status conference. Based on representations made at that status conference, I directed petitioner to file the report of a medical expert by July 25, 2006. As the original Rule 4 report had been filed by respondent before any of the medical records were received, I ordered respondent to file a new Rule 4 report by June 26, 2006.

The planned substitution of petitioner's counsel took place on April 21, 2006, and I conducted another joint recorded status conference on August 7, 2006 with petitioner's new attorney regarding this and several similar cases. Prior to that status conference, I vacated the previously imposed deadlines for petitioner's expert report and respondent's Rule 4 report. On July 25 and August 4, 2006, petitioner filed four additional exhibits: the affidavits of Ms. Howie and Mr. Mike McKernan (Kaleigh's grandfather); and two sets of medical records.

At the conclusion of the August 7, 2006 status conference, I ordered petitioner to file some additional medical records and the report of an expert by October 6, 2006. On October 5, 2006, petitioner requested a two week extension to file the expert report. I granted that request. On October 16, 2006, petitioner filed a status report indicating that she would not be filing an expert medical report and requesting that I decide the merits of the case based on the existing record. Respondent requested the opportunity to file matters in response to this status report; I granted that request and respondent filed a Response to Petitioner's Motion for Ruling on the Record/Supplemental Report on November 22, 2006.

[3] Section 300aa–11(c) of the Vaccine Act requires the petition to be accompanied by certain documentary evidence, including records pertaining to the vaccination and subsequent treatment. *See also,* Vaccine Rule 2(e), RCFC, Appendix B.

In order to prevail under the Program, petitioner must prove either a "Table" injury[4] or that a vaccine listed on the Table was the cause in fact of an injury. Petitioner did not suffer a "Table" injury. While Petitioner's Exhibit ["Pet. Ex."] 13, pp. 1 and 91 establish that she received a hepatitis B vaccination on March 7, 2000, as alleged in the petition, no reliable evidence submitted links her vaccination to any illness, disability, injury, or condition. *See* § 300aa-11(c)(1)(C)(i). I therefore hold that petitioner has failed to establish her entitlement to compensation.

I. Medical History[5]

Kaleigh was born by spontaneous vaginal delivery on February 4, 2000. Pet Ex. 6, pp. 8-9. During labor, Kaleigh's heart rate showed some decreased reactivity. When her mother received oxygen and was repositioned, Kaleigh's heart beat improved. Because the amniotic fluid showed some mild to moderate meconium staining,[6] Kaleigh's nasal passages and tracheal were bulb-suctioned after delivery. *Id*., pp. 8, 154. Two different accounts of the fluid obtained appear in the records. The birth records reflect that a bloody, light green fluid was obtained (*id*.); the dictated delivery note indicates that a small amount of clear to minimally-stained mucous material was suctioned from her nose and oropharynx. *Id*., p. 154. Kaleigh's initial Apgar[7] score was very low but after receiving oxygen and breathing assistance, she improved rapidly. The newborn nursing notes indicate that Kaleigh had good color, nursed well, and was voiding normally. *Id.*, p. 29. She received her initial hepatitis B vaccine shortly after birth. No ill effects from the vaccination were noted. *Id*., pp. 8-9.

Kaleigh was discharged to home the day after her birth. *Id*., pp. 10, 125. According to her pediatric records and her mother's affidavit (Pet. Ex. 13, pp. 91-94; Pet. Ex. 10, pp. 1-2), her first five weeks of life were entirely normal. She had her initial "well-baby" visit at Child Care Limited, in Kansas City, Missouri on February 8, 2000.

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[4] A "Table" injury is an injury listed on the Vaccine Injury Table, 42 C.F.R. § 100.3, corresponding to the vaccine received within the time frame specified. The hepatitis B vaccine is listed on the Table; however petitioner's medical condition is not an injury specified for compensation for that vaccine.

[5] Many of the medical records contained in Pet. Ex. 6 pertain to Ms. Howie's second pregnancy. Kaleigh was her first pregnancy.

[6] Meconium is a dark green material found in the intestine of a fetus. *Dorland's Illustrated Medical Dictionary* ["*Dorland's*"] 1110 (30th ed. 2003). Meconium staining of the amniotic fluid indicates that the fetus has had a bowel movement in utero. Meconium staining of the amniotic fluid puts a neonate at risk of asphyxia, aspiration syndrome, or pneumonia if the neonate aspirates the amniotic fluid. *Comprehensive Pediatrics* ["*Comprehensive Pediatrics*"] 287, 333-35 (Robert. L. Summit ed., 1990).

[7] The Apgar score is a numerical assessment of a newborn's condition, usually taken at one minute and five minutes after birth. The score is derived from the infant's heart rate, respiration, muscle tone, reflex irritability, and color, with zero to two points awarded in each of the five categories. *See Dorland's* at 1670. Kaleigh's initial score was three at one minute, but had improved to nine by five minutes. At one minute, she received a zero in respiration, reflexes, and muscle tone. Pet. Ex. 6, pp. 8-9.

Pet. Ex. 13, p. 93. Her one month check up occurred on March 7, 2000. Other than scaling on her scalp and face and some nasal congestion, she was again assessed as a well baby. *Id.*, p. 91. The developmental screening list indicates that she raised her head, fixed on objects in the midline, responded to voices and faces, and had a positive startle reflex. *Id.*, pp. 91-92. She received her second hepatitis B shot at this visit. *Id.*, pp. 1, 91.

The medical records next reflect a call to Child Care Limited on March 13, 2000 at 2050. The telephone message receipt at Pet. Ex. 13, p. 90, indicates that Kaleigh had "shakes" for the prior two days, placing onset of what were later diagnosed as seizures on March 11, 2000. The caller (identified as "Bowie" in this record, probably referring to Ms. Howie) reported that on the previous day, Kaleigh was displaying brief repetitive movements. She did not have a fever. The plan was to bring her in for an evaluation the next morning. *Id.*

Kaleigh was seen at Child Care Limited the next morning, March 14, 2000. The history provided is that she experienced another episode at 0530 that morning, lasting less than 10 seconds. She tightened up, but did not jerk. Her whole body shook and her eyes were open. *Id.* At the time of the visit, Kaleigh had a rectal temperature of 99.9 degrees, indicating that she was afebrile. She was active and alert during the exam and had good muscle tone. The doctor's impression was that Kaleigh looked okay and that seizures were doubtful. *Id.*

The next day, March 15, 2000, Ms. Howie and Kaleigh's father, Mr. Grimes, took Kaleigh to the St. Joseph's Hospital emergency room. Pet. Ex. 4[8], pp. 159-60. Mr. Grimes had videotaped one of Kaleigh's episodes that morning and showed the tape to the emergency room doctor. Her neurological examination was normal. A lumbar puncture was performed and the cerebral spinal fluid showed minimally elevated protein that was not grossly abnormal for an infant her age. *Id.*, p. 158. A CT scan of her head did not reveal any problems. *Id.*, p. 166.

Based on the videotape and her parents' reports of her episodic tremors, Kaleigh was admitted to St. Joseph's Hospital. *Id.*, pp. 157-58. She had three episodes after admission. Her doctors consulted with Dr. Fereuidoun Dehkharghani, a pediatric neurologist at Children's Mercy Hospital ["CMH"], who recommended that Kaleigh be transferred to CMH for an electroencephalogram ["EEG"]. *Id.* She was transferred that day. *Id.*, pp 180-81.

The EEG performed at CMH was clearly abnormal. *Id.*, pp. 178-79. Kaleigh had one clinical seizure lasting slightly less than two minutes during the EEG. There

[8] Petitioner's Exhibit 4 was renumbered by hand at some point. When I cite pages from Petitioner's Exhibit 4, I will be referring to the machine-generated page numbers at the bottom of the pages because they are more legible than the handwritten numbers.

were other electrographic abnormalities not clinically correlated with seizures. Doctor Dehkharghani recommended a brain magnetic resonance imaging ["MRI"], which was performed with and without contrast that day. The MRI was also abnormal. Pet. Ex. 13, p. 105. The ventricles and subarachnoid spaces within Kaleigh's brain were symmetrically enlarged. *Id*. Contrary to assertions in Ms. Howie's affidavit (*see* Pet. Ex. 10, p. 2, in which Ms. Howie asserts that Dr. Dehkharghani told her of demyelination in Kaleigh's brain), there was no evidence of demyelination on the MRI. Pet. Ex. 13, p. 105. The impression was cerebral atrophy. *Id*.

Kaleigh was discharged to home on March 16, 2000, with a prescription for seizure medication and a diagnosis of a seizure disorder. Pet. Ex. 8, p. 297. In spite of the medication, Kaleigh continued to have seizures and at her followup appointment with Dr. Dehkharghani on March 23, 2000, he noted that Kaleigh was now demonstrating "diffuse hypotonia and mild delay in her motor development." Pet. Ex. 4, pp. 175-76.

Over the next several months, evaluations of Kaleigh's condition were increasingly grim. In May 2000, Dr. Dehkharghani commented on her poor head control, delayed motor development, and spinal dysfunction. He remarked that the exact etiology of Kaleigh's seizure disorder was unknown and characterized her prognosis for future development as guarded. Pet. Ex. 8, p. 212, 208. In July 2000, another EEG was abnormal, demonstrating a "diffuse slowing" pattern of electrical activity in Kaleigh's brain. *Id*., p. 207. By August 2000, Dr. Dehkharghani indicated that her seizures and clinical course were typical of "infantile spasms." *Id*., p. 207. Infantile spasms are a type of epilepsy in which the prognosis for recovery is extremely poor.[9] He recommended that Kaleigh be treated with ACTH [adrenocorticotropic hormone] and prednisone, but Ms. Howie declined that treatment.[10] *Id.*, p. 207-08.

Later in August 2000, Ms. Howie took Kaleigh to see Dr. Andrew Campbell of the Center for Immune, Environmental, and Toxic Disorders, in Houston, TX. Although there were no medical records (other than test results) submitted from this and a subsequent visit in October 2000, the billing records reflect charges of approximately $12,000.00 in serologic and other tests from these two visits. Pet. Ex. 9, pp. 7, 9. These records reflect that Kaleigh had vitamin and antioxidant deficiencies and some abnormal serologic test results. *Id*., pp. 35, 37. Apparently Dr. Campbell told Ms. Howie that Kaleigh would benefit from gamma globulin therapy (and the submitted records contain an order for intravenous "Gamma Immune N"). *Id.*, p. 32.

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[9] *See Comprehensive Pediatrics* at 964-65.

[10] Adrenocortocotropic hormone is a recommended treatment for infantile spasms. While it may stop the seizures, there is no clear evidence that it can reverse neurologic damage or reduce the sequelae from the seizure disorder. *Comprehensive Pediatrics* at 965.

In a consultation with Dr. Dehkharghani in October 2000, Kaleigh's parents conveyed what they were told by Dr. Campbell concerning the etiology of Kaleigh's seizures. Doctor Campbell had apparently opined to them that her condition was related to the hepatitis B vaccine causing an immunological disorder. Pet. Ex. 8, pp. 202-04. Doctor Dehkharghani stated his position on this matter in a letter to Dr. Stein, Kaleigh's pediatrician. He noted the temporal relationship between onset of the seizures and the vaccination and commented that he had heard of extremely rare central nervous system complications of vaccination, but was not aware of whether such complications had been substantiated, particularly with infants. He remarked: "In my mind, etiology of Kaleigh's underlying neurologic condition remains unknown." *Id*.

Doctor Dehkharghani was unwilling to order intravenous gamma globulin therapy without further testing. *Id.* Doctor Amado, from CMH's Allergy, Asthma, and Immunology Section, examined Kaleigh and had her immunoglobulin levels tested. She was not exhibiting any signs of immune dysfunction and her immunoglobulin levels were all normal. Pet. Ex. 8, pp. 195-97.

Ms. Howie and her mother also reported to Dr. Amado that Dr. Campbell believed Kaleigh's myelin sheaths were damaged by her hepatitis B immunization. *Id.*, p. 195. The local doctors treating Kaleigh made repeated telephone calls to Dr. Campbell, but were unable to contact him. Pet. Ex. 13, pp. 69-70. Doctor Dehkharghani told Ms. Howie that he felt Dr. Campbell's approach was "alternative" and that he did not agree with Dr. Campbell's diagnosis or conclusion, nor did any of the neurologists with whom he had consulted. He offered to assist her in obtaining another neurologist's opinion. *Id.*

Earlier in the course of Kaleigh's treatment, Ms. Howie had indicated her belief that the hepatitis B vaccination that Kaleigh had received four days prior to the first seizure activity was responsible for Kaleigh's condition. On March 16, 2000, Ms. Howie contacted Child Care Limited to seek information on the vaccine Kaleigh had received. Pet. Ex. 13, p. 89. Dr. Stein indicated that he had not had any reports of a problem with this particular lot number, suggesting that he interpreted Ms. Howie's concern as one regarding a "hot lot" of a vaccine.[11] That same day, she reported to CMH nursing staff that she had a friend whose child had died from complications from a hepatitis B vaccination. Pet. Ex. 4, p. 189. Over a year later, Ms. Howie contacted Child Care Limited to determine if the vaccine Kaleigh had received contained thimerosal and was informed that it did not. Pet. Ex. 13, p. 51. In November 2000, Ms. Howie reported to Kaleigh's mental health case manager that she disagreed with medical personnel who

[11] A "hot lot" is a vaccine lot that has an unusual number of side effects, compared to other lots of the same vaccine. This suggests that something in the vaccine manufacturing process may have gone awry. There was no evidence submitted indicating that the vaccination Kaleigh received was from a "hot lot."

had indicated that Kaleigh's condition was inborn. She continued to attribute Kaleigh's condition to vaccines. Pet. Ex. 4, pp. 51-52.

After several years of treatment at CMH's neurology, endocrinology, and genetics departments, no etiology for her seizure disorder was found (*see, e.g.*, Pet. Ex. 8, pp. 145-87). Doctor Jerome Murphy, another CMH neurologist who saw Kaleigh in January 2001, also opined that Kaleigh's seizures were unrelated to the hepatitis B vaccination. He commented that her seizures occurred four days after her hepatitis immunization, but that he doubted that the vaccine was a "significant factor." *Id*., p. 134.

Kaleigh was evaluated at the Mayo Clinic in September 2003, where she was diagnosed with global developmental delay, severe hypotonia, seizures, severe carnitine deficiency, an episode of hypoglycemia, and a probable ketone utilization defect.[12] Pet. Ex. 12, pp. 46-48. A May 2004 evaluation at the Mayo Clinic added feeding difficulties and failure to gain weight, sleep disturbances, snoring and stridor, and a possible mitochondrial disorder to the previous diagnoses, and removed the carnitine deficiency, hypoglycemia, and ketone utilization defects from her diagnoses. Pet. Ex. 12, p. 76. Kaleigh's skin biopsy did not disclose any mitochondrial disorder, but in the absence of a muscle biopsy, the possibility of a mitochondrial disorder could not be ruled out. *Id.*, p. 125.

By November 2004, there was evidence that Kaleigh's brain had continued to atrophy. Pet. Ex. 12, p. 128. In a meeting with Kaleigh's grandmother, who was caring for Kaleigh, Dr. William Graf explained that in spite of the extensive testing, there was no clear etiology for Kaleigh's condition. Metabolic, genetic, and mitochondrial testing had all failed to pinpoint any reason for Kaleigh's seizure disorder and brain atrophy. In August 2005, Dr. Graf discussed the difficulty of attributing Kaleigh's condition to any particular causal factor. Based on her intractable seizure disorder, he characterized her condition as Lennox-Gastaut Syndrome.[13] *Id.*, p. 187.

The most recent exhibits filed indicate that Kaleigh lives with her grandmother, Mrs. Tammy McKernan.[14] Pet. Exs. 10 and 11. Her seizure disorder is only partially

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[12] The report from the Mayo Clinic comments that "Kaleigh's condition most likely is related to a disorder of ketone utilization and breakdown." Other portions of this report indicate that ketone utilization problems could be the cause of her hypotonia and lethargy; the report was not suggesting that the ketone disorder had caused her seizures. Pet. Ex. 12, p. 47.

[13] Lennox-Gastaut Syndrome is characterized by atypical absence, atonic, and myoclonic seizures. This syndrome is also characterized by slow spike-wave complexes on EEG and mental retardation. Gerald M. Fenichel, *Clinical Pediatric Neurology* 22 (3d ed. 1997).

[14] Ms. Howie's affidavit indicates that Kaleigh lives with her grandmother because Ms. Howie's job does not permit her to care for Kaleigh. While Mrs. McKernan has authority to consent to medical treatment for Kaleigh, the filed exhibits do not reflect a transfer of legal custody to or adoption of Kaleigh

controlled by medication. She is globally developmentally delayed, microcephalic, and underweight. Pet. Ex. 12, p. 165. No cause for her condition has been found. *Id.*, p. 187. According to her grandfather's affidavit, at age 6, Kaleigh weighs barely 30 pounds, cannot talk, walk, dress, or feed herself. She can hear but cannot communicate verbally. She has no control of her neck or trunk, and cannot sit up or lift her head without assistance. She has made little improvement since the beginning of her seizure disorder. Pet. Ex. 11. Medical personnel report that she is well-cared for by her grandmother. *See, e.g.*, Pet. Ex. 12, pp. 95, 166.

II. DISCUSSION

In order to prevail under the Program, petitioner must prove either a "Table" injury or that a listed vaccine was the cause of an injury. Petitioner does not contend that Kaleigh suffered a condition listed on the Vaccine Injury Table; therefore petitioner must prove by a preponderance of the evidence that the hepatitis B vaccination caused Kaleigh's seizure disorder. While the medical records establish that Kaleigh was vaccinated as alleged in the petition and continues to suffer from a seizure disorder and global developmental delays, no reliable evidence in the form of medical records or an expert opinion causally links her condition to the vaccine.

To satisfy her burden of proving causation, 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. Sec'y, HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992); *see also*, *Capizzano v. Sec'y, HHS,* 440 F.3d 1317, 1324 (Fed. Cir. 2006); *Althen v. Sec'y, HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Agarwal v. Sec'y, HHS*, 33 Fed. Cl. 482, 487 (1995).

Without more, "evidence showing an absence of other causes does not meet petitioner's affirmative duty to show actual or legal causation." *Grant*, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. *Hasler v. U.S.*, 718 F.2d 202, 205 (6th Cir. 1983), *cert. denied*, 469 U.S. 817 (1984). An award may not be based on petitioner's claims alone. 42 U.S.C. § 300aa-13(a)(1).

The only statements regarding vaccination causation for Kaleigh's seizure disorder come from Ms. Howie's report of what she was told by Dr. Campbell. While I am not bound by the rules of evidence (*see* § 300aa–12(d)(2)(B)), I am unwilling to accept Ms. Howie's statements as to what Dr. Campbell said as evidence of causation. I know nothing of Dr. Campbell's qualifications to render such an opinion. He apparently relied on medical tests purporting to show an immunological problem in Kaleigh, tests that could not be duplicated by Kaleigh's treating physicians back in Kansas City, MO. According to Ms. Howie, he determined that the hepatitis B vaccine

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by Mrs. McKernan.

stripped the myelin from Kaleigh's brain. No objective medical test, however, showed demyelinization. Doctor Campbell's second-hand opinion does not pass muster under *Althen's* three part test, as there is no biologically plausible explanation accompanying it, and no explication of a logical sequence of cause and effect between vaccination and injury. At best, there is a temporal relationship, a fact also noted by several treating neurologists. These same neurologists, however, have reiterated their opinions that the hepatitis B vaccination was not a factor in Kaleigh's seizure disorder, calling the disorder one of an unknown etiology.

No one who reads of Kaleigh's tragic illness can be unmoved. The devotion shown by her caregivers, particularly her grandmother, is remarkable. In spite of her severe impairments, Kaleigh has not suffered pressure sores or aspiration pneumonia, problems often encountered by children with similar disabilities.

While it is troubling that no cause for Kaleigh's seizure disorder and brain atrophy has yet been discovered, the lack of an etiology does not equate to vaccine causation. Respondent's burden to show an alternative cause–a "factor unrelated" in the language of § 300aa–13(a)(1)(B)–is not triggered until petitioner demonstrates vaccine causation by a preponderance of the evidence. I conclude that she has failed to meet that burden.

III. CONCLUSION

A special master can only authorize compensation when a medical condition either falls within one of the "Table" injury categories or when some reliable evidence causally connects the vaccine with the injury. No such evidence exists in the record before me. Therefore, the petition for compensation is DENIED. 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 with this decision.[15]

IT IS SO ORDERED.

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DATE Denise K. Vowell
Special Master

[15] 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.