

IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS
No. 06-840V
Filed: January 13, 2009

LYNNA TELLER, Parent and Next Friend of *
NAIYA N. NAMOKI, a minor *
Petitioner, * Decision on the Record;
* Febrile Seizures;
* DTaP
V. *
*
SECRETARY OF THE DEPARTMENT *
OF HEALTH AND HUMAN SERVICES, *
*
Respondent. *
*

Richard Gage, Cheyenne, WY, for petitioner.
Ryan Pyles, U.S. Department of Justice, Washington DC, for respondent.

RULING ON ENTITLEMENT¹

VOWELL, Special Master:

On January 11, 2006, Lynna Teller [“petitioner”], timely filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa–10, *et seq.*,² [“Program” or “Vaccine Act”] on behalf of her minor son, Naiya N. Namoki [“Naiya”]. The petition [“Pet.”] alleges that, as a result of his vaccinations on February 3, 2004, which included a diphtheria, tetanus, and acellular pertussis [“DTaP”] vaccination, Naiya suffered a

¹ Because this unpublished decision contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims’s website, in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 Part 2, National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all “§” references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa.

febrile seizure that lasted more than thirty minutes and continues to have seizures, as well as other neurological effects. Pet. at 2-4. The petition also alleges that within 72 hours of receiving his vaccinations, Naiya suffered a Vaccine Injury Table encephalopathy,³ consisting of a significantly decreased level of consciousness lasting more than 24 hours that has persisted for more than six months beyond the date of vaccination. Pet. at pp. 6-7. Alternatively, petitioner alleges that Naiya's injuries were caused-in-fact by his vaccines on February 3, 2004. Pet. at 9.

PROCEDURAL HISTORY

The petition filed on December 11, 2008, was accompanied by medical records including petitioner's birth and shot records. Additional medical records were filed on January 16, and February 5, and 8, 2007. On August 14, 2007, petitioner filed the medical expert report and curriculum vitae of Dr. Marcel Kinsbourne. On November 9, 2007, respondent filed a Rule 4(c) Report and the expert report and curriculum vitae of Dr. Max Wiznitzer. At petitioner's request, the case was scheduled for the earliest hearing date that would accommodate the schedules of the expert witnesses. That hearing, originally scheduled for April 4, 2008, was later postponed until October 17, 2008.

On October 2, 2008, respondent filed a Motion for Ruling on the Record. In response to this filing, the court held a status conference at which the parties agreed to cancel the rescheduled hearing, as petitioner did not oppose a ruling on the record with regard to the cause of Naiya's initial seizure and ensuing seizure disorder.

Based on the record as a whole, I find sufficient evidence to grant respondent's motion and issue a ruling as to the cause of Naiya's initial seizure and subsequent seizure disorder. I find that on February 3, 2004, Naiya suffered a prolonged febrile seizure that was caused by the DTaP vaccination he had received earlier that day. I further find that Naiya now suffers from a seizure disorder, a condition that has persisted for longer than six months, and that the seizure disorder is the result of the initial febrile seizure. Petitioner is therefore entitled to compensation. I make no findings at present as to what, if any, additional sequelae, may exist, beyond the seizure disorder.

THE EVIDENTIARY RECORD

Naiya was born on June 15, 2003, following a complicated pregnancy and poor prenatal care. Petitioner's Exhibit ["Pet. Ex."] 11 at 50-51. During labor, Naiya's mother was given oxygen, position change, and bolus IV fluid in order to correct apparent fetal distress. Pet. Ex. 11 at 2. These efforts were unsuccessful and Naiya was born by emergent cesarean section. At birth, there was meconium stained amniotic fluid. Pet

³ 42 C.F.R. §100.3(b)(2).

Ex. 1 at 10; Pet Ex. 11 at 2. Although his heart rate stayed above 100, his respiratory effort and his tone and color were described as poor. He required supplemental oxygen. Pet. Ex. 11 at 2. His Apgar⁴ scores were 7 at one minute and 9 at five minutes. Pet. Ex. 2 at 1.

At discharge on June 18, 2003, Naiya was suffering from breastfeeding jaundice. He was still slightly jaundiced at a followup visit on June 24, 2003. At that visit the health care provider also noted under “abnormal findings,” that Naiya went “rigid and bends back when put on stomach.” Pet. Ex. 2, p. 6-7.

On June 26 and August 26, 2003, Naiya was seen by a public health nurse for clogged tear ducts and possible left eye conjunctivitis. *Id.* at 9, 12. The provider noted “Needs WCC [well child checkup] next available.” *Id.* at 12 (emphasis original). On December 29, 2003, a public health nurse contacted petitioner at home about Naiya’s delinquent immunizations. *Id.* at 14.

On February 3, 2004, at a 9:00 AM doctor’s appointment, Naiya received his first immunizations. These consisted of Pediarix,⁵ pneumococcal vaccine, and haemophilus influenzae type b vaccine. Pet. Ex. 2 at 16; Pet Ex. 8. All are vaccines appearing on the Vaccine Injury Table, 42 C.F.R. § 100.3. The medical records indicate that Naiya had a fever the prior evening and presented for the visit with a 99.3 degree temperature and congestion and that he had been given Motrin that morning. Pet. Ex. 2 at 16.

Later that day, at 12:50 PM, emergency medical services [“EMS”] responded to a call for assistance indicating that Naiya was having a seizure. Pet. Ex. 2 at 16; Pet. Ex. 10. When EMS arrived at 1:12 PM, Naiya was still actively seizing, and had reportedly been seizing for thirty minutes. *Id.* at 2. Initially, his oxygen saturation level was 84%, but by 1:30 PM, it was up to 97%. *Id.* The EMS technicians responding noted generalized tonic/clonic seizure activity with Naiya’s eyes rolled back into his head. They administered oxygen while transporting him to the emergency room at the United States Public Health Service [“USPHS”] facility at Chinle, New Mexico. hospital. Pet. Ex. 2 at 21.

On arrival, Naiya had a fever of 103.5 degrees and a chest x-ray showed slight, hilar haziness. Pet. Ex. 2 at 18-19. The discharge records indicate Naiya’s diagnosis

⁴ 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 from zero to two points awarded in each of the five categories. See DORLAND’S ILLUSTRATED MEDICAL DICTIONARY, (30TH ED.) (2003) [“DORLAND’S MEDICAL DICTIONARY”], at 1670.

⁵ Pediarix vaccine is a combination of diphtheria, tetanus, and acellular pertussis vaccine, inactivated polio vaccine, and hepatitis B vaccine. PHYSICIAN’s DESK REFERENCE [“PDR”] at 1594 (61st ed. 2007)

as “atypical febrile seizure possibly related to DtaP administration and possibly not.” *Id.* at 23. The ER record noted no evidence of trauma and no immunizations until the day of admission. The only significant family history was a cousin who suffered seizures in infancy. *Id.* at 22. The discharge record further indicated that Naiya had suffered no further seizure activity while hospitalized, and that after his initial seizure, “his neurological examination completely normalized and he was back to his normal self according to his mother.” *Id.* at 24.

He was admitted to the hospital on February 17, 2004, with a positive test for respiratory syncytial virus. He was noted to be within developmentally normal limits at that time. Pet. Ex. 2 at 42-43. No febrile seizures were associated with the visit.

On June 2, 2004, Naiya was seen in the emergency department of Flagstaff Medical Center for a complaint of a five to ten minute seizure. Pet. Ex. 3 at 10-17. By the time EMS arrived, Naiya was no longer seizing and looked “quite good.” *Id.* This seizure occurred approximately four months after Naiya received his DTaP vaccination. The records do not indicate whether the seizure was febrile.

On April 28, 2008, Naiya received a neurological exam at Phoenix Children’s Hospital with Dr. Allan M. Kaplan, MD. Pet Ex. 32. In his report, Dr. Kaplan noted that Naiya had both generalized and partial-type seizure episodes. He referred to an abnormal EEG, but noted that he had not seen the EEG. Doctor Kaplan commented that Naiya “did have a MRI scan that revealed focal areas of abnormal signal in the subcortical white matter” which he considered to be “consistent with early occurring lesions.” *Id.* Doctor Kaplan diagnosed Naiya as suffering from a mixed seizure process. He prescribed antiepileptics for Naiya.⁶

DISCUSSION

In order to prevail under the Program, petitioner must prove either a “Table” injury⁷ or that a vaccine listed on the Vaccine Table was the cause in fact of an injury. Based on the record as a whole, petitioner has not established that Naiya suffered a Table injury. She has, however, established that the DTaP vaccine Naiya received on February 3, 2004, was the cause-in-fact of Naiya’s febrile seizure on that date and of his subsequent seizure disorder. See § 300aa-11(c)(1)(C)(i).

The Vaccine Act provides that a special master may not make a finding awarding compensation based on the claims of a petitioner alone, unsubstantiated by medical

⁶ Doctor Kaplan also referred to petitioner’s own history of significant seizures and her medication for this condition.

⁷ 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 records do not support the existence of a “Table encephalopathy” in this case.

records or medical opinion. See § 300aa-13(a)(1). Petitioner has proffered both medical records and an expert medical opinion by Dr. Marcel Kinsbourne causally linking his injuries to the DTaP vaccine.

To satisfy his burden of proving causation in fact, petitioner must "show by preponderant evidence that the vaccination brought about [his] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen v. Sec'y, HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). See also, *Hines v. Sec'y, HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). He must show "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). Circumstantial evidence and medical opinions may be sufficient to satisfy the second *Althen* factor. *Capizzano v. Sec'y, HHS*, 440 F.3d 1317, 1325 (Fed. Cir. 2006). Without more, "evidence showing an absence of other causes does not meet petitioner's 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. See *Hasler v. U.S.*, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984).

When a petitioner alleges an "off-Table" injury, eligibility for compensation—the *prima facie* case—is established when the petitioner demonstrates, by a preponderance of the evidence, that: (1) Naiya received a vaccine set forth on the Vaccine Injury Table; (2) that he received the vaccine in the United States; (3) that he sustained or had significantly aggravated an illness, disease, disability, or condition caused by the vaccine; and (4) that the condition has persisted for more than six months.⁸

According to the medical records, there is no dispute that Naiya received a covered vaccine administered in the United States. It is also clear that within a few hours of receiving the DTaP vaccine, Naiya suffered a febrile seizure that lasted at least thirty minutes and that a resulting seizure disorder has persisted well beyond six months from the time of the initial seizure. Therefore, the only issue left to resolve is whether the DTaP vaccination administered on February 3, 2004, was the cause-in-fact of Naiya's febrile seizure and any subsequent disorders.

In support of causation, petitioner offered Dr. Marcel Kinsbourne's medical expert opinion and the medical literature cited therein. Doctor Kinsbourne opined that seizures are a well-documented, albeit usually temporary complication of whole cell

⁸ Section 300aa-13(a)(1)(A). This section provides that petitioner must demonstrate by a preponderance of the evidence the matters required in the petition by section 300aa-11(c)(1)...." Section 300aa-11(c)(1) contains the four factors listed above, along with others not relevant in this case.

pertussis vaccine.⁹ He noted that Naiya's prolonged seizure would have qualified him as a "case child" under the National Childhood Encephalopathy Study ["NCES"], which found a significant association between DTP vaccination and "severe acute neurological illnesses." Relying on the NCES, the Institutes of Medicine found a causal connection between DTP and seizures lasting longer than 30 minutes.

Citing to studies showing a reduction in seizures following the replacement of DTP vaccine with DTaP vaccine, Dr. Kinsbourne noted that seizures continued to be a recorded event. See Pet. Ex. 26, L. Jackson, *et al.*, *Retrospective population-based assessment of medically attended injection site reactions, seizures, allergic responses and febrile episodes after acellular pertussis vaccine combined with diphtheria and tetanus toxoids*, PEDIATR. INFECT. DIS. J. Vol. 21, No. 8 (2002). Although the use of DTP vaccination studies to inform an opinion on the link between DTaP vaccination and seizures is unconvincing, the court does agree that both the whole cell and acellular pertussis types of the vaccine have been shown to cause neurological reactions.¹⁰ See, e.g., Physician's Desk Reference ["PDR"] at 1597-1599 (61st ed. 2007).

In response, respondent offered the medical expert opinion of Dr. Max Wiznitzer. Doctor Wiznitzer disagreed with Dr. Kinsbourne's opinion supporting vaccine causation of Naiya's seizure disorder, noting that studies connecting seizures with the DTP vaccine could not be applied to a different vaccine, the DTaP vaccine that Naiya received. Dr. Wiznitzer proposed an alternate cause for Naiya's fever, febrile seizure, and subsequent seizure disorder, noting evidence of an upper respiratory infection on the chest x-ray at the USPHS hospital. He also noted that Naiya was mildly congested

⁹ Doctor Kinsbourne's report had several weaknesses, including his discussion of the medical literature regarding the effects of the DTP vaccine, rather than tailoring his report to the association of febrile seizures with the DTaP vaccine. The DTP vaccine contained a whole cell pertussis component; the DTaP vaccine contains an acellular pertussis component. The literature Dr. Kinsbourne cited noted a significantly reduced rate of side effects from the DTaP vaccine as compared to the whole cell pertussis vaccine. Additionally, Dr. Kinsbourne's reliance on VAERS data to support his opinion carries little weight. Petitioners would be better served by opinions that focus on the *Althen* criteria and the vaccine actually administered, rather than opinions that rehash the issues regarding DTP vaccines. Doctor Kinsbourne appears quite frequently as an expert in Vaccine Act cases. To the extent that he presents recycled reports from the days of DTP vaccines, his credibility is not enhanced.

¹⁰ While the court is not bound by the decisions of other special masters, they can be informative. In *Simon v. Sec'y, HHS*, the chief special master found that petitioner met her burden of proof to show that the DTaP vaccination was the legal cause of her son's epilepsy. *Simon v. Sec'y, HHS*, No. 05-941V, 2007 U.S. Claims LEXIS 187 (Fed. Cl. Spec. Mstr. Jun. 1, 2007). Holding for petitioner, the special master noted the same weaknesses in Dr. Kinsbourne's opinion in that case that I have noted here. Specifically, the special master wrote that "The undersigned does not dispute that both vaccines may result in the same neurological reactions, however as Dr. Kinsbourne noted these events do not occur with the same frequency. Accordingly the relative risks of an adverse event from a DTP vaccine found in those DTP related epidemiological studies do not attach to a DTaP vaccine...Thus, it appears that the DTP studies cannot be used to support DTaP causation." *Id.* at *23-*25.

and had an elevated temperature prior to administration of the vaccinations to support his theory of alternate cause. Res. Ex. A.

Based on the medical journal articles cited, and considering the medical expert opinions offered, I conclude that the weight of the evidence favors a causal connection between DTaP vaccine and fever in this case. The vaccine-induced fever can trigger febrile seizures in some children predisposed to such seizures, and a small number of such children go on to develop seizure disorders. Febrile seizures are rare in children younger than nine months of age.¹¹ Naiya was not yet nine months old at the time of his initial febrile seizure. Fever is a relatively common side effect of the Pediarix vaccine. PDR at 1597. Although most children with one febrile seizure do not go on to develop seizure disorders, a small minority of such children do.¹² Sadly, Naiya is one of those children.

I note that this is in accord with the decisions of my colleagues in several cases. In *Simon*, the court found that the DTaP vaccination caused fever, which triggered febrile seizures and epilepsy. *Simon* at *25. In *Cusati v. Sec'y, HHS*, the court found that the MMR vaccine caused fever, which triggered petitioner's son's seizure disorder. *Cusati v. Sec'y, HHS*, 2005 U.S. Lexis CLAIMS 403 (Fed. Cl. Spec. Mstr. Sep. 22, 2005) at *35-*36.

CONCLUSION

Petitioner has established the statutory requirements for entitlement. Based on the record before me, I find that there is preponderant evidence that Naiya's DTaP vaccination was a substantial cause of his fever on February 3, 2004, that the fever triggered a febrile seizure, and that febrile seizure was the first manifestation of Naiya's seizure disorder. I further find that the seizure disorder has persisted for more than six months.

I hold that petitioner has established entitlement to compensation for Naiya's seizure disorder.

IT IS SO ORDERED.

s\Denise K. Vowell
Denise K. Vowell
Special Master

¹¹ Nelson Textbook of Pediatrics, 18th ed (Sanders 2007), Chapter 593, p. 2457.

¹² Naiya had several of the risk factors for development of recurrent seizures. He was under 12 months of age at the time of the initial seizure and initially presented with a complex seizure. There is also a family history of seizure disorders. *Id*, p. 2457-58.