In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 04-997V

Filed: July 9, 2007

Not To Be Published

LAURA M. MERSBURGH, parent and next friend of ELIJAH MERSBURGH, a minor,	*	Complex Febrile Seizure; DTaP Vaccine; Fever; Epilepsy; Developmental Delay
Petitioner,	*	
v.	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Richard Gage, Richard Gage, PC, Cheyenne, WY for petitioner.

Althea Walker Davis, United States Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT[1]

GOLKIEWICZ, Chief Special Master.

On June 14, 2004, petitioner, Laura M. Mersburgh (Ms. Mersburgh), filed a petition on behalf of her son, Elijah Mersburgh (Elijah), pursuant to the National Vaccine Injury

[1] Because this Ruling on Entitlement contains a reasoned explanation for the undersigned's action in this case, the undersigned intends to post this Ruling on Entitlement on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, "the entire" Ruling will be available to the public. Id.

Compensation Program[2] ("the Act" or "the Program") alleging that Elijah suffered an encephalopathy, seizures, and developmental delay, as a result of the Diphtheria-Tetanus-acellular-Pertussis (hereinafter "DTaP") vaccine he received on July 5, 2001.[3] Petition (Pet.) at 2-3. On January 6, 2005, respondent filed a Report pursuant to Vaccine Rule 4 contending that compensation was inappropriate and the petition should be dismissed. Respondent's Report, filed Jan. 6, 2005. To elicit expert testimony, a Hearing was held on August 17, 2005. Petitioner presented Marcel Kinsbourne, M.D., as an expert witness. Respondent presented Wendy Mitchell, M.D., as an expert witness. On April 20, 2007, the undersigned indicated to the parties in a Damages Order that the Court intended to issue in the near future a decision on behalf of the petitioner based upon a review of the parties' most recent filings, the medical records, the experts' reports and testimony, and the medical texts filed by the undersigned. Order filed April 20, 2007 at 1. This Ruling follows.

After reviewing the entire record, considering the testimony of both experts, in light of the undersigned's recent decision in Simon v. Secretary of HHS, No. 05-941V, 2007 WL 1772062 (Fed. Cl. Spec. Mstr. June 1, 2007) and Special Master Edwards' decision in Cusati v. Secretary of HHS, No. 05-5049V, 2005 WL 4983872 (Fed. Cl. Spec. Mstr. Mar. 9, 2006), and for the reasons set forth below, the Court finds petitioner has met her burden of proof required under the Act, and thus is entitled to compensation. A summary of the findings follow.

Elijah was born on February 22, 2001. Petitioner's Exhibit (Pet. Ex.) 1 at 2. Elijah received a DTaP Vaccination on July 5, 2001 at 11:55am. Pet. Ex. 1 at 1. That same day, Elijah experienced a fever, Transcript of August 17, 2005 Hearing (Tr.) at 20, and five hours subsequent to his vaccination suffered a seizure lasting at least 47 minutes.[4] Pet. Ex. 19 at 9. Petitioner's expert, Dr. Kinsbourne described Elijah's initial seizure on July 5, 2007 as a complex febrile seizure. Pet. Ex. 34. Elijah was diagnosed as having status seizures and was

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[2] The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C.A. §§ 300aa-10 et seq. (West 1991 & Supp. 2002) ("Vaccine Act" or the "Act"). Hereinafter, individual section references will be to 42 U.S.C.A. § 300aa of the Vaccine Act.

[3] The Petition alleged that Elijah suffered an encephalopathy and seizures as a result of the pneumococcal conjugate vaccine (PCV), DTaP, IPV, and HIB vaccinations. However petitioner elected to pursue compensation on the theory that the DTaP vaccination alone caused in-fact his seizure disorder. Petitioner did not pursue a Table claim. Tr. at 11-14; Pet. Ex. 14 at 2.

[4] The undersigned notes that respondent raised an issue as to the actual length of the initial seizure, whether the seizure lasted for 15 minutes or a minimum of 47 minutes, at the hearing held in this matter on August 17, 2005. Tr. at 32-36. The undersigned concurs with Dr. Kinsbourne and finds the emergency room records to be the best indication of the length of the initial seizure. Id. The emergency room records support a minimum seizure time of 47 minutes. Pet. Ex. 19 at 9.

described as having "presented with status epilepticus." Pet. Ex. 19 at 9, 11. From that time forward, Elijah continued to suffer from both febrile and afebrile seizures, and as his seizure disorder progressed, his development progressively lagged. Pet. Ex. 14 at 1-2, Pet. Ex. 29 at 3-4.

In the recently issued Simon decision, the undersigned noted that the following fact pattern is seen frequently in vaccine cases: "An otherwise healthy petitioner receives a vaccination, the vaccine causes a fever, which in turn causes or triggers a complex febrile seizure." Simon v. Secretary of HHS, No. 05-941V, 2007 WL 1772062 at *3 (Fed. Cl. Spec. Mstr. June 1, 2007). If a case fits this described pattern, as the case at hand does, the undersigned is strongly inclined to find in favor of the petitioner. As the literature explains,

> [c]omplex febrile seizures are "seizures lasting longer than 15 minutes, occurring more than once in a 24 hours, or having focal features." Gregory L. Holmes, M.D., Diagnosis and Management of Seizures in Children, 228 (W.B. Saunders Staff eds., 1987). As discussed by Dr. Holmes, if the first febrile seizure is complex, the risk for developing epilepsy increases significantly. Id. at 228-229; See also Jean Aicardi, M.D., Epilepsy in Children, 231 (Joseph French et al. eds. 1986). In addition, while recognizing that the impact of febrile seizures on intellectual and motor development "has been an area of controversy,"citing numerous studies Holmes reported that prolonged or complex seizures are recognized as the antecedent of sequelae. Holmes, supra, at 227-228; see also Aicardi, supra, at 231.

Id.[5]; See Cusati v. Secretary of HHS, No. 05-5049V, 2005 WL 4983872 (Fed. Cl. Spec. Mstr. Mar. 9, 2006)

Based upon the above teachings and the expert testimony presented in this case, the undersigned finds that petitioner has met her burden under the three part test of causation articulated in Althen v. Secretary of HHS, 418 F.3d 1274 (Fed. Cir. 2005). The Federal Circuit reiterated that petitioner's burden is to produce "preponderant evidence" demonstrating: "(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 the vaccination and injury." Id. at 1278.

Both Drs. Kinsbourne and Mitchell[6] agree on the following: vaccines can cause fevers,

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[5] The Holmes and Aicardi literature was filed into the record of this case as Court Exhibits 1 and 2 pursuant to the undersigned's Order dated March 21, 2007.

[6] In deciding this case, the experts' experience and credibility were not factors. Both experts are well-known to the undersigned and are highly respected for their knowledge and testimony.

Tr. at 78, DTaP can cause a fever, Tr. at 79, a fever is a precipitant of a febrile seizure disorder, Tr. at 78, and that Elijah suffers from developmental abnormalities. Tr. at 96. However, the doctors diverge on the cause of Elijah's developmental abnormalities and whether Elijah experienced any sequelae resulting from his July 5, 2001 vaccination.

Dr. Kinsbourne testified that the DTaP vaccination Elijah received on July 5, 2001 caused Elijah to experience a fever which resulted in Elijah experiencing a seizure that same day lasting at least 47 minutes, and that enough damage occurred as a result of this initial seizure (which was diagnosed as status epilepticus by Elijah's treating physician and which Dr. Kinsbourne clarified in Pet. Ex. 34 was also a complex febrile seizure) that Elijah continued to suffer from seizures, developed epilepsy and suffered developmental delay. Tr. at 23-26. Dr. Kinsbourne testified that the prolonged duration of Elijah's initial seizure is significant as "the longer a seizure lasts, the more likely it is to cause brain damage and even to threaten life . . . the longer it goes on, the more strain on the brain, the more metabolic problem of energy supply, the more likelihood that not enough oxygen is getting to the brain to keep its neurons alive." Tr. at 72. The undersigned questioned Dr. Kinsbourne "why if the child suffered a prolonged seizure causing some brain damage, why would you see the comments in the records for weeks following that the child was - there was indications of normality?" Tr. at 72-73. Dr. Kinsbourne explained that as "four month old baby is only using part of his brain. . . . you very often have an injury where the consequences are only apparent after months when the cerebral cortex should be working and isn't so - . . . ." Tr. at 73-74.

Respondent's expert Dr. Wendy Mitchell opined that the cause of Elijah's epilepsy was unknown, but in her opinion Elijah's seizure disorder was not caused in-fact by his July 5, 2001 DTaP immunization, although she noted "it is possible that DTaP precipitated the fever, and he clearly did have a seizure at that time." Tr. at 80. Rather, Dr. Mitchell hypothesized that Elijah may have a genetic predisposition to suffer from epilepsy. Id. Dr. Mitchell testified that as Elijah's parents both suffered from febrile seizures at some point in their lives it is possible there is a genetic basis for Elijah's epilepsy. Tr. at 80-84. However, the undersigned notes that Dr. Mitchell merely speculates that Elijah might have a genetic predisposition to suffer epilepsy and that nothing in the record evidences such a predisposition. Dr. Mitchell further testified that a DNA test was available that could potentially determine whether or not the cause of Elijah's epilepsy was genetic. Tr. at 81-83. However, respondent made no formal request for Elijah to undergo this genetic testing until the August 17, 2005 Hearing, which was "to say the least, untimely." Order filed Aug. 23, 2005. Subsequent to the Hearing, on September 16, 2005, respondent filed a written motion to require Elijah to have genetic testing and filed a supplemental expert report from Dr. Mitchell which described in greater detail the genetic testing procedure requested by respondent. Respondent's Response to the Chief Special Master's Order of August 23, 2005 filed Sept. 16, 2005; Resp. Ex. D at 4. However, as the undersigned addressed in the Order denying respondent's motion, "no 'objective data' addressing the reliability" of the test results was ever submitted by respondent and Dr. Mitchell's supplemental report "introduced a new issue, stating that the 'gene test is not completely specific and a positive test needs to be further evaluated by testing the parents.'" Order filed January 27, 2006 at 1-2. Accordingly, the undersigned denied respondent's motion. Order filed January 27, 2006.

Thus, the record is devoid of evidence of a genetic predisposition to epilepsy.

Dr. Mitchell also suggested that Elijah's July 5, 2001 fever and seizure was a result of a viral illness or gastroenteritis and not his vaccination that same day. Tr. at 78-79, 84-85; Resp. Ex. A at 2. However, the undersigned agrees with Dr. Kinsbourne that there is no reliable evidence in the record to support this theory. Tr. at 38, 70. Thus the undersigned finds that respondent has not identified an alternative theory of causation for Elijah's fever, which led to his initial complex seizure which resulted in his seizure disorder.

Finally, Dr. Mitchell opined that Elijah's seizure disorder and subsequent developmental delays were not the sequelae of his July 5, 2001 DTaP vaccination, Tr. at 79, because in her opinion Elijah was developmentally normal after his initial seizures, id., he had normal EEG test results, Tr. at 80, and that in the "vast majority of time, even a prolonged seizure does not cause long term sequelae." Tr. at 86. Dr. Mitchell testified that Elijah's seizures and his subsequent developmental problems were the result of his abnormal brain and not the sequelae of his July 5, 2001 vaccination. Tr. at 87, 95, 97. However, Dr. Mitchell noted that while she does not "think his developmental delay is ***directly*** the result of any of his seizures," Tr. at 86 (emphasis added), Dr. Mitchell agreed with Dr. Kinsbourne "you're not going to pick up developmental problems in a four month old . . . ," id., and finally conceded "a very bad - a very prolonged episode of status . . . may cause damage." Tr. at 96.

Dr. Kinsbourne addressed the issue of the sequelae following Elijah's July 5, 2001 and subsequent seizure disorder in a supplemental expert report filed with supporting medical literature on August 18, 2006. Pet. Ex.'s 29-32. First, Dr. Kinsbourne opined and provided supportive medical literature that febrile seizures (particularly prolonged or recurrent seizures) and the antiepileptic drugs used to treat these seizures can damage a child's developing brain. Pet. Ex. 29 at 1-2. Further, Dr. Kinsbourne as part of his opinion, quoted medical literature which stated "'[s]eizure induced behavioral and cognitive, deficits, which may not become obvious until long after the onset of epilepsy, might be equally or more detrimental to a child's overall functioning than the seizures themselves.'" Id. at 2 citing Pet. Ex.26. Dr. Kinsbourne opined in his report that he does not believe Elijah ever returned to normal after his initial seizure, as is evidenced by his subsequent neurological examinations.

> Elijah's first neurological examination after his hospitalization on July 5, 2001, by Dr. Okumura, was only three weeks later, on July 21, 2001 (Exhibit 1, page 7). Dr. Okumura records that Elijah's sleep patterns have changed, and that he had "mildly decreased tone in all four extremities", as well as a question of slight "decreased use of his right hand". At neurological examination on January 2, 2002, he had "mild right hemiparesis". On February 12, 2002, the record states "abnormal examination with mild right hemiparesis". Mild hemiparesis was also observed on March 15, April 14, May 6 and December 18, 2002.
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> Mild developmental delay is noted on April 14, 2002, only about nine months after July 5, 2001, the date of the status epilepticus. Mild developmental delay

> was again recorded on May 6, 2002. Elijah was said to be "slightly behind developmentally" on December 18, 2002 .

Pet. Ex. 29 at 3. Dr. Kinsbourne further explains,

> [d]evelopmental delay is diagnosed when a child has failed to meet a milestone within the expected time frame. Given the wide individual differences in the ages at which young children normally reach developmental milestones, the slowdown in development may have begun well before developmental delay can be diagnosed.
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> Had there in fact been a delayed onset of developmental delay in Elijah's case that would not have changed my opinion. . . . I did not come across any article that took issue with the fact that developmental delay following brain injury begins after a substantial delay. Developmental delay is quite variable in the timing of its presentation after status epilepticus. . . . In young children cognitive delays may become diagnosable quite a long time after the injury that caused them has occurred.

Id. at 3-4.

Based upon the totality of the record and as discussed above, the undersigned finds Dr. Kinsbourne more persuasive on this issue. In doing so, the undersigned does not cavalierly dismiss the testimony of Dr. Mitchell, but finds that her testimony is colored by requiring a higher level of proof of causation and sequelae, more closely resembling medical certainty than the preponderance of the evidence standard required by the Act. As the undersigned noted in Simon,

> [w]hat we face in this case is an unprovable event, unprovable utilizing the higher standard of medical certainty. However, on a probability scale, it is exceedingly reasonable to conclude that where the vaccine is associated with fever and seizure and the seizure is of a complex nature, in the absence of proof of an alternative cause, it is the vaccine that is responsible for a subsequent epilepsy and residual sequelae.

Simon, No. 05-941, at *6.

Accordingly, the undersigned finds that petitioner has established by a preponderance of the evidence that Elijah's July 5, 2001 vaccination was the legal cause of Elijah's seizure disorder and developmental delay. The undersigned finds that there is not a preponderance of the evidence that the legal cause of Elijah's seizure disorder and developmental delay was due to factors unrelated to Elijah's July 5, 2001 vaccination. Accordingly, petitioner is entitled to reasonable compensation.

IT IS SO ORDERED.

Gary J. Golkiewicz
Chief Special Master