OFFICE OF SPECIAL MASTERS

Filed: October 18, 2005

JEFFREY AMES, Parent of TESSA AMES, a minor,	*	
Petitioner,	*	
v.	*	No. 04-1706V
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Ronald C. Homer, Boston, Massachusetts, for Petitioner.

Lisa A. Watts, United States Department of Justice, Washington, D.C., for Respondent.

DECISION[1]

SWEENEY, Special Master

On November 23, 2004, Jeffrey Ames, as the parent of Tessa Ames ("Tessa"), filed a petition for compensation under the National Childhood Vaccine Injury Act ("Vaccine Act"). 42 U.S.C. § 300aa-1 to -34 (1991 & Supp. 2002). Mr. Ames then filed a detailed amended petition on May 20, 2005. The timely-filed petition, as amended, alleges that Tessa received a diphtheria, tetanus, and acellular pertussis ("DTaP")[2] vaccination on December 3, 2001, and as a result, suffered from seizures, encephalopathy,[3] and other neurological injuries. Unfortunately, Mr. Ames has not offered any medical evidence to support his allegation that Tessa's seizures,

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[1] The court encourages the parties to review Vaccine Rule 18, which affords each party 14 days to object to disclosure of (1) trade secrets or commercial or financial information that is privileged or confidential or (2) medical information that would constitute "a clearly unwarranted invasion of privacy."

[2] The DTaP vaccine is "a combination of diphtheria toxoid, tetanus toxoid, and pertussis vaccine; administered intramuscularly for simultaneous immunization against diphtheria, tetanus, and pertussis." Dorland's Illustrated Medical Dictionary 1998 (30th ed. 2003).

[3] Encephalopathy is a term used to describe "any degenerative disease of the brain." Dorland's Illustrated Medical Dictionary, supra note 2, at 610.

encephalopathy, and other neurological injuries were caused in fact by the DTaP vaccination. Sadly, because Mr. Ames was unable to present sufficient expert medical testimony in support of the allegations set forth in the petition, the special master is compelled to deny his claim and dismiss the petition.

Background

Tessa was born on June 4, 2001.[4] Am. Pet. at 1-2. Prior to the administration of the DTaP vaccination at issue in this case, Tessa was a healthy child who met all of her developmental milestones. Id. Tessa had her six-month well-child examination with pediatrician Michelle M. Pepitone, M.D., on December 3, 2001. Id. at 2. After being declared a healthy baby, Tessa was given several vaccinations, including her third DTaP vaccination. Id.

The next morning, on December 4, 2001, Tessa woke up at her usual time of 6:00 a.m. Id. Tessa felt hot to her mother, but seemed otherwise happy and healthy. Id. While Tessa was in her infant play seat, her parents briefly left the room. Id. Upon Tessa's father's return to the room, he found Tessa "slumped over, strangely, in her seat." Id. Tessa's "head was tilted down and to the side, her right arm was raised and stiff, and her hand was twitching." Id. Tessa's parents became alarmed, and initially believed that Tessa had injured her arm. Id. However, when her parents tried to get her attention, Tessa was unresponsive–her eyes would not track, she was unable to focus on her parents' voices, and she appeared to be "zoned out." Id. at 2-3.

Tessa's parents removed her from her infant play seat and placed her on her changing table. Id. at 3. After a few minutes, Tessa's right arm stopped twitching and became limp. Id. Realizing that Tessa's condition was serious, her parents drove her the short distance to the emergency room at California Pacific Medical Center. Id. During the trip to the emergency room, Tessa's left arm became stiff and Tessa's left hand began to twitch. Id. Tessa's problems with her left arm lasted for about five minutes, before her arm became limp. Id.

Upon the family's arrival at the emergency room, Tessa was examined by Bryan G. Chaffee, M.D. Id. At the time of Dr. Chaffee's examination, Tessa was beginning to recover the use of her arms, and was alert and stable. Id. However, while still in the emergency room, Tessa began to have "generalized myoclonic jerks"[5] affecting her entire body and "focalized

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[4] All references to the Amended Petition shall be designated herein as "Am. Pet. at __." All references to the pertinent Petitioner's Exhibit shall be designated herein as "Pet. Ex.__ at __."

[5] A myoclonic seizure is "one characterized by a brief episode of myoclonus, with immediate recovery and often without loss of consciousness." Dorland's Illustrated Medical Dictionary, supra note 2, at 1676. Myoclonus refers to "shocklike contractions of a portion of a muscle, an entire muscle, or a group of muscles, restricted to one area of the body or appearing synchronously or asynchronously in several areas." Id. at 1213.

twitching"[6] that affected her legs. Id. at 3-4. Dr. Chaffee observed these symptoms and decided to admit Tessa to the pediatric intensive care unit ("PICU") for "new-onset seizures." Id. Dr. Chaffee noted that Tessa was possibly experiencing a vaccine reaction. Id. at 4.

At about 6:00 p.m., while in the PICU, Tessa was evaluated by pediatrician John T. Tsukahara, M.D. Pet. Ex. 3 at 91-92. Dr. Tsukahara noted that Tessa was "awake, alert, [and] afebrile." Id. at 91; Am. Pet. at 4. Tessa did not have any further seizures in the PICU. Pet. Ex. 3 at 17, 94. On December 5, 2001, after a normal, seizure-free examination and a normal electroencephalogram ("EEG"),[7] Tessa was discharged home. Am. Pet. at 5.

Tessa's parents had been assured at the hospital by several physicians that "many infants experienced seizures, especially related to fever and high temperatures" and that Tessa's seizures were likely an isolated event brought on by her vaccinations. Id. However, three weeks after her discharge from the hospital, on December 26, 2001, Tessa experienced another seizure in her left arm. Id. Because the family was on vacation, Tessa's parents brought her to the emergency room at Southwestern Vermont Medical Center. Id. Even though no further seizures were observed, the emergency room physician referred Tessa to Albany Medical Center for a pediatric neurology evaluation. Id. at 6. Thus, the next day, Tessa was seen by Kelly Maton, M.D., who provided Tessa's parents with medication in the event that Tessa experienced a prolonged seizure. Id. at 6-7.

On January 8, 2002, Dr. Pepitone filed a Vaccine Adverse Event Reporting System ("VAERS")[8] report. Id. at 7. Tessa also underwent additional testing in January 2002. On

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[6] A focal seizure, also known as a partial seizure, is "any seizure due to a lesion in a specific, known area of the cerebral cortex; symptoms vary with lesion locations." Dorland's Illustrated Medical Dictionary, supra note 2, at 1676.

[7] An EEG is "a recording of the potentials on the skull generated by currents emanating spontaneously from nerve cells in the brain. . . . Fluctuations in potential are seen in the form of waves, which correlate well with different neurologic conditions and so are used as diagnostic criteria." Dorland's Illustrated Medical Dictionary, supra note 2, at 596.

[8] VAERS is

> a national vaccine safety surveillance program co-sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS collects and analyzes information from reports of adverse events following immunization. . . . By monitoring such events, VAERS helps to identify any important new safety concerns and thereby assists in ensuring that the benefits of vaccines continue to be far greater than the risks.

Frequently Asked Questions About VAERS, at http://vaers.hhs.gov/vaers.htm (last visited

January 14, 2002, Tessa had a normal magnetic resonance image ("MRI").[9] Id. Then, on January 18, 2002, Tessa had another normal EEG. Id.

During the morning of February 17, 2002, Tessa was taken by ambulance to the emergency room at California Pacific Medical Center after Tessa's father found her seizing in her crib. Id. The paramedics administered rectal Valium[10] and after ten minutes, Tessa stopped seizing. Id. Tessa was admitted to the hospital for observation and was discharged home later that morning in stable condition. Id. at 8.

Tessa was seen by pediatric neurologist Rowena Korobkin, M.D., at California Pacific Medical Center on February 19, 2002. Id. The examination was normal. Id. Dr. Korobkin noted that Tessa was taking phenobarbital[11] to control her seizures.

However, Tessa had another seizure on February 28, 2002, which was stopped after administration of Valium. Id. Dr. Korobkin recommended tapering the phenobarbital and introducing another medication. Id. Despite the change in medications, Tessa continued to have seizures throughout the spring of 2002. Id.

In May 2002, Tessa's parents began to notice "eye flickering and little head bobs that were almost imperceptible" in Tessa. Id. at 8-9. The eye flickering and head bobs increased in both length and frequency on a daily basis. Id. at 9. In June 2002, Tess underwent a 24-hour video EEG, which confirmed that Tessa was experiencing almost-constant atonic seizures.[12] Id. By September 2002, Tessa was experiencing as many as 300 atonic seizures per day. Id.

August 6, 2005). Any person can file a report with VAERS. Id.

[9] An MRI is "a method of visualizing soft tissues of the body by applying an external magnetic field that makes it possible to distinguish between hydrogen atoms in different environments." Dorland's Illustrated Medical Dictionary, supra note 2, at 908.

[10] Valium is the trademark for the drug preparation of diazepam. Dorland's Illustrated Medical Dictionary, supra note 2, at 2003. Diazepam is a benzodiazepine used as, among other things, an anticonvulsant and an antitremor agent. Id. at 512.

[11] Phenobarbital is "a long-acting barbiturate, used as a sedative, hypnotic, and anticonvulsant . . . ." Dorland's Illustrated Medical Dictionary, supra note 2, at 1418.

[12] An atonic seizure is "an absence seizure characterized by sudden loss of muscle tone." Dorland's Illustrated Medical Dictionary, supra note 2, at 1676. An absence seizure is "the seizure seen in absence epilepsy, consisting of a sudden momentary break in consciousness of thought or activity, often accompanied by automatisms or clonic movements, especially of the eyelids." Id.

In October 2002, Tessa and her family moved to New Zealand. Id. While back in the United States on August 29, 2003, Tessa was seen by pediatric neurologist Luis E. Bello-Espinosa, M.D., at California Pacific Medical Center. Id. Dr. Bello-Espinosa provided the following history:

> [Tessa] is a 2 years and 2 months old youngster, with a history of myoclonic epilepsy,[13] with a history of numerous febrile as well as nonfebrile seizures, atonic seizures, and episodes of status epilepticus.[14] These have been refractory to many antiepileptic medications.
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> Since the parents moved at the beginning of this year to New Zealand, she has had an episode of prolonged status epilepticus associated with pneumonia this past June. Her seizures lasted over an hour and required general anesthesia, after conventional medication . . . failed to control her seizures. . . . .
>
> According to the history provided by her parents, she is not able to walk independently except either four or five steps. She is still quite ataxic.[15] She has failed to progress with language but she tries to imitate. She appears to follow some simple directions.

Id. at 9-10 (footnotes added). Dr. Bello-Espinosa diagnosed Tessa as having idiopathic generalized epilepsy and noted that "[a]lthough she does not completely fulfill the criteria of a severe myoclonic epilepsy, it is probabl[y] close to the classical presentation." Id. at 10. Dr. Bello-Espinosa also noted that Tessa had undergone genetic testing in Australia to determine whether she had a gene mutation that "provokes generalized epilepsy febrile seizures plus all myoclonic epilepsy." Pet. Ex. 5 at 6.

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[13] Epilepsy is "any of a group of syndromes characterized by paroxysmal transient disturbances of the brain function that may be manifested as episodic impairment or loss of consciousness, abnormal motor phenomena, psychic or sensory disturbances, or perturbation of the autonomic nervous system. A single episode is called a seizure." Dorland's Illustrated Medical Dictionary, supra note 2, at 628.

[14] Status epilepticus is "a continuous series of generalized tonic-clonic seizures without return to consciousness." Dorland's Illustrated Medical Dictionary, supra note 2, at 1756. A generalized tonic-clonic seizure is "the seizure of grand mal epilepsy, consisting of a loss of consciousness and generalized tonic convulsions followed by clonic convulsions." Id. at 1676. Tonic convulsions are involuntary and are characterized by a "prolonged contraction of the muscles." Id. at 415-16. Clonic convulsions are also involuntary and are characterized by "alternating contraction and relaxation of the muscles." Id. at 415.

[15] Ataxia is the "failure of muscular coordination." Dorland's Illustrated Medical Dictionary, supra note 2, at 170.

On November 19, 2004, pediatric neurologist Ingrid Scheffer, Ph.D., FRACP, sent a letter to Tessa's pediatric neurologist in Auckland, New Zealand. Pet. Ex. 18 at 1. Dr. Scheffer stated that Tessa had been tested for the SCN1A gene mutation. Id. Significantly, Dr. Scheffer reported that Tessa had a mutation of the SCN1A gene, and opined that the mutation was "likely to be the cause of Tessa's epilepsy." Id. (emphasis added).

As of April 29, 2005, Tessa required "constant, hands-on supervision because she is physically unstable, has difficulty walking, and has absolutely no sense of danger." Am. Pet. at 10-11. In addition, Tessa had "cognitive and developmental delays, significant speech and language difficulties, and has trouble focusing her attention on even small tasks. Tessa will need a lifetime of specialized care . . . ." Id. at 11.

Respondent's Rule 4(b) Report and Petitioner's Motion for a Ruling on the Record

Counsel for the respondent filed the Rule 4 Report on July 20, 2005, indicating that in the government's view, this case was not appropriate for compensation because petitioner had proved neither a Vaccine Injury Table ("Table") injury nor actual causation. Resp't Rep. at 12-15. Specifically, respondent avers that the petitioner has not shown Tessa to have a Table encephalopathy nor has petitioner shown that the DTaP vaccination Tessa received on December 3, 2001, caused Tessa's seizures, encephalopathy, and other neurological injuries. Id. Respondent also notes that the medical records included evidence of a likely alternate cause of Tessa's injuries–a gene mutation. Id. at 14-15.

Thereafter, on September 6, 2005, petitioner's counsel filed Petitioner's Motion for a Ruling on the Record, requesting that the special master decide the case based upon the submitted medical records and respondent's Rule 4 Report.

The Vaccine Act

Pursuant to 42 U.S.C. § 300aa-13(a)(1), the court shall award compensation if petitioner[16] proves, by a preponderance of the evidence, all of the elements set forth in § 300aa-11(c)(1)[17] of

[16] Section 11(b)(1) requires that: (1) only the "person who sustained a vaccine-related injury, [or] the legal representative of such person if such person is a minor or is disabled" can bring an action for vaccine injury-related claims (so long as the requirements of subsection (c)(1) are satisfied) and (2) that no previous civil action was filed in the same matter.

[17] Petitioner, the parent of his minor child who was allegedly injured as the result of the administration of a Table vaccine, is the appropriate person to maintain this action. In addition, subsection (c)(1) requires, inter alia, that the following elements be satisfied: (1) that the vaccine in question is set forth in the Table; (2) that the vaccine was received in the United States or in its trust territories; (3) that the minor child either sustained an injury as a result of the administration of a Table-designated vaccine for a period of more than six months after the administration of the

the Vaccine Act and that the illness is not due to factors unrelated to the administration of the vaccine.[18] Section 300aa-11(c)(1)(C) describes the substantive elements petitioner must prove to recover in the Vaccine Program. In this case, petitioner can recover in one of two ways. First, petitioner can recover if he proves a Table injury; in other words, if he shows that Tessa received a vaccine listed in the Table, 42 C.F.R. § 100.3(a), and suffered from an injury associated with that vaccine within the prescribed time period. 42 U.S.C. § 300aa-11(c)(1)(C)(i).

Specifically, in this case, petitioner can recover if he demonstrates that Tessa suffered from an encephalopathy within 72 hours of receiving the DTaP vaccination. During an April 5, 2005 status conference, petitioner's counsel stated that petitioner was not pursuing a Table encephalopathy. See Apr. 6, 2005 Order. However, even if petitioner opted to pursue a Table encephalopathy, petitioner would be unable to meet this burden. Although the undisputed facts show that Tessa received the DTaP vaccination on December 3, 2001, Tessa's subsequent seizure activity does not meet the Table definition of encephalopathy.

The Table defines encephalopathy as an acute encephalopathy followed by a chronic encephalopathy persisting for more than six months past the date of vaccination. 42 C.F.R. § 100.3(b)(2). For children under the age of 18 months who present without a seizure, an acute encephalopathy is indicated by a "significantly decreased level of consciousness" lasting for at least 24 hours. Id. § 100.3(b)(2)(i)(A). For children presenting with a seizure, the significantly decreased level of consciousness must persist more than 24 hours and cannot be attributed to the seizure or medication. Id.

Further, a "significantly decreased level of consciousness" is defined by the presence of at least one of the following three clinical signs for 24 hours or longer: (1) decreased or absent response to the child's environment, (2) decreased or absent eye contact, or (3) inconsistent or absent responses to external stimuli. Id. § 100.3(b)(2)(i)(D). More importantly, "Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other

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vaccine, suffered illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention, or died from the administration of the vaccine; and (4) that the petitioner, as his daughter's legal representative, has not previously collected an award or settlement of a civil action for damages arising from the alleged vaccine-related injury or death. Here, petitioner was unable to offer the testimony of a qualified medical expert to support petitioner's theory of liability. Indeed, Dr. Scheffer's November 19, 2004 opinion letter to Tessa's pediatric neurologist states that the genetic test revealed that the source of Tessa's epilepsy was a SCN1A gene mutation. Clearly, this conclusion attributes Tessa's condition to a factor unrelated to the vaccine. Thus, the lack of expert opinion evidence supporting the allegations of the petition defeats the underlying claim.

[18] Of course, the petition must also be filed within the statutory period. 42 U.S.C. § 300aa-16(a). The petition in this case was timely filed.

evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy." Id. § 100.3(b)(2)(i)(E).

Tessa's seizure activity began during the morning of December 4, 2001. But, after the initial focal seizures evidenced by the arm stiffening and hand twitching, Tessa recovered the use of her arms and became alert and stable. Further, even though Tessa's seizures returned while she was in the emergency room, once she was admitted to the PICU, she appeared awake and alert and was seizure-free. Thus, from the above definitions, it is apparent that Tessa did not suffer from a Table encephalopathy as a result of the administration of the DTaP vaccination within the prescribed 72-hour period. Thus, petitioner proceeded on an actual causation theory.

Under an actual causation theory or "off-Table" claim, 42 U.S.C. § 300aa-11(c)(1)(C)(ii), petitioner must prove that Tessa's seizures, encephalopathy, and other neurological injuries were caused in fact by her DTaP vaccination. Congress explained what it intended by this causation requirement:

> [T]he petition must affirmatively demonstrate that the injury or aggravation was caused by the vaccine. Simple similarity to conditions or time periods listed in the Table is not sufficient evidence of causation; evidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation for such a petitioner.

H.R. Rep. No. 99-908, pt. 1, at 15 (1986). The United States Court of Appeals for the Federal Circuit amplified congressional intent:

> To prove causation in fact, petitioners must show a medical theory causally connecting the vaccination and the injury. Causation in fact requires 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 of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992) (citations omitted); Bunting v. Sec'y of HHS, 931 F.2d 867, 873 (Fed. Cir. 1991) ("A petitioner's burden is not to show a generalized 'cause and effect relationship' with listed illnesses, but only to show causation in a particular case."). As the Federal Circuit explained in Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999), two separate elements must be demonstrated by a preponderance of the evidence, namely, "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Thus, both the Vaccine Act and the case law clearly require an expert medical opinion.

Section 300aa-13(b)(1) specifically requires consideration of all relevant medical and scientific evidence presented to the court including:

> (A) any diagnosis, conclusion, medical judgment, . . . regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death, and
>
> (B) the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.

A review of the record now under consideration reveals no medical evidence[19] to support petitioner's theory that Tessa suffered from seizures, encephalopathy, and other neurological injuries as a result of the administration of the DTaP vaccination on December 3, 2001. Not only was petitioner unable to provide the necessary expert opinion supporting his theory of causation, the medical evidence derived from genetic testing indicated that a gene mutation was "likely to be the cause of Tessa's epilepsy."

The Vaccine Act specifically provides that "the special master or court may not make a finding [of eligibility and compensation] based on the claims of a petitioner alone, unsubstantiated by medical records or medical opinion." 42 U.S.C. § 300aa-13(a)(1). Thus, because petitioner is unable to prove by a preponderance of the evidence the matters required in § 300aa-11(c)(1),[20] petitioner cannot carry the "heavy burden" required in off-Table cases to prove that Tessa's seizures, encephalopathy, and other neurological injuries were more likely than not the result of the DTaP vaccination at issue here. There is no doubt that Tessa, and by extension, her family, have endured great suffering; nevertheless, the statutory requirements have not been satisfied.

CONCLUSION

Because petitioner is unable to present medical records and/or expert testimony to support a theory of causation, the special master finds that petitioner has not and cannot meet his burden to prove that the DTaP vaccination of December 3, 2001, caused Tessa's seizures, encephalopathy, and other neurological injuries. Therefore, the special master finds that petitioner must be denied compensation under the Vaccine Program.

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[19] Although the Federal Circuit made clear in Knudsen v. Secretary of HHS, 35 F.3d 543, 548-49 (Fed. Cir. 1994), that when proceeding under an off-Table theory, a petitioner is not required to identify and provide proof of the specific biological mechanism that caused the alleged vaccine injury, a reputable medical explanation of a logical sequence of cause and effect to support petitioner's theory of liability is necessary.

[20] See 42 U.S.C. § 300aa-13(a).

Accordingly, this petition is DISMISSED with prejudice. In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of Court is directed to enter judgment accordingly.

IT IS SO ORDERED.

Margaret M. Sweeney
Special Master