

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 07-784V

Filed: June 30, 2011

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|----------------------------------|---|---------------------------------|
| VERONICA ARGUETA, as the legal |) | |
| representative of her minor son, |) | |
| JOSHUA ARGUETA, |) | |
| |) | TO BE PUBLISHED |
| Petitioner, |) | |
| |) | Entitlement; Table injury; |
| v. |) | diphtheria-tetanus-acellular |
| |) | pertussis (DTaP) vaccine; Table |
| SECRETARY OF |) | encephalopathy; seizures; |
| HEALTH AND HUMAN SERVICES, |) | infantile spasms; coloboma |
| |) | |
| Respondent. |) | |

Curtis R. Webb, Twin Falls, ID, for Petitioner.

Katherine C. Esposito, U.S. Department of Justice, Washington, D.C. for Respondent.

DECISION ON ENTITLEMENT¹

LORD, Special Master.

I. INTRODUCTION AND SUMMARY

On November 8, 2007, Petitioner Veronica Argueta filed a petition under the National Childhood Vaccine Injury Act (“Vaccine Act” or “Act”) on behalf of her son Joshua.² Petitioner alleged that Joshua suffered a “Table encephalopathy” within 72 hours of a diphtheria-tetanus-acellular pertussis (“DTaP”) vaccine he received on

¹ The undersigned intends 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, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). 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.

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. §§ 300aa-10 et seq. (2006). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Vaccine Act.

November 10, 2004. An entitlement hearing was convened on August 3 and 4, 2010, and this case now is ready for decision.³

The only issue before me is whether Joshua suffered a Table injury, specifically, an encephalopathy as defined by the Secretary. The Secretary has defined a Table encephalopathy as consisting of an acute encephalopathy occurring within 72 hours of vaccination, followed by a chronic encephalopathy for a period of 6 months or more. Based on all the evidence, Joshua did not suffer an acute encephalopathy in the 72 hours following his vaccination on November 10, 2004, and therefore, he did not suffer a Table encephalopathy.

At the hearing, Petitioner and two other fact witnesses, Leonard and Eileen Stobbe, testified as to Joshua's condition before vaccination and his condition in the days and weeks following vaccination.⁴ Petitioner claimed that Joshua was developing normally, but in the 24 hours following vaccination he underwent a significant change for the worse. Petitioner asserted that Joshua became visually unresponsive and lethargic, indicating a decreased level of consciousness. Petitioner claimed that, because Joshua was visually unresponsive following his vaccination, he satisfied the criteria for showing that he suffered an acute encephalopathy under the regulations.

Petitioner also presented the opinion and testimony of Thomas A. Schweller, M.D., an expert in pediatric neurology. Based on Petitioner's assertions as well as observations in the medical records that Joshua was unresponsive to visual stimulation, Dr. Schweller opined that Joshua suffered an encephalopathy within 72 hours of vaccination. Respondent rebutted Dr. Schweller's opinion with that of Mary Anne Guggenheim, M.D., an expert pediatric neurologist. Dr. Guggenheim opined that the visual inattentiveness noted by Joshua's treating physicians post-vaccination was present before the vaccination and therefore was not a symptom of an acute encephalopathy.

To establish a prima facie case of entitlement to compensation under the Vaccine Injury Table, Petitioner must prove that (1) Joshua suffered the injury listed in the Table, encephalopathy (acute encephalopathy followed by chronic encephalopathy), following his DTaP vaccination; (2) he suffered the onset of the acute encephalopathy within 72 hours of the vaccination; and (3) no symptom or onset of the injury was manifested before vaccination. Whitcotton v. Shalala, 514 U.S. 268 (1995). I find that, based on the record as a whole, Petitioner has not satisfied the requirements for a prima facie case because (1) there is insufficient evidence that Joshua suffered an

³ A "Table injury" is an injury that is listed on the Vaccine Injury Table (Table). § 14(a); see Vaccine Injury Table, 42 C.F.R. § 100.3 (2010) (regulations amending the Table). Petitioner does not allege any off-Table injury, or significant aggravation of any pre-existing condition. § 11(c)(1)(C); § 33(4). See Vaccine Rule 8(f). The facts would not support compensation under those theories, in any event. See infra.

⁴ The Stobbes provided a home to Petitioner during Joshua's infancy. See Tr. at 9.

acute encephalopathy, as defined by the Secretary, within the 72 hours following his vaccination; and (2) there is preponderant evidence that Joshua exhibited symptoms before his vaccinations.

II. BACKGROUND

A. Vaccine Injury Table

To receive compensation under the Vaccine Act, a petitioner must prove either that: (1) he suffered a “Table injury” -- i.e., an injury falling within the Vaccine Injury Table corresponding to one of his vaccinations; or (2) he suffered an “off-Table” injury that was actually caused by or “caused-in-fact” by a vaccine. See §§ 13(a)(1)(A), 11(c)(1); Whitcotton, 514 U.S. at 270. To prove a Table injury, a petitioner must establish that he suffered an injury listed on the Vaccine Injury Table and that such injury first manifested within the period listed on the Table. § 14(a); Whitcotton, 514 U.S. at 274; see Vaccine Injury Table, 42 C.F.R. § 100.3(a) (2010). The injuries listed on the Table are further defined by the Qualifications and Aids to Interpretation (QAI). § 14(b); see § 100.3(b).

Petitioner here alleged the Table injury of encephalopathy resulting from administration of the DTaP vaccine to Joshua on November 10, 2004. See Tr. at 7. A “Table encephalopathy” occurs only if the vaccine recipient “manifests, within the applicable period, an injury meeting the description . . . of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination.” § 100.3(b)(2). For vaccines containing acellular pertussis toxin, including the DTaP vaccine, the applicable time period for manifestation of an acute encephalopathy is within 72 hours of vaccination. § 100.3(a)(II)(B).

The QAI defines an acute encephalopathy as “one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).” § 100.3(b)(2)(i). The QAI further specifies criteria for evaluating symptoms that may or may not indicate acute encephalopathy. § 100.3(b). For children younger than eighteen months, such as Joshua, who present without an associated seizure, an acute encephalopathy “is indicated by a significantly decreased level of consciousness . . . lasting at least 24 hours.” § 100.3(b)(2)(i)(A). A “significantly decreased level of consciousness” is

indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater . . . :

- (1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);
- (2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or

(3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

§ 100.3(b)(2)(i)(D).⁵ The QAI also states, “[t]he following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in . . . level of consciousness as described above: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle.” § 100.3(b)(2)(i)(E).⁶

B. Joshua’s Medical History

1. Pre-Vaccination History

Joshua was born on May 8, 2004. Pet’r Ex. 3 at 1, 4. He was slightly premature at thirty-six weeks gestation and weighed six pounds, nine ounces. Pet’r Ex. 2 at 18; Pet’r Ex. 3 at 1-3.⁷ Joshua failed his initial hearing screening. Pet’r Ex. 4D at 37. On May 16, 2004, a lactation consultant noted that Joshua had difficulty feeding by breast and bottle, and that he was jaundiced, with little activity. Pet’r Ex. 4A at 4.

The record reflects that Petitioner was an attentive mother, and she took Joshua to the doctor’s office whenever it seemed that he may have needed care. On June 7, 2004, Joshua saw pediatrician Stephen Shlafer, M.D., with complaints of vomiting and dacryocystitis. Pet’r Ex. 5A at 1-2.⁸ Petitioner brought Joshua to Dr. Shlafer’s office on July 7, 2004, with concerns about Joshua’s excessive crying and a possible hernia. Id. at 4.

⁵ Sections (b)(2)(ii)–(iv) of the QAI include guidance for determining whether a Table injury has been established when an encephalopathy may have been caused by factors other than vaccination. § 100.3(b)(2)(iii). It is not necessary to evaluate alternative factors here, because Petitioner has not carried her initial burden of presenting a prima facie showing of an acute encephalopathy within 72 hours of vaccination.

⁶ The QAI also states that, “In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy.” § 100.3(b)(2)(i)(E).

⁷ Several treating physicians noted that Petitioner’s pregnancy was marked by the use of crack cocaine, alcohol, “pain pills,” and tobacco during the first and second trimesters of the pregnancy. Pet’r Ex. 1 at ¶1; Pet’r Ex. 2 at 21; Pet’r Ex. 5B at 5; Tr. at 70. Avery H. Weiss, M.D., a pediatric ophthalmologist at Children’s Hospital in Seattle, noted that Petitioner was “actively drug addicted” during “the first five months” of Joshua’s gestation. Pet’r Ex. 6A at 13. “It is very possible that with his prenatal history of exposure to drugs there may be some mild cortical visual impairment and delayed visual maturation,” Dr. Weiss stated. Pet’r Ex. 6A at 13. Other doctors expressed similar concerns. See Pet’r Ex. 5B at 5; id. at 8.

⁸ Dacryocystitis is inflammation of the lacrimal (pertaining to the tears) sac. Dorland’s Illustrated Medical Dictionary (31st ed. 2007) 472, 989.

On August 16, 2004, Petitioner returned to Dr. Schlafer's office with concerns that Joshua might have acid reflux, because he was spitting up excessively. Id. at 5. Petitioner did not bring Joshua to his two-month well child exam scheduled for August 31, 2004. Id. at 6.

On September 11, 2004, Joshua presented to Dr. Schlafer's office for a high fever the day before and crying more than usual. Id. at 7. On September 13, 2004, Joshua returned to be treated for a diffuse rash. Id. at 8.

On October 25, 2004, Petitioner took Joshua to the Providence Everett Medical Center Emergency Room because she had noticed that the pupil of Joshua's left eye was irregular. Pet'r Ex. 1 at ¶8; Pet'r Ex. 4B at 8; Tr. at 71, 91. Petitioner reported that Joshua's left eye "has never been right." Pet'r Ex. 4B at 8. Joshua's irregular pupil shape was thought to be congenital and Petitioner was told to schedule an appointment with an ophthalmologist. Id. at 11-12. Petitioner testified that she followed up with Dr. Schlafer the next day, October 26, 2004. Tr. at 48-49; see Pet'r Ex. 5A at 9. During this visit, Petitioner testified that Dr. Schlafer reported to her that Joshua had no retinal response. Tr. at 48-49. A nurse explained to Petitioner that this typically meant that Joshua would be blind. Id. Petitioner decided to obtain a second opinion and scheduled an appointment with nurse practitioner Gregory A. Lind ("NP Lind"). Tr. at 49.

On November 5, 2004, NP Lind confirmed that Joshua had a coloboma. Pet'r Ex. 7 at 1-3; Tr. at 52.⁹ NP Lind referred Petitioner to an ophthalmologist at Seattle's Children's Hospital. Tr. at 53. NP Lind recommended that Joshua be put back on schedule for his vaccines, and an appointment was set for November 10, 2004. Id.

On November 10, 2004, Joshua presented to NP Lind for his six-month well child visit. Pet'r Ex. 7 at 4. During this visit, Joshua received several vaccinations including his first DTaP, inactivated polio virus (IPV), haemophilus influenza type B (Hib), and pneumococcal conjugate (PCV) vaccines. Id. at 4, 10.

2. 72-hour Post-Vaccination Period

Petitioner testified that Joshua cried for hours, late into the night and early into the next morning, on the evening after these vaccinations. Tr. at 54-55, 76-78. She testified that she had to leave a church event early because Joshua was crying. Tr. at 54-54. Petitioner also testified that Joshua did not eat that evening. Tr. at 55. Similarly, Eileen Stobbe testified that Joshua was "very fussy" the evening of the vaccinations, that he cried inconsolably, and that he was "just not a happy baby." Tr. at 25-26.

⁹ A coloboma is an absence or defect of the ocular tissue, usually due to malclosure of the fetal intraocular fissure, or sometimes from trauma or disease. Dorland's at 391. Joshua did not have a fully formed iris, so his pupil appeared to extend to the white of his eye.

Petitioner testified that on the following day, November 11, 2004, Joshua was “lethargic and limp” and that he appeared to be feeling very “blah.” Tr. at 56. By her gestures and expression while testifying, Petitioner indicated that Joshua’s condition was alarmingly different from his normal, pre-vaccination state. Based on Petitioner’s testimony at hearing, Joshua resembled a rag doll, *i.e.*, almost without any sign of consciousness. *See* Tr. at 56-58. Petitioner testified that Joshua did not make eye contact with her and that he took only a little bit of food. Tr. at 56-57, 100. She stated that Joshua seemed to be unresponsive to his environment. Tr. at 57, 78. At hearing, Petitioner was asked, “Did Joshua have any response to his environment on November 11?” She answered, “I don’t think he did.” Tr. at 78.

Petitioner also described Joshua’s condition in her Affidavit. Petitioner recalled that on the evening after Joshua’s shots:

I remember thinking that he had worn himself out, because after the crying stopped he was very lethargic. He didn’t want to suck on his bottle or breast feed that night. He would not smile or coo or try to sit up. He would not focus on me or anything.

Argueta Aff. at ¶14 (Pet’r Ex. 1). Petitioner also recalled that Joshua was “not himself again for a long time” after the shots. *Id.* at ¶16. She stated that Joshua would not interact, “started drooling a lot,” had purposeless arm and leg movements, “seemed uncomfortable,” and “clenched his thumbs into his fists all the time.” *Id.* at ¶17.

Significantly, in her Affidavit, Petitioner dated the onset of Joshua’s seizures (eventually diagnosed as infantile spasms), “During the week after the November 10, 2007 [*sic*] vaccinations.” *Id.* at ¶18. As she described the post-vaccination events in her Affidavit:¹⁰

Joshua began to have episodes in which his eyes rolled back, he’d get a strange look on his face, his head went back, and his arms would stiffen. At first he’d have a few -- maybe five episodes a day. An episode lasted about 10 minutes, with him stiffening and relaxing may [*sic*] times over that time. Neither I or [*sic*] Eileen [Stobbe] recognized these as seizures until later. All this lasted for about two months. . . .

Id. at ¶¶18-20.¹¹ Petitioner’s friend, Leonard Stobbe, also noted the temporal proximity between the vaccination and the seizures. He stated that, “After the shot there was a

¹⁰ Petitioner may have intended at some time to allege entitlement based on actual causation of Joshua’s infantile spasms, but such an allegation has not been pursued. *See* Vaccine Rule 8(f). In any event, Petitioner’s testimony at hearing and the medical records do not match the description of post-vaccination “episodes” in her Affidavit.

¹¹ In contrast, Petitioner did not testify at hearing that Joshua suffered seizures “during the week after” the November 10, 2004, vaccinations. As noted elsewhere in this decision, Petitioner provided many different dates for the onset of Joshua’s seizures. Because of the

sudden change. He did not respond to movement or voices and we were concerned that not only might he be blind but also deaf.” Pet’r Ex. 14. “It was as if the lights had been turned off in his head. Soon afterwards the mini seizures began.” Id.; see Tr. at 13.

The day after the vaccinations, on November 11, 2004, Petitioner took Joshua to his previously scheduled appointment with Dr. Weiss, the pediatric ophthalmologist at Seattle Children’s Hospital. Pet’r Ex. 6A at 12-14; Tr. at 59. On the “Patient History and Intake Form” that she completed and signed, Petitioner recorded that Joshua had symptoms of possible snoring, a runny nose, wheeze and cough for a week, and diarrhea for the past three days. Pet’r Ex. 6A at 16. She also checked a box indicating that he had “Trouble Seeing,” but she listed the duration of the problem as “??”. Id. Petitioner also checked boxes on the intake form indicating that she was not concerned about Joshua’s eating or drinking. Id. In answer to the question, “Why are we seeing your child today?” she answered “irregular pupils & vision.” Id. She left blank the space next to the question, “What other concerns or questions do you have about your child’s general health?” Id.

Dr. Weiss’s outpatient note from this visit stated, under “HISTORY,” that Joshua was being seen in the pediatric ophthalmology service “on a semiemergent basis for abnormal-appearing pupils and abnormal papillary light reflex.” Pet’r Ex. 6A at 12; see also id. at 14 (Dr. Weiss’s handwritten notes describing the problem as “abnormal pupils & poor vision”). “The mother first noted the abnormal shape of the pupils about three weeks ago. She feels that he can see but at other times he just does not pay attention to what is going on around him.” Pet’r Ex. 6A at 12. From this entry, and its location in the “HISTORY” section of the outpatient note, it appears that Petitioner’s complaint that Joshua at times “does not pay attention to what is going on around him” predated his vaccination by about three weeks.¹²

Dr. Weiss’s examination confirmed that Joshua was only intermittently attentive to his visual environment. Under “Physical Examination” Dr. Weiss noted, “This child intermittently seems to be alert, attentive and fixates on objects. At other times he ignores his visual environment.” Pet’r Ex. 6A at 12. Dr. Weiss stated further, “External exam reveals an alert, normal-appearing child . . . Muscle tone is good.” Id. Under “Motility” Dr. Weiss stated, “Generates purposeful conjugate eye movements at times but visual attention is short.” Id.

significant inconsistencies in her recollection of the events in the days following Joshua’s vaccinations, I must and do find Petitioner’s testimony to be unreliable concerning the timing of Joshua’s post-vaccine reaction and the onset of his infantile spasms. See infra.

¹² The “HISTORY” also noted normal height, weight and head circumference, a “completely normal” well-child exam the previous day, no previous hospitalization or medical issues, and no fever, runny nose or hearing loss. Pet’r Ex. 6A at 12. “Apparently, he has been a very active, healthy child with normal attainment of milestones.” Id.

Dr. Weiss recorded two issues under his “IMPRESSION.” Id. at 12-13. One, Joshua had bilateral iris coloboma. Id. at 13. Dr. Weiss noted that iris colobomas “can have the same – systemic implications as chorioretinal colobomatous malformations.” Id.¹³ Two, “subnormal visual orienting behavior. . . not age appropriate.” Id. “Either he has visual inattention or delayed visual maturation in the context of cortical visual impairment.” Id. As stated above, Dr. Weiss indicated that Joshua’s prenatal history might have caused visual impairment. Id. Dr. Weiss recommended that Joshua undergo formal acuity testing and stated that he would “wait to make any further recommendations” pending those results. Id.

Per the medical records, Petitioner did not inform Dr. Weiss that Joshua had been crying for several hours the previous night and was markedly unresponsive to his environment. Pet’r Ex. 6A at 12-17; Tr. at 78. Petitioner explained, “the visit wasn’t set up for that.” Tr. at 107-08. She testified further, “I remember talking to him a little about him not being responsive,” but added that she did not “remember a lot” about the visit to Dr. Weiss. Tr. at 78-80. Petitioner stated that she did not consider seeking further medical assistance for Joshua in the hospital on that day. Tr. at 80.

Petitioner testified that Joshua was lethargic for “probably at least a few days” after the November 10, 2004, vaccination. Tr. at 91. She stated that Joshua “was just kind of laying there, kind of blah” for about a week. Tr. at 56, 90. Petitioner stated that she did not consult a doctor because she believed that Joshua was “having a reaction” but that he would eventually improve. Tr. at 90. She testified that Joshua ate every day in the week after vaccination, but that she thought that his sucking was different and that he was not taking in as much food. Tr. at 101. Petitioner was not concerned about dehydration and she believed Joshua was receiving adequate nutrition. Tr. at 102. She testified that Joshua had wet and dirty diapers and that he did seem to improve in the week after his vaccination. Tr. at 103. Ms. Stobbe also testified that she did not have any concern that Joshua needed to see a doctor in the week after his vaccination. Tr. at 31.

3. Post-Vaccination Medical Records

Joshua was next seen for medical treatment on November 26, 2004, two weeks after his vaccinations, when Petitioner took Joshua to see NP Lind because Joshua “wasn’t getting any better, and then he was developing kind of a croupy cough also.” Tr. at 60; see Pet’r Ex. 7 at 6. NP Lind noted that Joshua had abnormal eye movement,

¹³ Dr. Guggenheim, the Respondent’s expert, interpreted Dr. Weiss’s note about the colobomas as consistent with an opinion of possible congenital brain dysfunction. Tr. at 196, 238. A genetics consultant who evaluated Joshua several weeks later apparently interpreted Dr. Weiss’s note in the same way. Anne Hing, M.D., the geneticist, described optic nerve/chorioretinal coloboma as a “disorder associated with . . . hypotonia, infantile spasms, developmental delay, and often structural CNS (central nervous system) malformations” Pet’r Ex. 5B at 9.

no red reflex, and assessed Joshua as blind. Pet'r Ex. 7 at 6.¹⁴ Petitioner returned to NP Lind on November 30, 2004, where Joshua was treated for bronchitis and right otitis media. Id. at 8.

On December 9, 2004, Joshua was seen by a medical assistant at his pediatrician's office, where he was noted to have symptoms of croup, including wheezing and drowsiness. Pet'r Ex. 5A at 11-12. Petitioner testified that she tried to get a nurse to come into the waiting room to observe Joshua's "episodes" (an apparent reference to his seizures), but she was unsuccessful, and Dr. Schlafer prescribed medication only for Joshua's breathing problems. Tr. at 83; Pet'r Ex. 1 at ¶26.

On December 13, 2004, Joshua was seen at the Providence Everett Medical Center Emergency Room for a three to four day history of croup, stridor, and dyspnea. Pet'r Ex. 4C at 16.¹⁵ Joshua was treated with a nebulizer, racemic epinephrine, and Decadron. Pet'r Ex. 4D at 26. Although Petitioner testified that Joshua was having seizures by this date, see Tr. at 83, there is no mention of them in the medical records of this emergency room visit.

On December 15, 2004, Joshua's visual evoked potentials (VEPs) were measured, which showed that he had normal to mildly abnormal visual function, despite no overt visual tracking. Pet'r Ex. 5B at 3; Pet'r Ex. 6A at 21.¹⁶ The results showed "an impairment of higher visual-cortical function, either due to immaturities in attention or sensory-motor integration." Pet'r Ex. 5B at 3.

The next day, Joshua was treated in the emergency room at Providence Everett Medical Center for croup and stridor. Pet'r Ex. 4D at 31. X-rays showed some abnormalities consistent with croup. Id. "The patient has been less active," according to the history provided. Id. Physician notes stated that Joshua had had "10-14 days of periodic tonic posturing, lasting up to ten minutes at a time – mom wonders if possibly seizures." Id. at 33. The treating physician noted a heart murmur, "floppy, poor tone," and "abnormal spastic movements in face of poor neuro-development." Id. at 34. Some seizure activity was noted by a nurse and treated with Phenobarbital. Id. at 55, 69.

¹⁴ Red reflex occurs when light passes through the eye and is reflected off the retina, similar to what a lay person would recognize as "red eye" in a photograph. Tr. at 122-23. The absence of a red reflex can indicate a physical problem with the eye. Tr. at 123.

¹⁵ Stridor is a high pitched wheezing sound that typically occurs when the upper airway is obstructed. Nelson's Textbook of Pediatrics (Robert Kliegman, M.D., et al. eds., 18th ed. 2007) at 1762.

¹⁶ Visual Evoked Potentials (VEPs) are assessed by measuring the brain's electrical response when a patient is shown visual stimuli. Nelson's at 2442-43.

On December 17, 2004, a pediatrician spent 90 minutes reviewing Joshua's history with Petitioner. Pet'r Ex. 4D at 35.¹⁷ The pediatrics note stated, "Per mom, she has been concerned re: baby's growth and development x several months but was not listened to by [Dr.] Shlafer." Id. at 36.¹⁸ The notes also stated that Petitioner was "very concerned about impact her past activities had on baby." Id. (emphasis in original). The history also stated that since Petitioner had run out of Zantac approximately three weeks earlier, Joshua "has had seizures [with] head back, sometimes nystagmus, arms twitching." Id. On examination, Joshua displayed impaired visual tracking, truncal weakness, increased tone in ankles and wrists, and a faint heart murmur. Id. at 36-37.

On December 18, 2004, Joshua underwent an EEG, the results of which were interpreted as abnormal, compatible with hypsarrhythmia and West syndrome. Id. at 42.¹⁹ An echocardiogram showed "no suggestion of intracardiac malformation." Id. at 44.

On December 21, 2004, Joshua underwent an occupational therapy evaluation in which he demonstrated significantly delayed motor skills. Pet'r Ex. 4E at 97-98. Joshua showed cortical thumbing seventy-five percent of the time. Id.²⁰ The records noted that Petitioner "stated that the seizure-like activity started 2 weeks ago, the same time as the croup. She said that his skills in all areas declined at that time." Id. at 97 (emphasis added). This would date the onset of Joshua's infantile spasms and associated decline as the first week in December 2004 (about three weeks after his vaccinations). The medical record confirmed the association between Joshua's croup, seizures, and developmental decline. "Per parent report Joshua's verbal and motor skills have significantly declined since his most recent illness and seizure-like behavior." Id. at 98.

A record dated December 20, 2004, from Community Health Center of Snohomish County stated, "3 weeks ago, mother noted tensing of both arms and throwing head back – uprolling of eyes." Pet'r Ex. 8 at 1. Three weeks before this note would be the beginning of December 2004.

On December 25, 2004, Joshua was treated in the emergency room at Providence Everett for croup and reported to have a history of 30-second jerks of the

¹⁷ The "Peds Note" was authored by a Dr. Zaret. Pet'r Ex. 4D at 30, 35-37.

¹⁸ Asked about this statement at hearing, Petitioner responded, "I'm not saying I didn't say it, but I wasn't concerned about Joshua's growth until after the vaccines." Tr. at 73. Petitioner explained that she "wasn't very careful with my timeline a lot of times." Tr. at 74.

¹⁹ Hypsarrhythmia is "an electroencephalographic abnormality sometimes observed in infants, with random, high-voltage slow waves and spikes that arise from multiple foci and spread to all cortical areas." Dorland's at 901. West syndrome is another term for infantile spasms. Dorland's at 2062.

²⁰ Cortical thumbing, or thumb in fist posture, indicates abnormal cerebral motor function. Resp't Ex. A at 4.

arms. Pet'r Ex. 4F at 125. The physician who examined Joshua suspected that Joshua might have a viral infection or "some other congenital abnormality." Id.

On December 29, 2004, Joshua was admitted as an in-patient to Seattle Children's Hospital by Anthony Bouldin, M.D., a pediatric neurologist. Pet'r Ex. 5B at 5-6. Dr. Bouldin noted that Joshua had a history of episodic clusters of events involving "head going back, eyes blinking, making a grunting sound, throwing arms forward and crunching forward at the trunk" for 10 to 40 minutes five times daily, since mid-November 2004. Id. at 5. "The onset of these events was associated with him becoming less interactive." Id.²¹

During this hospital admission, Joshua also was evaluated by Anne V. Hing, M.D., a geneticist. Pet'r Ex. 5B at 8. Petitioner reported to Dr. Hing that "the episodes began shortly after his second immunization in mid November." Id. Petitioner also stated that "prior to the onset of the infantile spasms," Joshua was able to roll over on one occasion, but he had not tried to do so since. Id. His verbalization, laughing, smiling, and head control also had declined. Id.

Dr. Hing was unable to identify any unifying syndrome to explain both Joshua's abnormal eyesight and eye formation and his infantile spasms. Id. at 9. She specifically noted several known genetic conditions in which infantile spasms can be seen with "optic nerve/chorioretinal coloboma (not involving the iris), such as Aicardi syndrome." Id. Joshua's clinical examination did not match those syndromes. Id.²²

Another EEG was conducted confirming Joshua's diagnosis of infantile spasms and hypsarrhythmia. Id. at 10. During his hospitalization, Joshua experienced a number of seizures and was treated with ACTH. Pet'r Ex. 5B at 10-11. On December 30, 2004, Joshua underwent an MRI, which was interpreted as normal. Pet'r Ex. 6B at 103.

Joshua was discharged on January 1, 2005, with a diagnosis of infantile spasms, GERD (gastroesophageal reflux disease), bilateral colobomas, with subnormal visual orienting behavior and developmental delay. Pet'r Ex. 5B at 11; Pet'r Ex. 6B at 40. The

²¹ Again, in most reports Petitioner gave to Joshua's treating physicians at this time it was the onset of seizures, not vaccination, that was associated with Joshua's diminished interaction with his environment. See also Tr. at 155 (Dr. Schweller, Petitioner's expert: "I think this child was also apparently in the midst of infantile spasms. . .").

²² In his report of the examination on November 11, 2004, Dr. Weiss, the ophthalmologist, also opined that there were "no obvious dysmorphic features to suggest an underlying genetic disease," but also noted that, "Iris colobomas can have the same-systemic implications as chorioretinal colobomatous malformations . . ." See Pet'r Ex. 6A at 13.

discharge summary also noted that Joshua “has had a loss of motor skills since 4 months of age.” Pet’r Ex. 5B at 11.²³

Joshua underwent another EEG on April 20, 2005, which was compatible with his previous EEG. Pet’r Ex. 5B at 12. Joshua’s ACTH was discontinued and replaced with Zonisamide, another anti-seizure medication. Pet’r Ex. 5B at 16. On June 22, 2005, he underwent a video EEG, which was abnormal. Pet’r Ex. 5B at 14-15. The EEG showed slowing while awake and spikes during his sleep cycle. Id.

On July 26, 2005, Joshua was seen again by Dr. Weiss, who noted improved visual behavior, farsightedness, accommodative esotropia, and coloboma. Pet’r Ex. 6A at 22.

On September 13, 2005, Joshua was treated for tinea versicolor. Pet’r Ex. 5B at 16.²⁴ He was treated for reactive airway disease six days later and again on May 29, 2005, August 30, 2006, March 12, 2007, and April 8, 2007. Pet’r Exs. 4J, 4K, 4M, 4O, 4P.

A note from the Community Health Center of Snohomish County dated September 6, 2005, stated, “Mother is still apprehensive about vaccines and she thinks that the 2 month vaccines may have triggered Pt’s seizures.” Pet’r Ex. 8 at 11.²⁵

On December 12, 2006, Joshua presented to Dr. Weiss for a follow-up visit in which Joshua was noted to be a child “with prenatal exposure to drugs associated with global developmental delay, history of infantile spasms that resolved, asthma, hypotonia, with normal MRI and normal chromosomes” Pet’r Ex. 6A at 31.

At the time of the hearing, Petitioner testified that Joshua (age six) was severely developmentally delayed. Tr. at 68. She testified that Joshua only began walking at age four, had difficulty with balance, could not talk, and wore diapers. Tr. at 68-69. Petitioner also testified that Joshua could eat only bite-size food. Tr. at 68-69. Petitioner stated that Joshua could learn how to use new toys, make eye contact and visually follow. Tr. at 69. Joshua no longer was receiving seizure medications and had been seizure free since 2005. Tr. at 69-70, 99.

C. Petitioner’s Case

²³ If accurate, this report would indicate that Joshua’s developmental delay had been noted in September 2004, two months before his November 10, 2004, vaccinations.

²⁴ Tinea versicolor is a relatively common long-term fungal infection of the skin. National Library of Medicine, Tinea Versicolor, Medline Plus (last updated: Oct. 10, 2010), <http://www.nlm.nih.gov/medlineplus/ency/article/001465.htm>.

²⁵ Joshua received the vaccinations typically administered at two months of age on November 10, 2004, when he was five months old.

Petitioner alleged in her Post-Hearing Brief that Joshua was “essentially normal” before his November 10, 2004, DTaP vaccination and that “there was a dramatic change in [Joshua’s] response to his environment in November of 2004.” Petr’s Post-Hr’g Br. at 2, 16. She claimed that Joshua’s symptoms of decreased consciousness following vaccination satisfied the legal definition of an acute encephalopathy. Id. at 10-13. The relevant facts were supported by the factual testimony of the Stobbes, and by the expert testimony of Dr. Schweller. Id. Petitioner further claimed that no persuasive evidence showed any symptoms prior to vaccination. Id. at 21-24.

Citing her own testimony as well as that of her friends, Leonard and Eileen Stobbe, Petitioner alleged that Joshua, before his vaccinations, was a typical infant except that he had coloboma of the iris in both eyes, and was cross-eyed. Id.; see Tr. at 19-20, 24-25, 32 (Leonard Stobbe testifying that “at times when you held him right in front of you he’d like look at your hair”); Tr. at 72 (Petitioner’s testimony that “[a] lot of time when he looked towards us to find us it seemed his eyes were looking above us or like right at our hair instead of at our faces”); Tr. at 94 (“you can’t tell exactly what he’s looking at”).²⁶

Petitioner asserted that a “very significant change” occurred in Joshua’s behavior “within 24 hours after his November 10, 2004 DTaP vaccination.” Petr’s Post-Hr’g Br. at 3.²⁷ Petitioner described Joshua’s condition on November 11, 2004, the day after vaccination as “lethargic,” he “just laid there” and did not make eye contact or interact with me. Id. at 4-5, 18-19. Joshua didn’t seem to know his mother was present and “didn’t really seem to know anything.” Id. at 19.²⁸ Petitioner asserted that Ms. Stobbe “also described the change in Joshua’s responsiveness to his environment,” id. at 3-4, and Mr. Stobbe’s testimony “provide[d] modest support” for an onset within two days of vaccination, id. at 19.²⁹

²⁶ At hearing, Petitioner explained her comment to Dr. Weiss on November 11, 2004, that Joshua seemed not to pay attention to what was going on around him as a reference to his “cross-eyes.” Tr. at 94.

²⁷ Petitioner admitted at hearing that her recollection of dates is unreliable, and that her recollection of November 11, 2004, was uncertain. See Tr. at 74-75, 77-79 (“I know I went [to Dr. Weiss on November 11, 2004,] but I just don’t remember a lot [about that visit]”). I find it to be so as well. For example, she did not recall telling Dr. Weiss that Joshua, as long as three weeks before the vaccinations, had been notably inattentive to his environment. See, e.g., Tr. at 94 (“I don’t remember saying that”).

²⁸ Omitted from Petitioner’s post-hearing brief (or her testimony) was any reference to the statement in her Affidavit that, “During the week after the November 10, 2007 [sic] vaccinations, Joshua began to have episodes in which his eyes rolled back . . . and his arms would stiffen.” Pet’r Ex. 1 at ¶18.

²⁹ Petitioner conceded that Mr. Stobbe’s recollection was uncertain. See Petr’s Post-Hr’g Br. at 17. Ms. Stobbe testified that she could not recall whether she actually saw Joshua the day after his vaccination, as she was at work. Tr. at 36-37.

Petitioner asserted that the notes from her visit to Dr. Weiss on November 11, 2004, in which the doctor observed that Joshua appeared to suffer from “visual inattention,” corroborated her description of Joshua’s post-vaccination condition. Id. at 5-6. She argued that Dr. Weiss described Joshua’s symptoms as mild because he did not know that they represented a dramatic change as compared to the baby’s normal behavior. See id. at 6. Petitioner claimed Dr. Weiss’s handwritten notes, which stated, “Random cont (continuous) eye movements without fixation on random stimuli; not following,” and “visually inattentive,” described decreased responsiveness to the environment under 42 C.F.R. § 100.3(b)(2)(i)(D). Petr’s Post-Hr’g Br. at 11-12. Petitioner supported her assertion by citing Dr. Schweller’s testimony that, when seen by Dr. Weiss, Joshua exhibited “decreased responsiveness and therefore . . . a decreased level of consciousness and acute encephalopathy”. Id. at 12. In Dr. Schweller’s view, any decrease in responsiveness may constitute evidence of an acute encephalopathy. Tr. at 150, 157-61; see Petr’s Post-Hr’g Br. at 12-13. Thus, “the definition of acute encephalopathy . . . includes infants who were awake but poorly responsive to their environment as well as those in a coma.” Petr’s Post-Hr’g Br. at 13.

Petitioner also pointed to testimony from the Secretary’s expert, Dr. Guggenheim, who agreed that Joshua “in a technical sense” met the Secretary’s criterion for “significantly decreased level of consciousness” based on “decreased or absent eye contact, [does] not fix gaze upon family members or other individuals.” Petr’s Post-Hr’g Br. at 13. Petitioner noted, however, Dr. Guggenheim’s opinion that the Secretary’s criteria probably assume “a child who has previously normal visual attentiveness which it seems Joshua probably did not.” Id.

Petitioner relied on the medical records of her visits to NP Lind to demonstrate a decline in Joshua’s visual attentiveness. See Petr’s Post-Hr’g Br. at 17-18. NP Lind’s records of his examination on November 5, 2004, stated that Joshua “seems to focus on people.” Id. at 17. At the same visit, NP Lind noted that Joshua’s colobomas “may be benign congenital but no red reflex please send results.” Id. (quoting Pet’r Ex. 7 at 3). When NP Lind next examined Joshua on November 26, 2004, he noted “blind, no eye movement @ hand, no red reflex,” and “Blind Coloboma.” Petr’s Post-Hr’g Br. at 17-18 (quoting Pet’r Ex. 7 at 6).³⁰

Petitioner also cited the records of Joshua’s admission to Seattle Children’s Hospital from December 29, 2004 to January 1, 2005. Petr’s Post-Hr’g Br. at 20. The notes of Dr. Bouldin, a neurologist, reported “episodic events which have been going on since early to mid-November. The onset of these events was associated with im [sic] becoming less interactive.” Petr’s Post-Hr’g Br. at 20 (quoting Pet’r Ex. 6B at 42). Similarly, the notes of Dr. Hing, geneticist, stated that Petitioner reported Joshua was having seizure episodes -- where “Joshua would blink his eyes, throw his arms forward,

³⁰ Petitioner’s brief cited the date of this note as “November 16, 2004,” but it was actually dated November 26, 2004.

and flex forward at the trunk with extension at the neck” -- and that Petitioner felt the episodes “began shortly after his second immunization in mid November.” Petr’s Post-Hr’g Br. at 20-21.

Petitioner reviewed Joshua’s medical history after vaccination in support of the proposition that the change in his neurologic status persisted and developed into a chronic encephalopathy. Id. at 6-8, 13-15. Petitioner asserted that Joshua never returned to a normal state, even after his infantile spasms stopped. Id. at 15. Therefore, according to Dr. Schweller, Joshua’s acute encephalopathy turned into a chronic encephalopathy.

Petitioner argued that the evidence did not show more likely than not that Joshua’s condition pre-dated his vaccinations. While conceding that some medical records indicated Petitioner had concerns prior to Joshua’s vaccination, Petitioner argued that all such statements were retrospective and ambiguous. Id. at 21-23, 29-31. She claimed the testimony of the fact witnesses was sufficient to show that Joshua was normal before his vaccinations. Id. at 22, 29-31.

Petitioner also argued that the Secretary had not demonstrated that Joshua’s condition was caused by factors unrelated to the DTaP vaccination because the Secretary did not establish (or even attempt to establish) the legal elements of a case of causation by an alternative factor. Pet’r Post-Hr’g Br. at 24-28; see also Pet’r Post-Hr’g Reply Br. at 7-10.³¹

D. The Secretary’s Case

The Secretary argued that Petitioner had not established by preponderant evidence that Joshua’s symptoms were sufficient to satisfy the definition of a Table encephalopathy (acute encephalopathy followed by a chronic encephalopathy). Respt’s Post-Hr’g Br. at 12.

The Secretary asserted that, to establish entitlement, the acute encephalopathy must manifest within the applicable period. The Secretary argued that Joshua’s “decreased or absent eye contact” did not manifest in the 24 hours after his vaccinations and maintained that Joshua’s visual attentiveness probably was not normal before his vaccinations. Id. at 15. She noted that the medical records reflected that Joshua had visual problems before his vaccinations. Id. at 13. She also noted that Petitioner and the Stobbes all recalled some irregularities in Joshua’s vision before vaccination. According to the Secretary’s expert, Dr. Guggenheim, the medical record suggested that Joshua’s visual problems arose from “the part of the visual system that projects from the visual cortex to the other parts of the brain that are part of our consciousness.” Id. at 14.

³¹ The arguments in Petitioner’s Reply brief are not discussed separately because they are substantially the same as those in the original post-hearing brief.

Even if Joshua's vision problems commenced on November 11, 2004, the Secretary explained that an acute encephalopathy is one sufficiently severe so as to require hospitalization. The Secretary refuted Dr. Schweller's opinion that Joshua should "probably" have been hospitalized some time after Dr. Weiss's examination. Id. at 15. The Secretary noted the absence in Dr. Weiss's November 11, 2004, notes of anything signaling "either concern of an acute encephalopathy sufficiently severe so as to require hospitalization, or that Joshua's clinical presentation had declined precipitously in the previous twenty-four hours." Id. at 14. Dr. Guggenheim found it "incredible" that "a university affiliated physician would not identify the symptoms of a child in a clearly encephalopathic state and insist on further immediate care." Id. at 14. Dr. Guggenheim felt that Dr. Weiss on November 11, 2004, simply was describing the specific vision problems previously noticed by Petitioner, which led to the ophthalmological referral.

The Secretary cited Shalala v. Whitecotton, 514 U.S. 268 (1995), for the proposition that a petitioner seeking to establish a Table injury must show that no evidence of the injury appeared before the vaccination. Respt's Post-Hr'g Br. at 16. The Secretary asserted that Petitioner could not show that the symptoms she claimed as evidence of an acute encephalopathy were not present before vaccination. Id. at 13-14, 16.

The Secretary also asserted that Petitioner had not satisfied the other component of a Table encephalopathy -- that Joshua suffered from a "chronic encephalopathy." See Respt's Post-Hr'g Br. at 17; § 100.3(b)(2). The Secretary pointed to regulatory guidance regarding a chronic encephalopathy, which states, "If a preponderance of the evidence indicates that a child's chronic encephalopathy is secondary to genetic, prenatal or perinatal factors, that chronic encephalopathy shall not be considered to be a condition set forth in the Table." Respt's Post-Hr'g Br. at 17. The Secretary asserted that "Joshua's condition is likely secondary to prenatal factors." Id.

The Secretary's expert, Dr. Guggenheim, testified that the medical record showed that Joshua's treating physicians believed his condition was attributable to a developmental abnormality. Id. at 18. Dr. Guggenheim stated that a treating neurologist's diagnosis of "symptomatic" infantile spasms denoted "that there was something wrong with this child's brain . . . as opposed to us having no clue and a perfectly normal child who then for no apparent reason starts having infantile spasms, and those we would call cryptogenic." Id. The Secretary asserted "there is functional evidence that Joshua experienced a prenatal process that interfered with brain development." Id. at 18.³²

³² My recitation of the Secretary's assertion that Joshua's condition was caused by prenatal factors should not be interpreted as an endorsement of that conclusion. In my view, this case does not require a finding on "alternative factor." I weigh the evidence that Joshua's disorder was congenital only to the extent the evidence bears on whether or not he suffered a sudden, acute brain injury within 72 hours of vaccination; since I conclude that he did not,

The Secretary asserted that the burden of proof did not shift because Petitioner had failed to make out a prima facie case of a Table injury. Id. at 18-19.

III. DISCUSSION

A. Petitioner's Burden of Proof

The Vaccine Act provides streamlined procedures as well as standards of proof for petitioners claiming vaccine injuries. Whitecotton, 514 U.S. at 269-70. While a claimant may establish prima facie entitlement to compensation by introducing proof of actual causation, the claimant also may obtain compensation by meeting the conditions set forth in the Vaccine Injury Table. Id. at 270.³³ Under the statute, a claimant makes out a prima facie case by showing the he “sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with [a] vaccine . . . and the first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition . . . occurred within the time period after vaccine administration set forth in the Vaccine Injury Table.” Id. (citing and quoting § 11(c)(1)(C)(i)); see also de Bazan v. Sec’y of Dep’t of Health & Human Servs., 539 F.3d 1347, 1351 (Fed. Cir. 2008). As the Court in Whitecotton observed, the rules governing Table injury cases turn “the old maxim on its head by providing that if the post hoc event happens fast, ergo propter hoc.” 514 U.S. at 270. When a Table injury is established, causation is presumed and the petitioner is entitled to compensation, unless Respondent can establish alternative causation.

The petitioner carries the burden of proof with respect to each of the requirements necessary to make out a prima facie Table injury.

Thus, a demonstration that the claimant experienced symptoms of an injury during the table period, while necessary, is insufficient to make out a prima facie case. The claimant must also show that no evidence of the injury appeared before the vaccination.

Whitecotton, 514 U.S. at 274.

Only after the prima facie case has been established does the question of alternative causation arise. The “factors unrelated” provision, which permits the Secretary to defeat a claim with evidence of a non-vaccine cause, is wholly independent

Petitioner’s prima facie showing is insufficient and the question of alternative factor does not arise.

³³ Injuries not listed on the Table or injuries suffered outside the specified times following vaccination are deemed off-Table injuries, and causation is not presumed. de Bazan, 539 F.3d at 1351. There was no allegation of an off-Table injury in this case. See Tr. at 138 (Dr. Schweller).

of the petitioner's prima facie case. "It does not relieve a claimant of the clear statutory requirements for making out a prima facie case," including the requirement that no symptom or onset of the injury was manifested before vaccination. Whitecotton, 514 U.S. at 275-76; see id. at 273-74 (noting that part of a claimant's prima facie case in proving a Table injury requires evidence that the first symptom of the injury occurred after vaccination); § 11(c)(1)(C)(i).

On the record in this case, I find no credible evidence of a Table injury. I need make no finding on alternative causation, because Petitioner has not established a prima facie case.³⁴ Reviewing the entire record, Petitioner cannot prevail because (1) there is insufficient evidence of an acute post-vaccination injury requiring hospitalization, and (2) there is preponderant evidence showing pre-vaccination symptoms. Because I find Joshua did not suffer from an acute encephalopathy, I need not address whether his vaccination caused a chronic encephalopathy.

B. Insufficient Proof of Acute Encephalopathy

The two components of a Table encephalopathy are an acute encephalopathy followed by a chronic encephalopathy. To constitute an "acute encephalopathy," the vaccinee's condition must be sufficiently severe to require hospitalization, whether or not hospitalization occurs. § 100.3(b)(2)(i). The Secretary's regulations state further that an acute encephalopathy "is indicated by a significantly decreased level of consciousness," § 100.3(b)(2)(i)(A), which may be indicated by clinical signs including "decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli)"; "decreased or absent eye contact (does not fix gaze upon family members or other individuals)"; or "inconsistent or absent responses to external stimuli (does not recognize familiar people or things)," § 100.3(b)(2)(i)(D). "In determining whether or not an encephalopathy is a condition set forth in the Table, the Court shall consider the entire medical record." § 100.3(b)(2)(iv). A special master may consider all the evidence presented, including that of respondent, in determining whether petitioners have met their burden of proof. de Bazan, 539 F.3d at 1353-54; see Doe 11 v. Sec'y of Dep't of Health & Human Servs., 601 F.3d 1349, 1357-58 (Fed. Cir. 2010).

Petitioner maintained that Joshua suffered an acute encephalopathy on November 11, 2004, within 24 hours of his vaccinations. No treating physician ever recorded an opinion that Joshua had suffered an acute brain injury at the time of his vaccination on November 10, 2004, or in the 72 hours following. Further, Petitioner's allegation is inconsistent with the medical records from Joshua's pre-scheduled examination on the day after his vaccination by Dr. Weiss, a pediatric ophthalmologist at Seattle Children's Hospital. See Cucuras v. Sec'y of Dep't of Health & Human Servs., 993 F.3d 1525, 1528 (Fed. Cir. 1993) (noting the reliability of contemporaneous medical records). Petitioner's testimony also is inconsistent with Petitioner's statements and conduct on that date, November 11, 2004, and with Dr. Weiss's statements and

³⁴ I reach this decision notwithstanding my sympathy for Petitioner and Joshua.

conduct. The preponderant evidence of record shows that Joshua did not require hospitalization on November 11, 2004.

1. Petitioner's Statements and Conduct

As noted in the discussion of the facts, during the relevant post-vaccination period Petitioner did not seek medical attention for Joshua for an acute encephalopathy. Petitioner did, however, bring Joshua to Seattle Children's Hospital for a pre-scheduled eye examination on the day after his vaccinations, on the exact date he allegedly succumbed to an acute encephalopathy. Petitioner's statements in the course of this visit, and more particularly, the omission from her statements of any indication that Joshua's condition had changed drastically in the previous 24 hours, do not comport with her allegations of a sudden, dramatic decline in Joshua's cognitive status on November 11, 2004.

According to the records of the hospital visit, Petitioner did not report any of the symptoms of acute encephalopathy about which she testified at hearing -- lethargy, complete unresponsiveness, failure to recognize familiar people. At hearing, Petitioner confirmed that she did not mention any of these symptoms to Dr. Weiss on the date that they allegedly occurred. See Tr. at 94-96, 108.

The record not only is devoid of any report of the symptoms of acute encephalopathy, it contains statements by Petitioner that, by implication, contradict the allegations of severe symptoms of lethargy and unresponsiveness arising suddenly following vaccination. Specifically, on the intake form Petitioner completed in conjunction with the visit to Dr. Weiss, Petitioner reported symptoms such as snoring, runny nose, wheezing and cough. She noted Joshua's "trouble seeing." She indicated no problems with his eating or drinking, and left blank the space asking about other concerns and questions. There is no mention of a sudden, marked decrease in responsiveness, visual or otherwise.³⁵

It is reasonable to assume that if Petitioner had noted symptoms on November 11, 2004, of a suddenly decreased level of responsiveness, she would have mentioned such symptoms somewhere on the form instead of simply reporting cold symptoms. If Joshua's "trouble seeing," for which he was taken to Dr. Weiss by appointment, were significantly worse or different on November 11, 2004, than they had been previously, so that he did not seem to be at all aware of what was going on around him, it is difficult

³⁵ Petitioner testified that she told Dr. Weiss about Joshua's crying the night before and "something about responsiveness." Tr. at 78. She also testified, however, that she did not remember much about that visit. Tr. at 79. Dr. Weiss's notes indicated that Petitioner's concern about Joshua's unresponsiveness predated his vaccination by a period of three weeks. Pet'r Ex. 6A at 12. Petitioner argued that she had used the present tense when referring to Joshua's unresponsiveness, and was not referring, as Dr. Weiss indicated, to the previous three-week period. Petr's Post-Hr'g Br. at 23. Nothing in the record corroborates Petitioner's post hoc construction of her report to Dr. Weiss.

to believe that Petitioner would not have indicated that information somewhere on the intake form, as well. Even if she did not write it down, she would have told Dr. Weiss about these new and alarming symptoms. Her failure to do so cannot reasonably be explained by the fact that this was not the purpose of the visit to Dr. Weiss. See Tr. at 107-08.

I am mindful that “[T]he absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance.” See Murphy v. Sec’y of Dep’t of Health & Human Servs., 23 Cl. Ct. 726, 733 (1991), aff’d per curiam, 968 F.2d 1226 (Fed. Cir. 1992), cert. denied, 506 U.S. 974 (1992). In the confusion surrounding a serious and baffling illness, records may be incomplete. Even significant events may not be mentioned simply through oversight, or because treating professionals did not seek information that, at the time, they deemed not to be important.

The circumstances here were not emergent, however. Dr. Weiss saw Joshua by appointment for pre-existing conditions which, as he noted, included malformation of the eyes, visual problems and developmental delay, all as reported by Petitioner to Dr. Weiss. The absence on the intake form of any reference to a sudden and dramatic decrease in Joshua’s responsiveness between November 10 and 11, 2004, is inexplicable under these circumstances.

Further, when Petitioner brought Joshua to the hospital to see Dr. Weiss, she did not seek any treatment for Joshua’s alleged acute encephalopathy. If Joshua’s symptoms on that date had been as she described them at hearing, Petitioner likely would have made some effort to have Joshua evaluated, particularly since she was already in the hospital with the child.

Petitioner testified that Joshua was essentially a normal baby before his vaccinations on November 10, 2004, and then overnight became almost completely unresponsive, “just laid there” and “didn’t really seem to know anything.” Tr. at 56-57. I observed Petitioner at hearing. She was mature, aware, articulate, caring, and experienced with raising children (Joshua is her fourth, see Tr. at 105). She testified that she did not seek help for Joshua immediately (indeed, not for another two weeks) because she thought he would improve. Tr. at 90-92. That does not explain the discrepancy between Petitioner’s actions on November 11, 2004, and what she later described as Joshua’s condition on that date. Accordingly, I find as a matter of fact that Joshua did not experience a sudden, marked decrease in responsiveness in the 72-hours following his November 10, 2004, vaccinations.

“A special master may “evaluate[] the testimony in light of the entire record, based on reasonable inferences born of common experience. . . .” Sword v. United States, 44 Fed. Cl. 183, 189 (1999). I cannot reconcile Petitioner’s description of Joshua on November 11, 2004, with her having taken no action to obtain treatment for him while she was at Seattle Children’s Hospital. Petitioner’s actions as well as her words on November 11, 2004, undermine the allegation that Joshua’s condition on that

date was sufficiently acute to require hospitalization, as necessary to establish a Table encephalopathy.

2. Dr. Weiss's Statements and Conduct

Dr. Weiss's notes of his outpatient examination of Joshua on November 11, 2004, contain no indication that Joshua was at that time experiencing an acute encephalopathy for which he required hospitalization. Indeed, Dr. Weiss's notes are inconsistent with such a condition. Dr. Weiss noted that the visit was scheduled because of Petitioner's observation some three weeks earlier that Joshua had irregularly shaped pupils and at times could see but at times "does not pay attention to what is going on around him." Pet'r Ex. 6A at 12. Further, Dr. Weiss's examination revealed "an alert, normal-appearing child Muscle tone is good." Id. This note does not describe a child suffering deep lethargy and almost completely withdrawn from his environment, as described by Petitioner at hearing. Dr. Weiss's impression was "subnormal visual orienting behavior . . . not age appropriate," in other words, a developmental rather than an acute disorder. This impression was confirmed by Dr. Weiss's observation that Joshua's prenatal history might have caused his visual impairment. Id.

Dr. Schweller asserted at hearing that Dr. Weiss's observation of Joshua's lack of attentiveness confirmed that the child was suffering an acute encephalopathy.³⁶ The medical record directly refutes this opinion. Dr. Weiss's examination confirmed only the conditions observed by Petitioner some three weeks earlier: iridical malformation and occasional failure to pay attention to what was going on around him. Dr. Weiss observed, "This child intermittently seems to be alert, attentive and fixates on objects. At other times he ignores his visual environment." Id. Had Dr. Weiss detected a failure

³⁶ Dr. Schweller indicated that Dr. Weiss may have been too focused on Joshua's vision problems to detect his cognitive difficulties. Tr. at 118-21. I cannot agree with Dr. Schweller that Dr. Weiss missed evidence of severe cognitive dysfunction during Joshua's examination on November 11, 2004. As Dr. Guggenheim testified, Dr. Weiss was

not just an ophthalmologist or an optometrist selling glasses on the street. He is a professor of pediatric ophthalmology. Seattle Children's Hospital is the teaching hospital for the University of Washington School of Medicine . . . so I give credence to what we have here [referring to his notes]. . . . He clearly indicates that although this child can see, he doesn't seem to pay attention. He only intermittently fixates on objects, at times he ignores his visual environment, but on several occasions he says this child is alert. And for a pediatric ophthalmologist who sees kids a lot, even though he's focused on the eye and we all have our specialty . . . it seems to me quite unlikely that a person of Dr. Weiss's experience and knowledge and familiarity with kids would overlook a significant acute encephalopathy.

Tr. at 190-92 (emphasis added).

of cognitive function more severe than the behavior that prompted Joshua's appointment with the ophthalmologist, the overwhelming probability is that he would at least have noted this fact in the record of his examination on November 11, 2004.

As the result of his examination, Dr. Weiss scheduled additional visual acuity testing for Joshua, before making any recommendations regarding treatment. Pet'r Ex. 6A at 12-13. Dr. Weiss did not take any action to obtain further evaluation of or treatment for Joshua on November 11, 2004. He did not refer Joshua to a neurologist or indicate any suspicion that Joshua's condition might have had an acute component. Certainly, he did not hospitalize Joshua or in any way indicate that Joshua needed to be hospitalized. Unless Dr. Weiss, a pediatric ophthalmologist at a teaching hospital in a major American city, simply missed an acute encephalopathic process occurring "right before his eyes," the record of his examination (which includes descriptors such as "alert," "attentive," and "normal-appearing") refutes the Petitioner's allegation of a Table injury. I am persuaded that, as Dr. Guggenheim testified, it is highly unlikely that Dr. Weiss simply failed to notice and/or act upon the alleged acute encephalopathy. I find as a matter of fact that Joshua did not suffer a cognitive decline or an acute encephalopathy in the 72-hours following his November 10, 2004, vaccinations.

3. Expert Testimony

Dr. Schweller testified for Petitioner that Joshua's condition merited hospitalization on November 11, 2004. I find this testimony to be unpersuasive for two reasons. First, Dr. Schweller relied on Petitioner's description at hearing of Joshua's acute change in condition on that date. See Tr. at 113. I find Petitioner's testimony not to be reliable, for the reasons already discussed. Second, Dr. Schweller's testimony conflicted with the records created contemporaneously by Dr. Weiss, who actually examined Joshua in the hospital on the date in question and did not consider ordering further evaluation for a possible acute encephalopathy, or admitting Joshua to the hospital.

As indicated above, I find Dr. Guggenheim's testimony for Respondent to be persuasive on these issues. Her testimony comported with the evidence in the medical records. Dr. Guggenheim focused on Joshua's development of infantile spasms during the same time frame in which his vaccinations occurred. Tr. at 184. Infantile spasms, she explained affect only "infants around four to eight months of age, and more times than not 80 percent plus [it] leaves the child with the kind of handicaps Joshua manifests." Tr. at 185. Dr. Guggenheim rejected Dr. Schweller's "simplistic" reliance on the testimony at hearing that this was a child who was "perfectly fine" before vaccination. She stated

Both in the affidavit and in the testimony that I heard . . . it would certainly appear that there was something different about this child's visual attention prior [to the vaccinations]. The exact nature of that, maybe we can never totally put a [] name on it, but there was something different

about how he paid attention to visual stimuli. It's in the affidavit. It's in the history I heard [at hearing].

Tr. at 186.

I agree with Dr. Guggenheim in rejecting the testimony at hearing concerning a normal child who suddenly and dramatically deteriorated overnight. For example, both Petitioner and Mr. Stobbe testified that, even before his vaccination, Joshua sometimes appeared to be looking at a person's hair rather than the person's face. He had strabismus, it is true, but that would not explain Petitioner's own report to Dr. Weiss concerning Joshua's occasional failure to focus his attention, as well as his vision, appropriately. The history given to Dr. Weiss indicated that Joshua was occasionally inattentive to visual stimuli, and Dr. Weiss observed the same behavior on examination. Pet'r Ex. 6A at 12-13. Dr. Weiss did not ascribe this behavior to strabismus, but to a developmental disorder.

Dr. Guggenheim's testimony was bolstered by her reliance on the records of examination by Drs. Weiss and Bouldin. See Tr. at 206-11. As discussed above, Dr. Weiss, according to his records, observed no signs of acute encephalopathy. When Petitioner and Joshua saw Dr. Bouldin, the pediatric neurologist at Children's Hospital, the history provided by Petitioner was "totally lacking as are all of the other contemporaneous records for any reference to an abrupt change in this child's behavior immediately following the immunizations." Tr. at 209. Dr. Guggenheim also noted the neurologist's conclusion that Joshua suffered "a preexisting brain abnormality of some type." Tr. at 210. Dr. Guggenheim testified that other medical records supported Dr. Bouldin's conclusion. She explained that Joshua "really had not in any consistent fashion rolled over which for a six month old is a substantial delay. . . this child's preexisting brain abnormalities manifested by delayed development prior and the colobomata, which are a marker in the eye from something abnormal developmentally in the visual system of the brain." Tr. at 212.

C. The Record Shows That Joshua More Likely Than Not Suffered Symptoms Before His Vaccinations.

The record contains no credible corroboration of Petitioner's testimony that Joshua was a normal child before vaccination and suddenly deteriorated in the immediate aftermath of his vaccinations. Instead, the medical records from the months immediately before and after his vaccination indicated that the first manifestation of Joshua's visual attention problems occurred before vaccination. In addition, as Dr. Guggenheim testified, there is evidence in the medical records of a pre-existing abnormality in Joshua's brain, with symptoms that preceded his vaccinations.

-- Joshua's iris colobomas clearly predated his vaccinations. See supra. Petitioner took Joshua to Providence Everett Medical Center on October 25, 2004 because of that condition, reporting that Joshua's left eye had "never been right." See Pet'r Ex. 4B at 8, 11. At that time, she was instructed to make an appointment with a

specialist. The treating physician recorded that the colobomas were “probably congenital.” Id. at 11.

The next day, Joshua was examined by Dr. Shlafer, who reported that Joshua exhibited no retinal response. A nurse practitioner then confirmed the diagnosis of coloboma.³⁷ Dr. Weiss, an expert pediatric ophthalmologist and Joshua’s treating physician, subsequently associated these colobomas with visual-cortical dysfunction.

When Dr. Weiss saw Joshua on November 11, 2004, he recorded that “The mother first noted the abnormal shape of the pupils about three weeks ago. She feels that he can see but at other times he just does not pay attention to what is going on around him.” Pet’r Ex. 6A at 12. The import of Dr. Weiss’s notation is that the colobomas were associated with an apparent visual attention deficit noted by Petitioner weeks earlier, not with an acute process occurring overnight on November 10-11, 2004. Petitioner seemed to maintain that the colobomas were merely cosmetic, see Tr. at 124, but Dr. Weiss, a specialist, assessed them in the context of a possible developmental disorder due to prenatal factors, as did Dr. Guggenheim, see Pet’r Ex. 6A at 31 (Dr. Weiss noting “prenatal exposure to drugs associated with global developmental delay”); Tr. at 196-97 (Dr. Guggenheim discussing how colobomas can have same developmental implications as retinal malformations); see also Pet’r Ex. 5B (genetics consultant reviewing Dr. Weiss’s examination of Joshua: “he did not appear to fix and follow appropriately for his age”). Accordingly, I find as a matter of fact that Joshua’s vision problems and visual inattention were present prior to his November 10, 2004, vaccinations.

-- The medical records from Joshua’s treatment at Providence Everett on December 16, 2004, stated: “Per mom, she has been concerned re: baby’s growth and development x several months but was not listened to by [Dr.] Shlafer.” Pet’r Ex. 4D at 36. “Several months” before this visit would date Petitioner’s concern about Joshua’s growth and development to mid-September 2004, two months before the vaccinations. Petitioner did not deny making this statement but denied it was true, stating “[I] wasn’t very careful with my timeline a lot of times.” Tr. at 73-75. I agree that Petitioner’s statements as to the timing of Joshua’s symptoms are unreliable, but in a Table injury case, unreliability of testimony concerning the timing of onset is a critical deficit. Faced

³⁷ Petitioner seemed to argue that because NP Lind evaluated Joshua as blind on November 26, 2004, but not on November 5, 2004, this constituted evidence of an acute encephalopathy occurring between those dates. Petr’s Post-Hr’g Br. at 29-30; Tr. at 257-58. The reasoning is specious and not probative. For one thing, if an injury occurred between November 5 and 26, it did not necessarily happen within 72 hours of November 10, 2004, which is the critical time period for determining whether a Table Injury occurred. NP Lind, moreover, was not even a physician, much less an expert ophthalmologist. Further, Petitioner was informed by Dr. Shlafer on October 26, 2004, that Joshua would likely be blind. See Tr. at 48-49. Using Petitioner’s reasoning, this would be proof that Joshua’s condition did not worsen as a consequence of his vaccinations on November 10, 2004, because ultimately it was determined that he was not blind. I reject this superficial reasoning.

with a contradiction between what Petitioner told Joshua's treating physician in December 2004 and the testimony she provided at hearing six years later, I must choose the recorded account, documented in the month following the event, as the more reliable. See Cucuras, 993 F.2d at 1528 ("With proper treatment hanging in the balance, accuracy has an extra premium"). Therefore, I find as a matter of fact that Joshua's development problems started before his November 10, 2004, vaccinations.

-- In the discharge summary following Joshua's hospitalization in late December 2004, it was noted that Joshua "has had a loss of motor skills since 4 months of age." Pet'r Ex. 5B at 11. Joshua was seven months of age at the time of his vaccination on November 10, 2004, again indicating that his developmental problems pre-dated his vaccination by several months.

-- The History and Physical recorded on December 29, 2004, when Joshua was admitted to Children's Hospital, documented the onset of Joshua's spasms as "early to mid November." Pet'r Ex. 5B at 5. That would place Joshua's symptoms at or even before the date of his vaccinations, including the symptom of "delayed development" which cannot by definition have occurred overnight between November 10 and 11, 2004. See, e.g., id. at 11; Pet'r Ex. 6B at 42. Even if one construes this confused record as dating the onset of seizures as late as the beginning of December, a decline in Joshua's condition over a couple of weeks would not likely be described as a developmental delay. See Tr. at 163 (Dr. Schweller agreeing that a problem of two weeks duration would not accurately be described as a developmental disorder).³⁸ Thus, the admission record from Children's Hospital supports the conclusion that the delay in Joshua's development predated his vaccinations on November 10, 2004.

In sum, the record as a whole will not support Petitioner's allegation of a sudden onset of neurological symptoms for the first time on November 10-11, 2004, following Joshua's vaccinations. Based on the evidence of record, I find that Joshua displayed symptoms of visual inattentiveness and delayed development for several weeks if not several months before his vaccinations. This evidence has not been effectively refuted. Petitioner's testimony concerning the timing of Joshua's injury was unreliable, was not persuasively corroborated by the Stobbes' testimony, and cannot support a finding of a prima facie Table injury. § 13(a)(1). Dr. Schweller' testimony, based on Petitioner's unreliable account of the facts, fails to persuade for that reason. See, e.g., Burns v. Sec'y of Dep't of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (finding that the "special master concluded that the expert based his opinion on facts not substantiated by the record," and holding that "the special master properly rejected the testimony of petitioner's medical expert").

³⁸ According to Dr. Bouldin's records, Joshua, seen by him on December 29, 2004, had been having infantile spasms that had been going on for an unknown duration, "probably . . . for the last several weeks." Pet'r Ex. 6B at 42-43; see Tr. at 209. In the emergency room on December 16, 2004, Petitioner reported that Joshua had had 10 to 14 days of seizures. Pet'r Ex. 4D at 31.

IV. CONCLUSION

Petitioner did not satisfy the requirements for proving that Joshua's vaccination resulted in a Table injury. Therefore, I find that Petitioner has not established entitlement to compensation under the Vaccine Act, and her Petition must be **DISMISSED**. In the absence of a timely motion for review filed pursuant to Vaccine Rule 23, the Clerk is directed to enter judgment according to this decision.

IT IS SO ORDERED.

s/ Dee Lord
Dee Lord
Special Master