

**IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS
No. 08-882V
Filed: May 15, 2014**

LUIS VERGARA and JACKELINE *
MORA ANGARITA, parents and natural *
guardians of J.A.V., a minor *

Petitioners, *

v. *

SECRETARY OF HEALTH *

AND HUMAN SERVICES, *

Respondent. *

Contemporaneous Records;
Testimony Contradicting
Records; Autism; Onset;
Lack of Factual Predicate for
Table Injury Claim

Donald M. Gerstein, Esq., Richard Gage, P.C., Cheyenne, WY, for petitioners;
Justine E. Daigneault, Esq., U.S. Dept. of Justice, Washington, DC, for respondent.

RULING ON FACTS¹ AND ORDER

Vowell, Chief Special Master:

On December 11, 2008, pro se petitioners Luis Vergara and Jackeline Mora Angarita ["Mr. Vergara," "Ms. Mora,"² or "petitioners"] timely filed a Short-Form Autism Petition for Vaccine Compensation³ under the National Vaccine Injury Compensation

¹ I intend to post this ruling on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire decision will be available to the public.

² Prior to beginning the hearing, Ms. Jackeline Mora Angarita indicated her preference was to be addressed as Ms. Mora. Accordingly, I refer to her as Ms. Mora throughout this ruling.

³ By electing to file a Short-Form Autism Petition for Vaccine Compensation, petitioners alleged that:

[a]s a direct result of one or more vaccinations covered under the National Vaccine Injury Compensation Program, the vaccinee in question has developed a neurodevelopmental disorder, consisting of an Autism Spectrum Disorder or a similar disorder. This disorder was caused by a measles-mumps-rubella (MMR) vaccination; by the "thimerosal" ingredient in certain Diphtheria-Tetanus-Pertussis (DTP), Diphtheria-Tetanus-acellular Pertussis (DTaP), Hepatitis B, and Hemophilus Influenza Type B (HIB) vaccinations; or by some combination of the two.

Program, 42 U.S.C. §300aa-10, *et seq.*⁴ [the “Vaccine Act” or “Program”], on behalf of their minor son, J.A.V. By filing a short-form petition, petitioners joined the Omnibus Autism Proceeding [“OAP”].

The OAP was created to resolve what ultimately totaled about 5700 petitions alleging that vaccines or the thimerosal preservative contained in some vaccines caused autism spectrum disorders. In an omnibus proceeding, test cases are selected for hearing based on the commonality of their causation theory. The parties (other than those in the test cases selected) are not bound by the results in the test cases, but the test cases create a body of evidence that can be used to resolve the remaining cases. In the OAP, three test cases were selected for each of the two theories of vaccine causation advanced by the petitioners’ bar in the OAP. Hearings were conducted and decisions issued.⁵ The decisions in the Theory 1 test cases (which advanced the theory that the measles, mumps, and rubella [“MMR”] vaccine, either alone or in concert with thimerosal-containing vaccines caused autism) were appealed; the decisions in the Theory 2 test cases (that thimerosal-containing vaccines caused autism) were not appealed. A more detailed explanation of the OAP can be found in *Dwyer*, 2010 WL 892250, at *2-4.

I. Procedural History.

J.A.V.’s case was filed after the hearings in the test cases began, but before the decisions were issued. Thus, unlike the early OAP petitioners, Mr. Vegara and Ms. Mora were required to produce some medical records in order to position J.A.V.’s case for resolution after the special masters’ decisions were issued in the test cases and appellate review concluded. See Order, issued Jan. 8, 2009.

When the final appellate decision in the test cases was issued in August, 2010,⁶ the court began the process of notifying petitioners in the approximately 4800 remaining OAP cases of the results and asking them how they intended to proceed. When

Autism General Order #1, 2002 WL 31696785 (Fed. Cl. Spec. Mstr. July 3, 2002), Exhibit A, Master Autism Petition for Vaccine Compensation at 2.

⁴ National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all “§” references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2006).

⁵ The Theory 1 cases are *Cedillo v. Sec’y, HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff’d*, 89 Fed. Cl. 158 (2009), *aff’d*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. Sec’y, HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff’d*, 88 Fed. Cl. 473 (2009), *aff’d*, 604 F.3d 1343 (Fed. Cir. 2010); *Snyder v. Sec’y, HHS*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff’d*, 88 Fed. Cl. 706 (2009). Petitioners in *Snyder* did not appeal the decision of the U.S. Court of Federal Claims. The Theory 2 cases are *Dwyer v. Sec’y, HHS*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *King v. Sec’y, HHS*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *Mead v. Sec’y, HHS*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

⁶ *Cedillo v. Sec’y, HHS*, 617 F.3d 1328 (Fed. Cir. 2010).

notified, Mr. Vergara and Ms. Mora indicated that they intended to pursue J.A.V.'s case. Response, filed Oct. 6, 2010. On October 18, 2010, petitioners were ordered to file a statement setting forth a theory for how the vaccines J.A.V. received caused his injuries, as well as all available medical records.

Petitioners filed a statement identifying their theory of causation on November 18, 2010. According to petitioners, J.A.V. developed a vaccine-induced encephalopathy soon after receiving the MMR vaccine on April 24, 2007, thus implicating the hypothesis considered and rejected in the Theory 1 test cases. In response to the court's January 8, 2009 order to produce medical records to position J.A.V.'s case for resolution, petitioners filed Petitioners' Exhibits ["Pet. Exs."] A-D on December 20, 2010.⁷

This case was reassigned to me on December 21, 2010. On May 23, 2011, I ordered petitioners to file an expert report by August 10, 2011. On August 15, 2011, I granted petitioners' motion for an extension of time until September 26, 2011, to file that expert report. On September 13, 2011, Mr. Richard Gage entered his appearance on behalf of petitioners.⁸ Because Mr. Gage had recently entered his appearance in a number of OAP cases on behalf of pro se petitioners, I granted the petitioners in this case additional time to decide how they would proceed. See Order, issued Sept. 19, 2011. I terminated petitioners' deadline for filing an expert report, and ordered them to instead file a status report. *Id.*

In their November 3, 2011 status report, petitioners indicated that they were attempting to schedule an MRI to provide support for their causation theory in J.A.V.'s case. Petitioners filed another status report on December 7, 2011, providing their own background and their plans for prosecuting their case. Mr. Vergara and Ms. Mora stated that they were medical doctors trained in Colombia where they practiced internal medicine and pediatrics, respectively. With regard to J.A.V.'s condition, they referenced a neurology record containing a diagnosis of "encephalopathy." Status Report, filed Dec. 7, 2011, at 2 (citing Pet. Ex. C (now Pet. Ex. 3), p. 2). They also asserted that "their son's encephalopathy was the result of a vaccination" and that his brain injury would be shown on a "SPECT" scan.⁹ Finally, they conveyed that they were attempting to raise the money to pay for testing and that testing could not be scheduled until the financial arrangements were made.

⁷ The convention in the Program is that petitioner's exhibits are assigned numbers and respondent's exhibits are assigned letters. Subsequent petitioners' exhibits were assigned numbers, beginning with Pet. Ex. 5. On March 1, 2013, I ordered Exs. A-D redesignated as Petitioners' Exhibits 1-4.

⁸ On October 31, 2012, I granted petitioner's motion to substitute Donald Gerstein for Richard Gage as counsel of record.

⁹ A SPECT (single-photon emission computed tomography) scan is a technique used to study regional cerebral blood flow. It "is particularly useful in investigating cerebral vascular disease in children (systemic lupus erythematosus) as well as herpes encephalitis, and for localization of focal epileptiform discharges and recurrent brain tumors." R. Kliegman, et al., NELSON TEXTBOOK OF PEDIATRICS (18th ed. 2007) at 2442.

On December 22, 2011, I ordered petitioners to file an amended petition clearly explaining their theory of vaccine causation.¹⁰ Instead, petitioners filed a status report on May 2, 2012, expressing their intent to remain in the program and requesting additional time to raise funds to have a SPECT scan performed. On May 11, 2012, following a status conference held that day, I ordered petitioners to file the results of the SPECT scan by July 10, 2012. Petitioners filed J.A.V.'s SPECT scan results (Pet. Ex. 5) on June 21, 2012.

On July 9, 2012, I again ordered petitioners to file an amended petition and an expert report supporting their theory of causation. Petitioners filed the amended petition ["Am. Pet."] on August 23, 2012, in which they alleged that J.A.V. suffered a "Table" encephalopathy on the evening of April 24, 2007, after having received the diphtheria, tetanus, and acellular pertussis ["DTaP"],¹¹ MMR, pneumococcal conjugate, hepatitis A, haemophilus influenzae type b ["Hib"], and varicella vaccines earlier that day. Am. Pet. at ¶¶ 2-4. Alternatively, petitioners alleged that the vaccines J.A.V. received on April 24, 2007, caused him to suffer an off-Table encephalopathy.¹² Am. Pet. at ¶ 5.

On October 9, 2012, petitioners requested a fact hearing to explain what they observed at the time of J.A.V.'s vaccinations and over the course of the following months before filing an expert report. Petitioners' Request for Fact Only Hearing. Included with petitioners' request were the affidavits of Mr. Vergara (Pet. Ex. 6) and Ms. Mora (Pet. Ex. 7). During the hearing, conducted in Miami, Florida, on February 22, 2013, Ms. Mora testified in person. On May 20, 2013, petitioners filed photo and video evidence as well as transcribed notes from Dr. Jose Vargas. Pet. Exs. 22-35. On June 5, 2013, petitioners filed transcribed notes of Dr. Jose Bengochea. Pet. Ex. 36. My factual findings are set forth in Section III below.

II. Scope of Ruling and Pertinent Law.

A. Scope of this Ruling.

The record in this case consists of medical records, educational evaluations, petitioners' affidavits, videos, and photographs, as well as Ms. Mora's testimony at the hearing. According to Mr. Vergara and Ms. Mora, the contemporaneous records concerning the period shortly after J.A.V.'s April 24, 2007 vaccinations do not detail

¹⁰ As I informed petitioners during a status conference on December 7, 2011, the MMR-caused brain inflammation theory of causation had been considered and rejected in the OAP Theory 1 test cases, and an amended petition was needed to differentiate J.A.V.'s case from the test cases.

¹¹ There is no evidence that J.A.V. received a DTaP vaccination on April 24, 2007, although he did receive the other vaccinations listed in the petition on that date. See Pet. Exs. 1, pp. 15-16; 2, p. 98; 4, pp. 114-15 (vaccination records). J.A.V. received his fourth DTaP vaccination on November 5, 2007, but this occurred at the same visit when J.A.V. was diagnosed with a developmental language delay and referred to a neurologist for evaluation. *Id.*; Pet. Ex. 2, p. 75.

¹² Although petitioners do not use the term "off-Table" to describe their alternative theory in their Amended Petition, their intent to advance an actual causation claim is apparent from context.

J.A.V.'s reaction to those vaccinations. Petitioners state that they cared for J.A.V. at home, using their medical training and experience. Because of the alleged insufficiency of the record, I conducted a hearing.

In this ruling I determine, to the extent possible without expert testimony, what transpired following the vaccinations in question. J.A.V. received Table vaccines¹³ on April 24, 2007. What is at issue is whether the symptoms, if any, J.A.V. displayed after these vaccinations are consistent with a Table encephalopathy and when the first symptoms of what has been diagnosed as an autism spectrum disorder arose. This requires resolving some conflicts between the contemporaneously created medical records and later accounts of J.A.V.'s symptoms and condition.

A determination of what actually caused J.A.V.'s injuries will require the testimony of experts. Therefore, I do not draw any conclusions with regard to what caused J.A.V.'s symptoms. I note that many of the symptoms J.A.V. displayed are consistent with the symptoms displayed by other children with autism. If petitioners intend to pursue an MMR-based causation in fact theory, they will need to produce evidence not already considered in the context of the Theory 1 test cases, which found the then-existing evidence of MMR causation to be inadequate.

B. Law Pertinent to Resolving Evidentiary Conflicts.

Conflicts between contemporaneous records and testimony given several years later at a hearing are common in Vaccine Act cases, and this case is no exception. Two general legal principles guide the resolution of conflicts between contemporaneous records and later-adduced evidence. The first is that the absence of a reference to specific symptoms in a medical record does not conclusively establish the absence of symptoms during that time frame. *See, e.g., Murphy v. Sec'y, HHS*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir. 1992) (“[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” (citation omitted)).

The second principle addresses the degree of reliance commonly accorded to contemporaneous records. Special masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recounted in later medical histories, affidavits, or trial testimony. “It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.” *Murphy*, 23 Cl. Ct. at 733 (citation omitted); *see also Cucuras v. Sec'y, HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993) (medical records are generally trustworthy evidence). Memories are generally better the closer in time to the occurrence reported and when the motivation for accurate explication of symptoms is more immediate. *Reusser v. Sec'y, HHS*, 28 Fed. Cl. 516, 523 (1993). Inconsistencies between testimony and contemporaneous records may be overcome by “clear, cogent, and

¹³ A Table vaccine is one listed on the Vaccine Injury Table, § 300aa-14(a); 42 C.F.R. § 100.3 (2009). Only claims pertaining to the listed vaccines are cognizable under the Vaccine Act.

consistent testimony” explaining the discrepancies. *Stevens v. Sec’y, HHS*, No. 90-221V, 1990 WL 608693, at *3 (Fed. Cl. Spec. Mstr. Dec. 21, 1990). The following medical history and the conclusions drawn therefrom are presented with these legal principles in mind.

C. Credibility Determinations.

Although post vaccination fever and lethargy were not documented in the medical records, I accept the testimony of Ms. Mora¹⁴ regarding what transpired within a day or two of J.A.V.’s April 24, 2007 vaccinations, as the symptoms of fever and lethargy J.A.V. displayed were ones commonly occurring after vaccinations. Furthermore, the parents’ decision to treat J.A.V. at their home rather than seeking outside medical assistance is logical as both parents have medical degrees and J.A.V. was their fourth child. Under these circumstances, the absence of any contemporaneous medical record documenting the fever and lethargy are not surprising. However, I did not accept testimony and affidavits concerning a possible seizure event shortly after vaccination, as neither parent witnessed any seizure or seizure-like activity after vaccination, and Ms. Mora testified that she was speculating that a seizure had occurred based on J.A.V.’s deterioration over the next several months.

On several points, primarily involving conflicts between the medical records and the histories contained therein and the testimony and affidavits of Mr. Vergara and Ms. Mora, I did not find sufficient indicia of reliability to credit their statements over the medical record evidence. I considered the length of time that had passed since the events of late April and early May 2007, to be an important consideration when evaluating the accuracy of the petitioners’ recollection of events. I note that their affidavits and statements outside those in the medical records suffer from the same infirmity. I emphasize that I am not questioning the sincerity of Mr. Vergara and Ms. Mora. To the contrary, Ms. Mora’s testimony and the affidavits of both parents appeared to reflect their sincere and honest beliefs about what transpired and when symptoms arose. I simply found the contemporaneous records, including videos of J.A.V., to be more reliable.

III. Factual Findings.

A. Facts Not Reasonably Subject to Dispute.

J.A.V.’s medical history before he was 13 months old is not remarkable and is not a matter in conflict. J.A.V. was delivered prematurely by cesarean section on January 1, 2006, after 37 weeks of gestation. Pet. Ex. 2, p. 90; Tr. at 10. Although his

¹⁴ Although Mr. Vergara did not testify at the February 22, 2013 hearing, he filed a sworn affidavit, Pet. Ex. 6, on October 9, 2012.

Apgar scores were 9 and 9, reflective of a healthy newborn,¹⁵ J.A.V. suffered from several medical problems in the perinatal period and after discharge from the hospital. Pet. Ex. 2, pp. 90-91; Tr. at 11. Shortly after his birth, J.A.V. was diagnosed with respiratory distress, suspected sepsis,¹⁶ hypocalcemia,¹⁷ and jaundice. Pet. Ex. 2, pp.90-91. Each of these conditions was resolved by the time of his discharge from the hospital on January 12, 2006. J.A.V. was also diagnosed with hyponatremia¹⁸ and anemia shortly after his birth. Pet. Ex. 2, p. 91. These conditions persisted at the time of his discharge. *Id.*, p. 92.

J.A.V. had well child checkups on February 2, May 16, June 29, and October 4, 2006.¹⁹ Pet. Ex. 2, pp. 78-80, 87. The only problems noted at these well child visits were a markedly high platelet count from blood drawn after the February 2 visit and gastroesophageal reflux at the May 16 visit. See Pet. Exs. 2, pp. 80, 87; 33, p. 4. He also had a high platelet count in May 2006 in blood drawn at one of his sick child visits. Pet. Ex. 2, p. 82. It does not appear that his pediatrician took any action as the result of these high platelet counts. J.A.V. was well at the June 29 visit with his reflux resolved. Pet. Exs. 2, p. 79; 33, p. 5. J.A.V.'s behavior and development were assessed as within normal limits at his October 4, 2006 well child visit. Pet. Ex. 2, p. 78. J.A.V. did not have a well child visit at one year of age. Ms. Mora testified that she had no concerns about J.A.V.'s health in his first year of life. Tr. at 12.

J.A.V. received his first dose of hepatitis B vaccine at the February 2, 2006 visit, and during subsequent well child visits he received another two doses of hepatitis B, and three doses of DTaP, polio, Hib, and pneumococcal conjugate vaccines. Pet. Exs. 1, pp. 15-16; 2, p. 98; 4, pp. 114-15. A note from his June 29, 2006 well child visit indicated that he was behind on his vaccinations due to illness. Pet. Ex. 33, p. 5.

J.A.V. had several sick child visits, primarily for upper respiratory or lung problems during his first nine months. He was seen for five days of congestion on April 28, 2006, and on examination was afebrile and had chest pain, cough, and wheezing.

¹⁵ The Apgar score is a numerical assessment of a newborn's condition (with lower numbers indicating problems), usually taken at one minute and five minutes after birth. The score is derived from the infant's heart rate, respiration, muscle tone, reflex irritability, and color, with from zero to two points awarded in each of the five categories. See DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (32nd ed. 2012) ["DORLAND'S"] at 1682.

¹⁶ Sepsis is "the presence in the blood or other tissues of pathogenic microorganisms or their toxins." DORLAND'S at 1693.

¹⁷ Hypocalcemia is low blood calcium. DORLAND'S at 900.

¹⁸ Hyponatremia is low blood sodium. DORLAND'S at 903.

¹⁹ J.A.V.'s pediatrician was Dr. Jose Vargas. There were problems deciphering a number of his entries in J.A.V.'s records, and I accordingly ordered petitioners to file a transcription of specific pages of his records. The transcribed records were filed as Pet. Ex. 33 on May 20, 2013.

He was diagnosed with bronchitis²⁰ versus bronchiolitis.²¹ A chest X-ray performed on the same day revealed “mild peribronchial thickening.” Pet. Exs. 2, pp. 84-85; 33, p. 1. On May 1, 2006, he returned with decreased appetite, a cough, and nasal congestion, and was seen again on May 9, when he had bilateral rhonchi and wheezing and was diagnosed with bronchiolitis. He was also having some reflux. Pet. Exs. 2, pp. 81, 83; 33, pp. 2-3.

There were no records of health care visits between J.A.V.’s nine month well child visit on October 4, 2006, and his 15 month well child visit on April 24, 2007 (when he was nearly 16 months old), at which he received the vaccinations identified in the petition as causal.²² Based on Ms. Mora’s testimony and the pattern of taking J.A.V. to his physician when he was acutely ill, I conclude that J.A.V. was a well infant during this period.²³

At the well-child visit on April 24, 2007, Dr. Vargas recorded that J.A.V.’s developmental history and behavior were within normal limits. J.A.V. had about five words (“dada,” “nana,” “tete,” and “vala” and one word which even Dr. Vargas could not decipher when the records were transcribed); however, it is unclear how J.A.V. was using these words and whether he was currently using all of them. Pet. Exs. 2, p. 77; 33, p. 7; see also Tr. at 14-18 (describing J.A.V. vocabulary at 13 months).

Between this visit and November 4, 2007, J.A.V. was not seen by any health care provider. His next medical visit was on November 5, 2007. Pet. Ex. 2, p. 75; Tr. at 52.

B. Matters in Conflict.

The matters in conflict appear to be J.A.V.’s symptoms within a few days of the 15 month well child visit, his behavior and symptoms in the next six months, and the time frame when he lost the use of some words and other symptoms of autism manifested. With regard to the matters in controversy, I first set forth J.A.V.’s condition as described in the contemporaneous medical records and in medical histories in these records, followed by petitioners’ more recent accounts and testimony. These are followed by my factual findings. I then address in Part C whether J.A.V.’s symptoms constitute a Table encephalopathy.

²⁰ Bronchitis is “inflammation of a bronchus or bronchi. . . . Symptoms usually include fever, coughing, and expectoration.” DORLAND’S at 252.

²¹ Bronchiolitis is “inflammation of the bronchioles, usually occurring in children less than 2 years old and resulting from a viral infection, particularly with respiratory syncytial virus.” DORLAND’S at 252.

²² J.A.V. received his initial MMR, varicella, and hepatitis A vaccinations at this visit, along with his fourth doses of Hib and pneumococcal conjugate vaccinations.

²³ It is possible that the lack of medical visits during this period was the result of a lack of health insurance. Mrs. Mora testified that she was without medical insurance from February 2007 through September 30, 2007. Tr. at 16-17, 34-35.

1. Symptoms within a Few Days of Vaccination.

a. Medical Records.

There are no contemporaneous records describing J.A.V.'s condition within a few days of his April 24, 2007 vaccinations. J.A.V.'s next medical visit did not take place until November 5, 2007. J.A.V., then 22 months old, was seen for a check-up. Pet. Ex. 2, p. 75; Tr. at 24.

At this visit, Mr. Vergara reported that J.A.V. had been "drooling a lot" and "doesn't respond well to his name today." Pet. Exs. 2, p. 75; 33, p.8; Tr. at 24-25. Under "Interval History,"²⁴ Dr. Vargas checked "within normal limits" for both developmental history and behavior. Pet. Exs. 2, p. 75; 33, p. 8. Upon examination, Dr. Vargas found J.A.V. to be awake, alert, and in no acute distress. He was walking and running, but not talking. His eye contact was "fair." He could count "1-2-3," suggesting rote counting, rather than an understanding of numbers. *Id.* Although there is a slight check mark in the box for normal development at the bottom of the page, Dr. Vargas placed an "X" in both the boxes for "No" and "Referred" in the normal development box. *Id.* His diagnoses were listed as "developmental speech delay" and "well child." Doctor Vargas referred J.A.V. to an early intervention program and to a neurologist. *Id.* During this visit, J.A.V. received his second hepatitis A, third polio, and fourth DTaP vaccinations. *Id.*; Pet. Ex. 1, pp. 15-16.

b. Other Evidence.

In affidavits²⁵ and testimony, Mr. Vergara and Ms. Mora stated that Dr. Vargas warned them during the April 24, 2007, visit "of possible fever and aches which could be alleviated with Tylenol." Pet. Affidavit at ¶ 6; Tr. at 19. According to Ms. Mora, J.A.V. was quiet and appeared tired during the afternoon of April 24. Tr. at 41.

Around 4-5 PM that day, Ms. Mora took J.A.V.'s temperature and discovered he had a mild fever. Tr. at 19, 40-41; Pet. Affidavit at ¶ 6. She testified that she and her husband took J.A.V.'s temperature every five hours and gave him Tylenol every six hours, but that his fever reached 102° Fahrenheit during the night, at about 1 or 2 AM. Tr. at 20, 41-43. According to Ms. Mora, when J.A.V.'s fever reached 102°, he was placed immediately in the bathtub²⁶ with his father for about 20 minutes to avoid a febrile seizure. Tr. at 20, 42-43; see *also* Tr. at 50 (Ms. Mora testifying that she and her husband know that high fevers can cause seizures).

²⁴ An interval history generally encompasses what transpired between the previous medical visit and the visit at which the history was recorded.

²⁵ Absent pronouns and references to the other spouse, petitioners' affidavits are identical. I will refer to Mr. Vergara's affidavit (Pet. Ex. 6) and Ms. Mora's affidavit (Pet. Ex. 7) as "Pet. Affidavit."

²⁶ Petitioners' affidavits indicate that he was placed in the shower. Pet. Affidavit at ¶6.

After the bathtub treatment, J.A.V.'s temperature did not reach 102° again, although he continued to run a fever for about 20 hours. Tr. at 44. According to Ms. Mora, J.A.V. displayed malaise and weakness for around 24 hours. Tr. at 20-21, 44; Pet. Affidavit at ¶¶ 6, 7. She noted in her affidavit that he looked "very tired" and "as though he was in pain and was easily bothered." Pet. Affidavit at ¶¶ 8, 10. She stated that she and her husband decided not to take J.A.V. to the hospital when he began to display symptoms following his vaccinations because, "[a]s parents with medical backgrounds," they managed to care for him by controlling his temperature. Pet. Affidavit at ¶ 7; Tr. at 44-45. She testified that she and her husband did not perceive the situation to be an emergency "because we didn't expect anything worse than a fever and we could control the fever." Tr. at 53-54.

Ms. Mora and Mr. Vergara now suspect that J.A.V. "may have suffered a partial seizure that [they] were not aware of" during the first 24 hours after his vaccination. Pet. Affidavit at ¶ 8. Ms. Mora testified, however, that she did not observe a seizure. Tr. at 52. She added that she did not report that J.A.V. had a seizure at his subsequent doctor visits because she and her husband did not witness J.A.V. having any seizures. Tr. at 52-53. Ms. Mora acknowledged during her testimony that J.A.V. has never been diagnosed with seizures. Tr. at 52. Asked on cross-examination whether she reported any seizures to Dr. Vargas on November 5, 2007, Ms. Mora answered, "He didn't have any seizure." *Id.* With regard to J.A.V.'s post-vaccination fever, Ms. Mora stated that she did not report it to a doctor in November 2007 because "we didn't think that it was relevant because we controlled [it]." Tr. at 53.

c. Factual Findings.

(1) Fever.

I find that J.A.V. did have a fever in the 24 hours after his April 24, 2007 vaccinations. Ms. Mora's testimony with regard to J.A.V.'s fever was clear, cogent, and internally consistent, and did not appear to be exaggerating what transpired. See Tr. at 19-21, 40-45. Additionally, her testimony was consistent with the statements she and her husband made in their affidavits. Moreover, her testimony about administering Tylenol is consistent with the advice commonly given by health care professionals after administration of vaccinations to treat a post vaccination fever.

Additionally, it is not unreasonable for petitioners to have treated J.A.V.'s fever without making any report, contemporaneous or otherwise, to his pediatrician. The fever Ms. Mora described in her testimony was one that was easily treated. As experienced parents and medical doctors, petitioners knew what treatment to provide. J.A.V.'s fever peaked at 102° Fahrenheit and did not remain at that level for a prolonged period of time.

(2) Seizure.

I find that J.A.V. did not experience a seizure, febrile or otherwise, after his April 24, 2007 vaccinations. The evidence Ms. Mora and Mr. Vergara offered regarding a possible “partial or generalized seizure” was speculative, as neither parent witnessed a seizure. Their speculation appears to be based on J.A.V.’s fatigue, a condition that is not surprising considering he was feverish and receiving home treatment, including a bath at 1 or 2 AM. As experienced parents and medical professionals, they would have sought medical treatment if they truly believed that J.A.V. had experienced a seizure. At the very least, they would have reported a possible seizure after the development of the behavioral concerns prompted the November 2007 visit to Dr. Vargas.

It was not until after they conducted internet research concerning the causes of encephalopathy (see Tr. at 26-27, 29-30, 57-58)—research which likely would have yielded articles and postings describing the relationship between seizures and encephalopathy—that Ms. Mora and Mr. Vergara postulated that J.A.V. suffered a seizure following his vaccinations. I cannot accept their speculation as fact.

2. J.A.V.’s Behavior between April and November 2007.

a. Medical Records.

J.A.V. had no medical visits between the allegedly causal vaccinations and the November 5, 2007 visit to Dr. Vargas. However, J.A.V. saw several health care providers from November 2007 through January 2008. At these visits, petitioners had the opportunity to describe J.A.V.’s symptoms and behavior during the April-November 2007 time frame.

On November 29, 2007, J.A.V. was seen for an initial neurology consultation with Dr. Kenneth Butler. Pet. Ex. 8, pp. 28-29. Summarizing the history of J.A.V.’s condition, Dr. Butler noted: “20 [month old male with] lang[uage] delay. Says only 3 words: bye, mama, papa and can count (mama specific). Eye contact was [decreased] but now better for 2-4 sec[onds]. He socializes and plays [with] sib[lings] and other children. Knows name sometimes. Understands a few commands: No, name 50%, and few other commands. Tends to drool a lot. At 13 [months] said mama, agua and other words and regressed.”²⁷ Pet. Ex. 8, p. 28; see also Tr. at 15.

In recording J.A.V.’s family history, Dr. Butler noted speech delay among J.A.V.’s brothers. Pet. Ex. 8, p. 28. J.A.V.’s older brother Gabriel did not begin speaking until 2½ years of age. His older brother Luis was also delayed in speech. Another brother, Raphael, had no speech problems. *Id.*

²⁷ This entry is ambiguous regarding the time when the regression began, but less than a month later, Dr. Butler wrote that J.A.V.’s regression “began at 13 months of age.” Pet. Ex. 8, p. 31 (Report from Dec. 19, 2007 Video EEG). Ms. Mora testified that, at 13 months of age, J.A.V. said “mama,” “water” (in Spanish), and “moon.” Tr. at 15. J.A.V. was 13 months of age in February 2007, before the allegedly causal vaccinations were administered in April 2007.

During his neurological exam, Dr. Butler found J.A.V. to be alert, but with abnormal speech, comprehension, and social interaction. Pet. Ex. 8, p. 29. His diagnoses were encephalopathy, language impairment, language regression, and excessive drooling.²⁸ He also listed “R/O PDD”²⁹ and “R/O Landau Kleffner,”³⁰ which I interpret as differential diagnoses that he would attempt to “rule out” through testing. Pet. Ex. 8, p. 29. Doctor Butler ordered a brain MRI,³¹ a video EEG³², a brainstem auditory evoked response [“BAER”] test, speech and language therapy, and a follow up in six weeks. Pet. Ex. 8, p. 29.

The BAER test performed on December 6, 2007, revealed that J.A.V. had normal hearing in both ears. Pet. Ex. 8, p. 30. The brain MRI performed December 11, 2007, was also normal. *Id.*, p. 33. On December 19, 2007, a video EEG was performed. *Id.*, pp. 31-32. The results were normal, as “no clinical or electrographic events [were] recorded.” *Id.*, p. 32. In his “Video-EEG Monitoring Report,” Dr. Butler noted that J.A.V.’s language regression began at 13 months of age, and that he was still “language impaired.” *Id.*, p. 31.

In December 2007, J.A.V. was evaluated through Florida’s Early Steps Program.³³ This evaluation was subsequently reviewed by members of the Miami-Dade County Public Schools Office of Special Education and Psychological Services. See Pet. Exs. 1, pp.19-21; 15.1, pp. 1-3. Testing revealed significant developmental delays in a number of domains of development, including adaptive, personal-social,

²⁸ Mrs. Mora testified that J.A.V. was not diagnosed with an encephalopathy until May 2008. Tr. at 26. This record establishes that she was mistaken in her recollection. See Pet. Ex. 8, p. 29.

²⁹ “PDD” likely stands for “pervasive developmental disorder,” the umbrella term used in the DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS (4th ed.1994) at 65, for the broad category of what are now termed “autism spectrum disorders” by the DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS (5th ed. 2013) at 31-32, 50-59.

³⁰ Landau-Kleffner Syndrome is a condition that frequently resembles autism spectrum disorders. It is an acquired epileptic aphasia presenting in childhood. See DORLAND’S at 1836. It can be ruled out by EEG testing, as it presents with a characteristic pattern of bilateral spikes in the temporal region on EEG. *Id.*; see also Pet. Ex. 8, p. 31.

³¹ A magnetic resonance imaging (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 at 916.

³² An electroencephalogram (EEG) is “a recording of the potentials on the skull generated by the currents emanating spontaneously from nerve cells in the brain. . . . [f]luctuations 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 at 600.

³³ Early Steps is run by Florida’s Children’s Medical Services, and is funded by Part C of the Individuals with Disabilities Education Act (IDEA). Through the program, eligible children can receive early intervention services. See <http://www.mch.com/medical-services/early-steps-southernmost-coast.aspx>; http://www.floridahealth.gov/AlternateSites/CMS-Kids/families/early_steps/early_steps.html (last visited May 14, 2014).

communication, and cognitive. Pet. Ex. 1, pp. 17-18 (results of Battelle Developmental Inventory (BDI-2) assessment), 25. The school system evaluator noted the reports of the parents to Early Steps which indicated that J.A.V. “interacts with brothers,” will “say a word with a prompt” but does “not use spontaneous language,” and “tries to sing along with TV actions.” *Id.* at p. 21. The evaluator also noted Dr. Butler’s diagnosis of PDD. *Id.*

Asked about their areas of concern, Mr. Vergara and Ms. Mora reported that J.A.V. “[d]rools a lot when focused on activity but not when humming (listening to singing) or interactin[g] with others. Reduced eye contact at first which increases with a desired activity. Uses [own] sign language and grunt patter[n]s but is on a s[ch]edule to anticipate needs and prevent frustration. He does not point to communicate wants.” Pet. Ex. 1, p. 24. His parents asked that Early Steps help J.A.V. to use words to express wants and emotions. *Id.* Also noted on the intake form was the information that both parents are now employed, but that Ms. Mora was J.A.V.’s “main caretaker until 8 months ago.” *Id.* This would indicate that Ms. Mora returned to work in April or May of 2007.

Specific findings on evaluation included a significant developmental delay in the social/emotional sphere and in his receptive and expressive communication. Pet. Ex. 1, p. 25. His evaluators noted, “J.A.V. shows appropriate affection toward people, expresses likes or dislikes for certain activities, and is aware of his hands and feet.” *Id.* They added, “He does not display independent behavior and did not play peek-a-boo.” *Id.* He had a short attention span for his age but was able to “search for a removed object, attend to an ongoing activity for 15 or more minutes, and place a circle and a square in a form board.” J.A.V. “played independently and had limited interaction with the testers.” *Id.* The Rossetti Infant Toddler Language Scale (RITLS) placed his receptive language skills at the level of a typical six to nine month old, and his expressive language skills were solidly at six to nine month old level and scattered at the level of a typical one year old. *Id.*

On January 15, 2008, J.A.V. returned to Dr. Butler for a follow up neurology consultation. Pet. Ex. 8, p. 34. J.A.V. was alert and socially interactive, but had abnormal speech and comprehension. *Id.*, p. 35. Again, Dr. Butler diagnosed J.A.V. with encephalopathy and language impairment. He ordered chromosomal microarray³⁴ testing, chromosome analysis, and a Fragile X DNA test.³⁵ Pet. Ex. 8, p. 35. These test results were normal. *Id.*, pp. 36-40.

³⁴ Microarray refers to “an arrangement of DNA samples, consisting of a set of DNA spots, typically 200 µm or less in diameter, on a substrate; used for automated high-throughput matching of known and unknown DNA samples. DORLAND’S at 1156.

³⁵ “Fragile sites are regions of chromosomes that show a tendency for separation, breakage, or attenuation under particular growth conditions. . . . The main clinical manifestations of fragile X syndrome in affected males are mental retardation, autistic behavior, macro-orchidism, and characteristic facial features. . . . Diagnosis of fragile X is possible by DNA testing that shows an expansion of a triplet DNA repeat inside the FMR1 gene on the X chromosome.” R. Kliegman, et al., NELSON TEXTBOOK OF PEDIATRICS (19th ed. 2011) at 411.

b. Other Evidence.

Ms. Mora and Mr. Vergara contend that J.A.V. “changed from being the precocious, loving and smiley kid to a passive, quiet, and uninterested child” after his April 24, 2007 vaccinations Pet. Affidavit at ¶ 10; Tr. at 21. They alleged that he “lost his eye contact, his verbal communication and started drooling.” Pet. Affidavit at ¶ 10; Tr. at 21, 35. Ms. Mora testified that these behaviors did not appear abruptly, but were “progressive,” appearing four to five months after J.A.V.’s April 24 vaccinations. Tr. at 22, 35, 53. Ms. Mora stated that she and her husband “didn’t [feel] anything [was wrong] because you as parents didn’t expect something bad on your child after vaccination. You’re not expecting more than a regular reaction like fever and that’s it.” Tr. at 21.

According to Ms. Mora, she and her husband were alerted to J.A.V.’s behavioral changes by his caretaker, Mrs. Rosa. Tr. at 22; Pet. Affidavit at ¶ 12. Because Ms. Mora and her husband were working and away from J.A.V. for more than eight hours a day, they did not notice the changes themselves.³⁶ Tr. at 22, 55-56. On the weekends, Ms. Mora entertained the children indoors and was not concerned by J.A.V.’s quiet demeanor because he was engaged in docile activities such as watching television or playing with toys. Tr. at 67-68. Ms. Mora testified that she would take J.A.V. to daycare each morning (often while he was still sleeping), pick him up in the evening, give him a shower, and prepare everything for the next day. Tr. at 22, 35. In September or October 2007, Mrs. Rosa told them that J.A.V. was “being more quiet than usual” and “drooling so much” that Mrs. Rosa had to change his clothes a few times a day. Tr. at 22, 24, 34-35, 55; see also Pet. Affidavit at ¶ 11. Ms. Mora added that her own family also noticed J.A.V.’s unusual behavior, but did not say anything because they didn’t want to be intrusive. Tr. at 23.

On cross-examination, Ms. Mora was asked about the onset of each of J.A.V.’s symptoms, which she described as appearing progressively. Concerning J.A.V.’s cessation of eye contact, she testified that J.A.V. “stopped” making eye contact “in the first week, two first weeks [after his April vaccinations].” Tr. at 54. She added, however, that she and her husband “saw it, but [they] didn’t pay any attention to it,” because they did not expect anything abnormal to occur following vaccinations. *Id.*

Asked when J.A.V. stopped using words, Ms. Mora testified that J.A.V. “was talking before [his vaccinations], but [h]e didn’t say any more after that, I’m pretty sure.” Tr. at 55-56. However, she did not explain why Dr. Vargas recorded that J.A.V. had five words at the November 2007 visit. Ms. Mora testified that she did not report to Dr. Butler during J.A.V.’s November 29, 2007 visit that J.A.V. started regressing at 13 months. Tr. at 37. She added, “I don’t know why he put [regressed], but that’s not - -

³⁶ The video and photographic evidence filed on May 20, 2013 indicates petitioners and other family members had more interaction with J.A.V. after the April 2007 vaccinations than this testimony would suggest. See Pet. Exs. 23A-H; 28.

we report the regression was with Dr. Vargas.” Tr. at 37-38. Asked about the note on the EEG report indicating that the loss of language occurred at 13 months of age, Ms. Mora stated, “I don’t know why he put that. Maybe it’s 18 months. I don’t know. I cannot answer that.” Tr. at 38. She added that the notation could be incorrect. *Id.*

Ms. Mora testified that, after hearing of J.A.V.’s behaviors and language problems from Mrs. Rosa, she thought he might have something wrong with his brain. Tr. at 23. Ms. Mora and Mr. Vergara stated that on a Saturday afternoon they observed J.A.V.’s drooling and unresponsiveness to his name. Pet. Affidavit at ¶ 14; see also Tr. at 56-57. It was then that they realized that they “had spent too much time at work and had not noticed that [their] son could have a problem.” Pet. Affidavit at ¶ 14. After closely observing J.A.V.’s behavior, Mr. Vergara and Ms. Mora attributed his drooling, lack of verbal communication, decreased appetite, lethargy, unresponsiveness to external stimuli, including a lack of eye contact, and generally decreased consciousness, to an encephalopathy. *Id.* at ¶ 14. Ms. Mora testified that she became insured in late-September 2007, and thereafter made an appointment with Dr. Vargas for November 5, 2007, primarily to address J.A.V.’s excessive drooling.³⁷ Tr. 24, 34-36, 52; Pet. Affidavit at ¶ 15.

The video and photographic evidence suggests that J.A.V.’s excessive drooling existed before the vaccinations in question, and long before Mrs. Rosa brought it to petitioners’ attention in September or October 2007. The February 11, 2007 video (Pet. Ex. 28) shows J.A.V. wearing a bib at a time when he was not eating. Although most of the photographs in Pet. Ex. 22 that were taken before the April 2007 vaccinations do not show J.A.V. wearing a bib, Pet. Exs. 23A through 23D, photographs of J.A.V. taken primarily out-of-doors between May and June 2007, do show him wearing a bib. These photographs suggest that petitioners were aware of J.A.V.’s excessive drooling prior to Mrs. Rosa’s report. Additional photographs taken between October 3 and December 9, 2007, also show J.A.V. wearing a bib at times and places when it does not appear that he was eating. See Pet. Exs. 23E-L.

c. Factual Findings.

(1) Onset of Autistic Behaviors in General.

It is impossible to pinpoint precisely when each of J.A.V.’s autistic behaviors began. I credit that portion of Ms. Mora’s testimony reflects that these behaviors began gradually in the four to five months following the vaccinations in April 2007. Gradual onset is consistent with the manner in which autistic behaviors present in many children, and would explain why petitioners, who were both experienced parents and medically

³⁷ Ms. Mora likely misspoke when first recounting the events leading to the scheduling of J.A.V.’s November 5, 2007 doctor visit. She testified that she made an appointment with Dr. Vargas in late-September 2007, right after she became insured. Tr. at 24, 34-35. She also testified that she did not become concerned about J.A.V.’s condition until October 2007, after hearing from Mrs. Rosa. Tr. at 22-24. On cross-examination, however, Ms. Mora testified that she learned of J.A.V.’s behaviors from Mrs. Rosa in September 2007. Tr. at 36.

trained individuals, did not note most of them until their caregiver brought J.A.V.'s behaviors to their attention. In J.A.V., these behaviors included diminished eye contact³⁸; words that J.A.V. once used, but used no longer; lack of response to his own name; and problems in social interaction.

(2) Language Regression.

It is difficult to tell precisely when, if ever, J.A.V. experienced a true language regression. Although Dr. Vargas used the term “regressed” in November 2007 to describe the change in J.A.V.'s vocabulary, it is impossible to tell from the records or the testimony whether J.A.V.'s use of words prior to and after the April vaccinations constituted a true loss of language.³⁹

The only record that pinpoints precisely when J.A.V. began to lose language specifies that it happened at 13 months of age. While not precisely contemporaneous, this record was prepared by a neurologist who was attempting to determine if J.A.V. had Landau-Kleffner syndrome, and the loss of language and when it occurred could be significant for that diagnosis. I thus conclude that the evidence preponderates towards finding a loss of language occurring prior to the allegedly causal vaccinations. In any event, it is clear that the change in language was not sudden and did not involve a complete loss of the words he had used at the time of the April 2007 visit. Although J.A.V. may not have been talking at the November 2007 visit with Dr. Vargas, he was using at least three words as reported at the November 2007 visit with Dr. Butler.

(3) Unresponsiveness to External Stimuli.

I specifically reject petitioners' testimony regarding J.A.V.'s unresponsiveness to external stimuli and generally decreased consciousness in the period after J.A.V.'s April 2007 vaccinations. Not only is this testimony unsupported by any medical record, it is contradicted by petitioners' contemporaneous statements to health care providers and the observations of those health care providers as set forth in the medical records. J.A.V. was described as alert by Dr. Vargas in November 2007. In the Early Steps evaluation in December 2007, J.A.V. was described as helping with dressing by holding out his arms or legs, discriminating between familiar and unfamiliar people, physically exploring his surroundings, playing with toys, and paying attention to music. Pet. Ex. 1,

³⁸ Although Ms. Mora testified that J.A.V. “stopped” making eye contact after the April 2007 vaccinations, reports to his physicians indicate that it was diminished or decreased. They reported to the school system that his eye contact was reduced at first but would increase when doing a desired activity. Moreover, a complete cessation of eye contact is so striking that it would likely prompt even non-medically trained parents to seek medical advice. I thus conclude that J.A.V.'s eye contact was diminished, but not entirely absent.

³⁹ Expert testimony provided in other autism cases has indicated that the definition of a true language regression is more restrictive than simply the loss of a word spoken occasionally. The testimony provided in this case and in the medical records does not reflect that J.A.V. lost words that he once he used spontaneously and reliably. I am not concluding that J.A.V. did or did not experience a true language regression, simply that the evidence is inadequate for me to reach such a conclusion.

p. 26. These all demonstrate responsiveness to external stimuli and his environment. Moreover, had J.A.V. actually displayed unresponsiveness to external stimuli and decreased consciousness throughout a six to seven month period, I am confident that such symptoms would have prompted a visit to an emergency room or health care provider, given the medical training of both parents.

C. Findings regarding a Table Encephalopathy.

1. Requirements for a Table Encephalopathy.

To establish their Table encephalopathy claim, petitioners must demonstrate that J.A.V. manifested an injury encompassed in the definition of an acute encephalopathy and that a chronic encephalopathy was present for more than 6 months after the acute encephalopathy. 42 C.F.R. § 100.3(b)(2).⁴⁰

For a child younger than 18 months, presenting without an associated seizure event, an acute encephalopathy is indicated “by a significantly decreased level of consciousness . . . lasting for at least 24 hours.” § 100.3(b)(2)(i)(A). A significantly decreased level of consciousness is demonstrated by the presence of one of three clinical signs for a period of at least 24 hours: “(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). Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle are not, alone, or in combination, a demonstration of an acute encephalopathy. § 100.3(b)(2)(E). An acute encephalopathy is an event “that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).”⁴¹

2. J.A.V.’s Specific Circumstances.

In April 2007, J.A.V. received only one vaccine with encephalopathy listed as a Table injury. That was the measles component of his MMR vaccination. According to the Vaccine Injury Table, the symptoms of a Table encephalopathy must manifest between five and 15 days after the vaccination. Ms. Mora did not testify to any specific symptoms arising within this time frame, nor did petitioners’ affidavits address specific symptoms during this specific time period.

⁴⁰ See 42 C.F.R. § 100.3(b)(2). The Qualifications and Aids to Interpretation [“QAI”] section of the Vaccine Injury Table, 42 C.F.R. § 100.3(b), contains definitions for the terms used in the Table. See *Althen v. Sec’y, HHS*, 58 Fed. Cl. 270, 280 (2005), *aff’d*, 418 F.3d 1274 (Fed. Cir. 2005) (noting that the QAI should be used to interpret key terms found in the Table).

⁴¹ § 100.3(b)(2)(i). When revising the QAI definition it was noted that the hospitalization requirement was not intended “as an absolute requirement to establish an acute encephalopathy, but rather as an indicator of the severity of the acute event.” Revision of the Vaccine Injury Table, 60 Fed. Reg. 7685, 7687 (Fed. 20, 1997) (preamble to final rule).

Rather, the testimony and affidavits appeared to focus on the first 24 hours after the April 24, 2007 vaccinations. This may have stemmed from petitioners' belief that J.A.V. received a DTaP vaccination in April, as alleged in their amended petition. I find that J.A.V. did not receive a DTaP vaccination in April 2007.

3. Findings Regarding Table Encephalopathy.

a. Even accepting petitioners' testimony of the events on the evening of April 24, 2007, at face value, their descriptions of J.A.V.'s fever and lethargy are insufficient to constitute an acute encephalopathy as defined by the Vaccine Injury Table. Not only did these symptoms occur in the wrong time frame after an MMR vaccination, they were not of the nature and quality required by the Table, as fever and lethargy alone do not constitute an acute Table encephalopathy.

b. Assuming *arguendo* that an acute encephalopathy occurred in the required time frame, J.A.V.'s behavior and symptoms in the six months after the April 2007 vaccinations do not meet the requirements for a chronic encephalopathy. J.A.V. may not have responded to external stimuli and his environment in the same manner that he once did, although that is far from well-established by this record, but by petitioners' own reports, J.A.V. played with his siblings, ate meals with the family, enjoying picture books, made some eye contact, and showed affection to family members. These behaviors are inconsistent with the Vaccine Injury Table's definition of a chronic encephalopathy.

c. There is no evidence that the November 2007 vaccinations had any adverse impact on J.A.V.'s symptoms or behavior.

IV. Conclusion and Orders to the Parties.

Although I have rejected petitioners' contention that the encephalopathy referenced in J.A.V.'s medical records constitutes a Table encephalopathy, and have rejected some of their testimony, I emphasize that I do not think petitioners were untruthful. Ms. Mora testified forthrightly, based on her best recollections of events that had occurred many years earlier. Some of her recollections may well have been colored by the research she has conducted into J.A.V.'s condition in the ensuing years. Petitioners are competent and caring parents who have engaged in an exhaustive search for therapies to aid J.A.V. in developing to his fullest potential. They remain committed to finding the cause of J.A.V.'s condition.

Although I have rejected petitioners' attempt to establish that J.A.V. suffered a Table encephalopathy, their actual causation claim remains open. To prevail, they must produce evidence that one or more of the vaccines that J.A.V. received in April 2007 can cause an autism spectrum disorder, and that they did so in J.A.V.'s case. Because this case was filed as a part of the OAP, and thus far petitioners have primarily implicated the MMR vaccine, they must produce evidence not considered during the Theory 1 test cases. At a minimum, this will require the report of a medical expert.

The parties are directed to provide a copy of these factual findings to their respective experts, and the experts shall conform their expert opinions to these factual findings. Should an expert disagree with any factual finding herein, that expert shall clearly state in a supplemental report: (1) the finding involved; (2) the reasons for the expert's disagreement; and (3) the impact, if any, of my contrary finding on the expert's conclusions regarding causation.

Petitioners shall file their expert report by no later than Monday, July 14, 2014. Respondent shall file her responsive expert report by no later than 60 days after the filing of petitioners' expert report. Thereafter, if needed, a causation hearing will be scheduled.

IT IS SO ORDERED.

s/ Denise K. Vowell
Denise K. Vowell
Chief Special Master