In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 12-553V

(Filed: July 12, 2018)

NATHANIEL LADUE, *as the Parent and Natural Guardian of* B.L., *an infant,*	*	To Be Published
Petitioner,	*	Human Papillomavirus ("HPV") Vaccine; Seizures; Epilepsy; Denying Entitlement to Compensation.
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Mark Sadaka, Esq., Mark T. Sadaka, LLC, Englewood, NJ, for petitioner.
Darryl Wishard, Esq., U.S. Dept. of Justice, Washington, D.C., for respondent.

DECISION DENYING ENTITLEMENT[1]

Roth, Special Master:

On August 30, 2012, Nathaniel Ladue ("Mr. Ladue" or "petitioner") timely filed a petition for compensation on behalf of his minor child, B.L., under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*[2] ("Vaccine Act" or "Program"). Petitioner

[1] This Decision has been designated "to be published," which means I am directing it to be posted on the Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). **This means the Decision will available to anyone with access to the internet.** However, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen 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 whole Decision will be available to the public. *Id.*

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (1986). Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

alleges that B.L. developed a seizure disorder as the result of the human papillomavirus ("HPV") vaccination that he received on November 24, 2010. Petition at ¶ 2, 7.

At the time of the allegedly causal vaccine, B.L. was an eleven year old who had been diagnosed with severe autism at the age of 18 months. B.L. was nonverbal with intellectual disabilities and was functioning at a preschool level. The parties agree that the only issue to be resolved is whether the HPV vaccine that B.L. received on November 24, 2010 caused B.L.'s seizure disorder. Petitioner failed to meet his burden to show, by a preponderance of evidence, that it was more likely than not that B.L. developed seizures and/or epilepsy as a result of receiving the HPV vaccine. Based on evidence presented by respondent, it is more likely that B.L. developed seizures and/or epilepsy as a result of his severe autism and intellectual disabilities. For the reasons detailed below, I find that petitioner is not entitled to compensation.

I. Factual Background

A. B.L.'s Health Prior to Receiving the HPV Vaccine

B.L. was born on September 3, 1999. Pet. Ex. 1 at 2. The medical records provided for the time frame between his birth and 2010 are minimal.[3] The following was filed: an incomplete visit to Eskenazi Health on February 25, 2003, for active asthma along with a note to schedule an appointment to see a child psychiatrist in the autism clinic and a subsequent visit on March 13, 2003 for coughing and wheezing. Pet. Ex. 42 at 2-4. B.L. had a past medical history of asthma and was taking Pulmicort QD and Singulair QD for maintenance; he also used Xopenex aerosols as needed. *Id*. at 2.

B.L. was autistic with developmental disabilities and was non-verbal. B.L. did not have seizures. A CT scan of the brain with contrast performed on April 23, 2008 due to headaches was unremarkable. Pet. Ex. 4 at 325; Pet. Ex. 12 at 20. At a visit to Wishard Memorial Hospital on December 10, 2009, B.L. was well-appearing but had an upper respiratory infection, active asthma, and autism. Pet. Ex. 1 at 3. B.L. was prescribed Clonidine for sleep disturbance. *Id*. The record noted that B.L.'s father had recently gained custody, and that B.L. was last seen at Riley Hospital in 2008. *Id*.

Records were provided from Dr. Broderick Rhyant, a pediatrician, beginning in March, 2010. The records document that B.L received a Gardasil vaccine ("HPV") on March 30, 2010; pneumococcal conjugate vaccine on April 16, 2010; rotavirus vaccine on May 14, 2010, and measles-mumps-rubella ("MMR") vaccine on May 21, 2010. All vaccines were received without event. Pet. Ex. 12 at 2.

[3] It appears that Nathaniel Ladue was granted custody of B.L. sometime in the winter/spring of 2010 and at that time, routine medical care began. *See* Pet. Ex. 1 at 3; Pet. Ex. 34 at 1.

The first full medical examination filed for B.L. was a visit to Dr. Rhyant on July 26, 2010. Dr. Rhyant noted that B.L. was abnormal in appearance, autistic, non-communicative, and socially withdrawn. Pet. Ex. 12 at 6. He was receiving occupational and physical therapy.[4]

On September 22, 2010, B.L. was presented to Dr. Rhyant for his eleven year old well child physical. He received meningococcal conjugate, tetanus-diphtheria-acellular pertussis, and HPV vaccines on that date, without event. Pet. Ex. 1 at 1; Pet. Ex. 12 at 3.

B. B.L.'s Health After Receiving the HPV Vaccine

B.L. received the allegedly causal HPV vaccine on Wednesday, November 24, 2010 at approximately 2:30 p.m. according to a VAERS report filled out by petitioner in December of 2010.[5] Pet. Ex. 1 at 5; Pet. Ex. 12 at 10, 11.

On Monday, November 29, 2010, at approximately 8:30 a.m., B.L. suffered his first seizure while on the bus ride to school. Pet. Ex. 4 at 188. The paramedics were called; when they arrived, an aide explained that B.L. had autism and that, since getting off the bus, he had been lethargic and not responding appropriately. Pet. Ex. 2 at 61. He was observed to have rapid random eye movements, but no other signs of seizure. *Id*. He was placed on oxygen and transferred to the hospital. *Id*.

Upon his arrival at the emergency department at St. Francis Hospital ("St. Francis"), B.L. was noted to be incontinent and unresponsive to touch, with eyes "darting back and forth." Pet. Ex. 4 at 188. A CT scan was negative, as were lab results for bacteria and yeast infection. Pet. Ex. 2 at 63-67. A lumbar puncture was within normal limits, but his glucose was high. *Id*. at 70-73. An EEG was abnormal and showed evidence of "mild slow activity consistent with a mild encephalopathy." Pet. Ex. 4 at 206. There was also "excessive beta activity consistent with possible sedative/hypnotic drug side effects." *Id*. There were no epileptiform abnormalities. *Id*. B.L was given phenobarbital for seizures and transferred to Riley Hospital for Children ("Riley") for further assessment. Pet. Ex. 2 at 57; Pet. Ex. 4 at 176.

Upon admission to Riley, B.L. was noted to have become unresponsive and limp on the school bus. Pet. Ex. 4 at 176. He was taken to the emergency department at St. Francis where he was noted to have had a seizure lasting one hour. He was given phenobarbital, Ativan, and Versed. *Id*. Tests performed were unremarkable. *Id*. His history included developmental delay. At baseline, he was nonverbal, but would make eye contact, recognize familiar people, and make audible noises that his family understood. Pet. Ex. 4 at 177. B.L. had recently received an HPV vaccination. *Id*. at 188-89. B.L. had no prior known seizure history. *Id*. at 179. Petitioner advised B.L.'s doctors

[4] No records for these therapies were filed.

[5] There are no records of an office visit for this vaccination.

that there was no family history of epilepsy except for his father, who may have had seizures as an adult.[6] *Id*. at 189.

A note in the record by Dr. Deborah Sokol, B.L.'s treating neurologist, stated, "We did look up and found that there is a high seizure frequency with the use of this immunization. Usually, seizures occur within three days of receiving immunization, without it turning into epilepsy, but the length of time attributable to [Gardasil] is unknown." Pet. Ex. 4 at 190.

B.L. was discharged from Riley on November 30, 2010 at his baseline nonverbal state. Pet. Ex. 4 at 187. Despite extensive testing, no etiology for his seizure was identified. *Id*. The discharge summary described B.L. as an 11 year boy with history of autism and a new onset of seizure activity. "Patient's mother's history of patient just remaining non-responsive in the bus is not too concerning for seizure in a child with Autism, but report from osh (sic) of darting eye movements and urinary loss is more concerning. Patient does have a family history of seizures." *Id*. at 189. Dr. Sokol added:

> 11 year old boy with history of autism, received [Gardasil] day before Thanksgiving, said to have one hour seizure like event yesterday with staring, going limp, urinary incontinence. Pt. worked up at St. Francis with negative head [CT], negative LP. This AM, back to baseline with agitation, moving all [extremities], no speech. Father states no FH epilepsy except his FA who may have had seizures as an adult. This patient has not had seizures.

Id. at 189. B.L. was discharged without any medication.

On December 3, 2010, Dr. Rhyant documented a phone call from petitioner in which he reported that B.L had "dose number 2 of 3 of HPV/Gardasil vaccine" on November 24, 2010 with a seizure event on November 29, 2010. Pet. Ex. 13 at 2.

On February 25, 2011, B.L. had a second seizure. Pet. Ex. 2 at 33. The paramedics were called and B.L. was transported to the emergency department at St. Francis with urinary incontinence, loss of consciousness, and a seizure that lasted 10 minutes. *Id*. It was noted that B.L. had a seizure in November of 2010 after receiving the HPV vaccine. B.L. had been banging his head against the wall intermittently for the last 2 days. *Id*. at 30. A head CT without contrast showed "mild ethmoidal sinusitis"[7] but was otherwise negative. *Id*. at 40. A repeat EEG was ordered. Pet. Ex. 4 at 201.

[6] The family history in other parts of the record state that B.L.'s paternal grandmother and grandfather have a history of seizures. Pet. Ex. 4 at 188. Petitioner has since denied any seizure history in the family. Pet. Ex. 43.

[7] "Ethmoidal sinusitis" is the inflammation of the ethmoid sinus, a hollow space in the bone in the upper part of the nose between the eyes. *Ethmoid Sinus*, PUBMED HEALTH, https://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0024562/ (LAST VISITED July 9, 2018).

On March 2, 2011, B.L presented to Dr. Sokol for follow up of focal seizures[8] and autism. Pet. Ex. 4 at 152. Dr. Sokol documented a second seizure "last week," which involved eye deviation and generalized shaking. *Id*. Trileptal had been started. At the time of the appointment, B.L. had no further spells and no side effects from the Trileptal. *Id*. Dr. Sokol's assessment was secondary generalized seizures.[9] *Id*.

On March 7, 2011, an MRI without contrast was performed and compared to a head CT from April 23, 2008. Pet. Ex. 4 at 116. The MRI showed "[m]ild asymmetric thinning of the left hippocampal formation, of uncertain significance as there were no other findings to suggest mesial temporal sclerosis."[10]

On May 17, 2011, B.L. was again examined by Dr. Sokol. Pet. Ex. 4 at 89; Pet. Ex. 16 at 665. Dr. Sokol noted the recent MRI from April as showing asymmetry of the hippocampus. An EEG showed mild slowing without epileptiform discharges. *Id*. He was taking Trileptal, and had not had any further seizures. *Id*. B.L. was noted to be alert and rather calm. *Id*. Dr. Sokol's impression was autism and seizures with mild abnormality on the brain MRI. *Id*. B.L.'s dosage of Trileptal was increased.[11] *Id*.

On August 12, 2011, B.L. suffered another seizure. His parents reported finding him standing next to the stairs holding the rail; he was unresponsive and his eyes were moving back and forth. Pet. Ex. 6 at 6. Diastat was administered and B.L. then had a tonic-clonic seizure which lasted 20 minutes. *Id*. He was transported by ambulance to St. Francis. Pet. Ex. 4 at 93. B.L. had not had any recent illnesses or sick contacts. Pet. Ex. 6 at 6. He had been sleeping since the seizure stopped, but could be aroused with movement. *Id*. at 7. B.L.'s parents were informed that further testing was deemed unnecessary; he was instructed to follow up with the neurologist to readjust his medications. *Id*.

On October 14, 2011, B.L. had a seizure on the school bus; he was disoriented and drooling, with eye rolling, body shaking, and right arm twitching. Pet. Ex. 4 at 18. He was transported via ambulance to St. Francis. Pet. Ex. 6 at 31. B.L. continued to have tonic-clonic movements at St. Francis and was noted to have nystagmus with deviated gaze to the right. *Id*. at 31-32. He was

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[8] A focal seizure, also known as a "partial" seizure, is any seizure that occurs due to a lesion in a specific, known area of the brain. *See Dorland's Illustrated Medical Dictionary* 1688 (Saunders eds., 32nd ed. 2012), hereinafter "Dorland's."

[9] Dr. Kinsbourne explained that "secondary generalized seizures" are seizures where the seizure activity begins at a single source in the brain, and spreads to involve both sides of the brain. Tr. 73.

[10] Mesial temporal sclerosis is scarring in the inner portions of the temporal lobe. It may be caused by oxygen starvation to the brain, head trauma, or brain infection; however, it can also occur without an apparent cause. It can cause a form of temporal lobe epilepsy with partial (focus) seizures that can spread or secondarily generalize and affect other areas of the brain. *Mesial Temporal Sclerosis*, JOHNS HOPKINS MEDICINE, http://www.hopkinsmedicine.org/neurology_neurosurgery/centers_clinics/epilepsy/seizures/causes/mesial_temporal_sclerosis.html (LAST VISITED June 7, 2018).

[11] There was no explanation for the increase of Trileptal at that time.

noted to have had a similar episode six months ago. *Id*. at 30. Petitioner's mother reported that B.L. had missed his dose of Trileptal that morning. Pet. Ex. 4 at 18. B.L.'s family denied any recent illnesses, but his stepmother and siblings all had colds. *Id*. at 26. The opinion was that B.L. had outgrown his dose of Trileptal. *Id*. at 10, 21. B.L.'s treater noted that his first seizure occurred 11 months ago, about 10 days after receiving an HPV vaccination, which B.L.'s family believed to be the etiology of his epilepsy. *Id.* at 26. It was further noted that B.L.'s grandmother and grandfather had seizures, but there was no family history of neurodegenerative disease or genetic disorders. *Id*. at 27.

On November 4, 2011, B.L. presented to Dr. Sokol. Pet. Ex. 5 at 204; Pet. Ex. 16 at 677. He was well behaved upon examination and had a steady gait. *Id*. Dr. Sokol described B.L.'s seizure in October as a "prolonged breakthrough seizure" while taking Trileptal. *Id*. She noted that the seizure had lasted about two hours and involved decreased alertness and going limp. *Id*. Dr. Sokol further noted that, after the seizure, B.L. had been started on Dilantin and was taking that concurrently with an increased dose of Trileptal. *Id*. She prescribed Topamax, and noted that B.L. was to be weaned off of Dilantin, but continue with his current dose of Trileptal. *Id*.

On December 8, 2011, B.L. had a seizure at school lasting approximately 8 minutes, according to his teacher. Pet. Ex. 6 at 70. An ambulance was called; B.L. was administered Versed and noted to be incontinent. *Id*. He arrived at the emergency department at St. Francis in a post-ictal state and non-responsive; he was intubated. *Id*. at 71. The seizures continued in the ER, but there was no fever or focality noted. *Id*. at 73. Petitioner explained that B.L. had not received his last two doses of Trileptal because the pharmacy was out of the medication. *Id*. at 71. Petitioner further reported that B.L. was recently taken off Dilantin and placed on Topamax. *Id*.

On March 18, 2012, B.L. was presented to the emergency department at Riley with a seizure ongoing for 15 minutes. Pet. Ex. 6 at 124. Petitioner reported that they were in the family van when B.L. started making guttural sounds and then began seizing. Pet. Ex. 5 at 144. He was not breathing on his own and required intubation. Pet. Ex. 6 at 124, 127. He was given Versed in the ambulance and "loaded" with fosphenytoin. Pet. Ex. 5 at 144. He was still seizing upon arrival. *Id*. B.L. was admitted to the pediatric intensive care unit; once seizure free, he was taken off sedation and later extubated. *Id*. at 150. His medication regime was adjusted. *Id*. at 152. An EEG study was abnormal, with diffuse slowing in the background and lack of posterior rhythm indicative of nonspecific encephalopathy, likely static in nature. Pet. Ex. 16 at 436. A head CT confirmed otitis media and sinusitis. Pet. Ex. 6 at 128, 142. The final impression at that time was status epilepticus,[12] respiratory failure, and "CO2 retention." *Id*. at 128.

On April 17, 2012, B.L. was presented to Dr. Sokol for medically refractory seizures with multiple breakthrough seizures. Pet. Ex. 5 at 139. Upon exam, B.L. made eye contact and had a steady gait. *Id*. He was taking Trileptal and Topamax for his seizures, and clonidine for sleep,

[12] Status epilepticus is a continuous series of grand mal seizures without return to consciousness. It is a life-threatening emergency. *Dorland's* at 1688, 1767.

which his parents reported was not helping much. *Id*. A recent MRI showed "a smallish hippocampus but no MTS."[13] B.L. was diagnosed with "medically refractory focal seizures."

At his 12 year old check up on May 24, 2012, B.L. was noted to have a history of autism, was nonverbal with a seizure disorder. Pet. Ex. 3 at 1. His immunizations were up to date. *Id*.

B.L. had seizures requiring emergency services on July 4, 2012; August 11, 2012; and August 16, 2012. *See* Pet. Ex. 6 at 221, 230, 232; Pet. Ex. 5 at 23, 34, 40, 58, 89, 90, 107; Pet. Ex. 9 at 299.

On September 12, 2012, B.L. was presented to Dr. Walsh at the neurology clinic at Riley for a follow-up visit. Pet. Ex. 5 at 12. It was noted that B.L. had been treated at Riley on August 12 and August 17 for seizures, but had not had any additional seizure events. *Id*. B.L.'s stepmother reported that the increased dose of Trileptal was working well. *Id*. B.L.'s diagnosis was listed as "complex partial seizures."[14] He was deemed to be "fairly stable." *Id*.

On November 19, 2012, B.L.'s father called Dr. Walsh's office, to report that B.L.'s obsessive-compulsive disorder was getting worse; he was constantly opening and closing curtains, locking and unlocking doors, and getting very upset and agitated with change. Pet. Ex. 5 at 3, 15. B.L. had been violent with a teacher. *Id*. B.L. was noted as having a seizure every two to four months but had recurrent events about one month before. It was unclear as to whether he had three separate seizure events or one prolonged non-convulsive status seizure punctuated by three complex partial seizures. *Id*. at 3. B.L. was referred to psychiatry and prescribed Zoloft. *Id*. at 4.

B.L.'s next seizure was six months later in May of 2013 after missing his last two doses of Trileptal. Pet. Ex. 9 at 345. Upon arrival to the emergency department at St. Francis, B.L. was postictal and had audible coarse rhonchi[15] sounds. *Id*.

At a routine pediatric visit on June 6, 2013, B.L. was described as a 13 year old with autism and intractable complex partial seizures. Pet. Ex. 8 at 283. He had two breakthrough seizures in August, after which Trileptal was increased, and B.L.'s behaviors improved. *Id*. B.L. was attending school and reportedly enjoyed it. *Id*. Petitioner, who accompanied B.L. at this visit, raised concerns about B.L.'s obsessive-compulsive behaviors. *Id*. B.L. was prescribed Prozac. *Id*. at 283-84.

On September 7, 2014, B.L. had a seizure for the first time in a year. Pet. Ex. 34 at 38. Upon arrival, EMS found B.L. seizing, cyanotic, and unresponsive, with erratic and slow breathing. *Id*. at 65. He required intubation. *Id*. No further records were filed.

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[13] "MTS" stands for mesial temporal sclerosis. *Infra,* n. 9.

[14] A complex partial seizure is a partial seizure characterized by varying degrees of impairment of consciousness; the person affected performs non-purposeful, repetitive movements which he may not remember. *Dorland's* at 1688.

[15] Rhonchi are snore-like sounds produced in the throat or bronchial tube and are caused by partial obstruction or secretions. *Dorland's* at 1642.

II. Procedural History

The petition was filed on August 30, 2012. *See generally*, Petition, ECF No. 1. Petitioner filed medical records through April 1, 2013. Pet. Ex. 1-2.2, ECF No. 5; Pet. Ex. 3, ECF No. 9; Pet. Ex. 4.1-4.7, ECF No. 13; Pet. Ex. 5.1-5.7, ECF No. 16; Pet. Ex. 6.1-6.9, ECF No. 17.

On May 23, 2013, respondent filed his Rule 4(c) Report stating that this matter was not appropriate for compensation. Resp. Rpt., ECF No. 22.

On April 4, 2014, petitioner filed an expert report from Dr. Marcel Kinsbourne. Pet. Ex. 11, ECF No. 40. On June 5, 2014, petitioner filed Dr. Kinsbourne's C.V. Pet. Ex. 17, ECF No. 47.

On August 27, 2014, respondent filed an expert report and CV from Dr. Shlomo Shinnar. Resp. Ex. E-F, ECF Nos. 49-51. On December 30, 2014, respondent filed a supplemental expert report from Dr. Shinnar. Resp. Ex. BB, ECF No. 58.

A status conference was held on February 3, 2015, to discuss Dr. Shinnar's supplemental expert report. The chief special master noted that, while "Dr. Shinnar states in his report that there 'is a large body of reliable literature that establishes a high rate of seizures and epilepsy, especially in the second decade of life, in children with autism,'…Dr. Shinnar has not set forth a specific theory as to how the child's autism caused or contributed to the development of his seizure disorder." Scheduling Order at 1, ECF No. 60. Respondent was ordered to file either a supplemental expert report addressing the foregoing issue, or a status report indicating that he would not be pursuing an alternative causation theory. *Id*. at 2.

The chief special master also discussed petitioner's expert report, noting that "Dr. Kinsbourne states that the HPV vaccine is capable of causing the production of proinflammatory cytokines leading to neuroinflammation. He further states that neuroinflammation is a well-established mechanism for generation of epilepsy." *Id*. Petitioner was advised that, should he file a responsive expert report that, "Dr. Kinsbourne should explain…what fact or facts in this case support his theory that there is a production of proinflammatory cytokines" and "address whether he thinks the child would have developed the seizure disorder if he had not received the HPV vaccine." *Id*.

On March 13, 2015, respondent filed a second supplemental expert report from Dr. Shinnar. Resp. Ex. DD, ECF No. 61. Respondent also filed an Amended Rule 4(c) Report in which he further addressed his alternative causation theory. Am. Resp. Rpt., ECF No. 63. Petitioner was then ordered to file a responsive expert report by April 27, 2015. Petitioner filed a responsive expert report from Dr. Kinsbourne on June 29, 2015. Pet. Ex. 32, ECF No. 68.

This case was reassigned to me on October 21, 2015. ECF No. 71. A prehearing order was issued on December 9, 2015, setting a two-day hearing in New York, NY, for November 7 and 8, 2016. Prehearing Order, ECF No. 76.

Due to scheduling conflicts of the parties, this case ultimately went to hearing on February 27 and 28, 2017 in Washington, D.C. *See* Prehearing Order, ECF No. 83. Ms. Samantha

Domangue, B.L.'s stepmother, testified as petitioner's fact witness. Dr. Kinsbourne testified as petitioner's expert witness. Dr. Shinnar testified as respondent's expert witness.

Based on testimony given at the hearing, a post-hearing order was issued directing petitioner to file an updated CV for Dr. Kinsbourne, an affidavit clarifying references to a family history of seizures, all medical records for B.L. dating from 1999 to 2008, and all testing and IEPs that have been prepared for B.L. since his diagnosis of autism at 18 months of age. Scheduling Order at 1-2, ECF No. 104. On May 8, 2017, petitioner filed additional medical records and an updated CV for Dr. Kinsbourne. Pet. Ex. 39-40, ECF No. 109. On May 30, 2017, petitioner filed B.L.'s school records and IEPs as well as additional medical records. Pet. Ex. 41, ECF No. 118; Pet. Ex. 42, ECF No. 120.

On June 15, 2017, petitioner filed an affidavit, in which he stated that there was no family history of seizures. Petitioner further stated, "At the hearing on February 28, 2017, I stated I was unsure as to B.L.'s seizure history within his maternal family….I have since confirmed that there is no seizure history known in any of his maternal blood relatives."[16] Pet. Ex. 43 at 1, ECF No. 124.

On June 29, 2017, petitioner filed a status report stating that the record was complete. Pet. S.R., ECF No. 127. Respondent filed his post-hearing brief on September 29, 2017. ECF No. 128. Petitioner filed his post-hearing brief on October 16, 2017. ECF No. 132.

This matter is now ripe for determination.

III. Affidavits and Testimony

A. Affidavit and Testimony of Samantha Domangue

Samantha Domangue ("Ms. Domangue") testified by videoconferencing. She is B.L.'s stepmother and has been his acting mother since 2008. Tr. 204. B.L. lives with Ms. Domangue and the petitioner, who is B.L.'s father. Ms. Domangue and petitioner have two children together. Tr. 205; Pet. Ex. 35 at 1. Petitioner and Ms. Domangue purchased their two story home in August of 2010, where B.L. has his own room. Tr. 205-06.

Ms. Domangue stated that she is B.L.'s primary caregiver in the mornings. Pet. Ex. 35 at 1. B.L.'s daily routine includes waking around 5:00 or 6:00 a.m., getting himself ready for school, and eating breakfast. Tr. 206-07. Although B.L. can dress himself, he usually puts his clothes on inside out or backward. Tr. 207. He also needs assistance and prompting to shower. *Id*. He can take a Pop-Tart or donut holes himself, but cannot prepare anything. *Id*. On non-school days, he gets up about the same time, but stays in his room. Tr. 233.

According to Ms. Domangue, B.L. takes a bus to school, which picks him up at the doorstep around 6:45 or 7:00 a.m. Tr. 208. In 2010, B.L. was 11 years old; he would say "no," "yes," and "more," and had limited sign language abilities. Tr. 208-09. Ms. Domangue explained that B.L.'s

[16] Petitioner did not testify at hearing.

signs were versions of what he perceived them to be, not regular signs. Tr. 209. She added that the family understood him, but an outsider would not understand words the way he said them. Tr. 209. B.L. does not verbalize pain, even intense pain, or other physical discomfort. Pet. Ex. 35 at 2.

Ms. Domangue testified that B.L. always had sleeping problems and without medication he would be up for days. The medication is just to get him to go to sleep, then he only sleeps about four hours a night. Tr. 237-38; Pet. Ex. 35 at 1. He is given the medication around 8:00 pm on a school night and around 9:00 pm on a non-school night. Tr. 238.

Ms. Domangue did not recall B.L. getting any vaccines in September of 2010, but she did remember his father taking him to the doctor in November of 2010. Tr. 211-12. She stated that B.L. received the HPV vaccine in November of 2010 and three days later, he had a seizure for the first time. Tr. 212.

With further questions from her counsel, Ms. Domangue elaborated that B.L. received his vaccine on November 24, 2010 and was groggy, sluggish, and fatigued the next morning. Tr. 216-17; Pet. Ex. 35 at 1. She testified that B.L. was usually a "very up person," but that morning, she had to pull him out of bed, "…he just didn't seem like he was awake at all." He got dressed very slowly and did not want to eat breakfast. He slept at school that day and they had to go pick him up. *Id.*

On cross examination, when it was pointed out that the day after B.L.'s vaccination was Thanksgiving Day, Ms. Domangue agreed that it would not have been a school day and they would have gone to petitioner's father's house for Thanksgiving. Tr. 232-33; 212. Ms. Domangue had no memory of giving B.L. any medication the night of his vaccination. Tr. 234.

According to Ms. Domangue, B.L. seemed "fairly happy" over the holiday, like his normal self; there was nothing unusual about his appearance at that time. She stated that there was nothing unusual the Monday after the Thanksgiving holiday. B.L. woke up. She helped him shower and dress, and made sure he had breakfast. Then he "ran off to his bus, just like normal." Tr. 213-14.

Ms. Domangue recalled later that morning, she and petitioner received a phone call from B.L's teacher saying that he had had a seizure on the bus. Tr. 214-15. Petitioner went to the school; Ms. Domangue went to the hospital later, after she got a sitter for the other two children. Tr. 215. According to Ms. Domangue, B.L. was pale, on a respirator, and unconscious. When he regained consciousness, he tried to pull out all the tubes and IV; she tried to comfort him by stroking his back, rubbing his head, and telling him he would be ok. Tr. 215-16. Ms. Domangue added that B.L. has been on a respirator several times. Tr. 220. After coming home from the hospital, B.L. was sluggish and tired. Tr. 218. He only wanted to lay down in his bed and rest; he did not want to eat, just to sleep. *Id*. His behavior returned to normal after a few days. Tr. 219.

Ms. Domangue does not recall being told anything about B.L.'s prognosis after the first seizure, only to follow up with his regular physician. No one told them that B.L.'s seizures could be associated with his autism. Tr. 218-19. None of the doctors told them that the HPV vaccine may have caused B.L.'s seizure disorder. Tr. 230-31. They were told that his EEG's were "normal for him." Tr. 231. No one ever mentioned encephalopathy to them. Tr. 231.

According to Ms. Domangue, when B.L. has a seizure, he looks to one side, drools, fails to make eye contact, has head and eye movements, and occasionally has movements with his arms or legs. Tr. 224-25. After every seizure, B.L. seems sluggish, run down, and tired. Tr. 227. Currently, he takes Trileptal and Topiramate. Tr. 235. B.L.'s seizures are less frequent now; at the time of hearing, he had not had a seizure in four months. Tr. 235. Ms. Domangue noted that they now have Viracept, and as long he is not aspirating, they can control the seizures at home. Tr. 240.

Ms. Domangue explained that, before B.L. started having seizures, he enjoyed alone time in his room, and his behavior was manageable, unless his routine was disturbed. Pet. Ex. 35 at 1. B.L. spent the majority of his time in his room with the door closed, but they were able to get him to go on family outings without resistance, and he would go in the backyard and play with his brothers. Tr. 223-24. He would also watch a movie with the family and eat popcorn. *Id.*

After his seizures began, B.L.'s personality changed; he now requires much more supervision and attention. Pet. Ex. 35 at 1. He "became more of a loner" and kept his door shut. Tr. 226. He will only come to movie night long enough to eat his popcorn before going back to his room; if they try to make him play outside, he constantly tries to go into the house. Tr. 226. His obsessive-compulsive behavior has become more intense; he becomes frustrated more easily and acts out in frustration. Pet. Ex. 35 at 2. Now that B.L. has had several major seizures, Ms. Domangue feels the need to monitor him more closely. "I realized that before I started watching him so closely, B.L. likely suffered seizures that no one even noticed, because he is non-communicative and was often left alone for stretches of time."[17] *Id*. at 2; Tr. 239. During a hospital stay in January of 2016, B.L. aspirated, turned blue, and had to be intubated. They removed his bedroom door after that in order to hear him if he had a seizure at night. Tr. 221, 225-26.

According to Ms. Domangue, B.L. was originally in a special classroom in a regular school. Tr. 228-29. He loved school and was known as a "prankster." Tr. 209. In 2010, he was learning how to count coins and their values. Tr. 210. Ms. Domangue helped B.L. with his homework, which usually included typing a vocabulary list several times on his "Alphasmart," a keyboard with a screen. *Id*. He was able to spell the words on the list – house, home, tomorrow. Tr. 210-11. Prior to his seizures, he was progressing in school fairly well. Ms. Domangue believed that there was a possibility that he could live a mildly supervised lifestyle, but as a result of the seizures, he now needs constant supervision. Tr. 230. B.L. had an individual education plan ("IEP") prior to developing seizures, and still has one. Tr. 237.

According to Ms. Domangue, B.L. now attends a special needs school due to his obsessive compulsive behaviors ("OCD"). Tr. 228-29. At the beginning of the year, most of his schooling dealt with controlling his obsessive-compulsive disorder. Tr. 227. He has to be the first to turn on the lights at school in the morning and has gotten physical trying to complete his OCD behaviors at school. Tr. 228-29. He has since calmed down and his teachers are now working on his education. Tr. 229-30. B.L. is learning simple math, sorting, and adding and subtracting up to triple digits with a calculator. Tr. 226-27, 236. He likes playing with the white board or the smart board at school; he also likes swimming. Tr. 226.

[17] After prompting from counsel, Ms. Domangue stated that she meant after having the vaccination. Tr. 239.

B. The Affidavits of Nathaniel Ladue

The petitioner was present via videoconference on the second day of the hearing. After Ms. Domangue's testimony, petitioner's counsel advised that petitioner would not be testifying but would rely on his affidavits. I gave petitioner the opportunity to make a statement. He chose not to, responding that "they got about everything that they need…to do whatever they need to do and you guys can pretty much take it from there." Tr. 241-42.

Petitioner submitted an affidavit on January 16, 2017. Petitioner described B.L as a "non-verbal, extremely autistic child" with "the mental acuity of a very young child. He is unable to bathe, wash, shave, clean after using the toilet, or otherwise care for himself independently in any way." Pet. Ex. 34 at 1. Petitioner explained that B.L. suffers from compulsive behaviors, and relies heavily on daily routines and rituals that his family has developed. These routines help B.L. to cope with his autism and allow for B.L. to have time alone unsupervised. *Id*. at 2. For example, dinner is at 6:00 p.m.; if B.L. is called down to dinner before then, he will wait until 6:00 p.m. to come down. If no one calls him, he will come downstairs at 6:00 p.m. looking for dinner. The only time he won't respond to being called is if he is asleep or the TV is too loud. *Id*. According to petitioner, when B.L. returns home from school, he goes straight to his room to change his clothes and play on his tablet or watch T.V.; he can be left alone for about two hours. *Id*. at 2. B.L. usually keeps his bedroom door open, but will close it if he needs to reduce his stimulation levels. *Id*. B.L. occasionally makes small noises, which can be heard from outside the room. *Id*. Either Ms. Domangue or B.L.'s brothers will occasionally "pop into his room" to check on him. *Id*.

Petitioner recalled taking B.L. to the doctor for a check-up on November 24, 2010; he stated that the nurse told him that B.L. should get the HPV vaccine, and he consented. *Id.* at 2. Petitioner observed that the morning after the vaccination, B.L. was fatigued and sluggish when he normally wakes up early and "ready to start his day." *Id*. at 3. Petitioner stated that he and Ms. Domangue attributed this behavior to the medicine that they had given him the night before. *Id*. Petitioner observed that B.L. successfully completed his daily routines and seemed "more refreshed over the Thanksgiving weekend." *Id*. He noted that there were many points over the weekend that B.L. was alone and unattended. *Id*.

Five days after the vaccination, B.L. had a seizure while on the bus to school. *Id*. at 3. Before the vaccination, he never had a seizure. *Id*. Petitioner explained that B.L. cannot communicate an oncoming seizure, and since he does not respond outwardly to pain, it is impossible to know if he has pain or discomfort. *Id*. at 1, 3. Petitioner stated that his family is now on constant alert in case of a seizure; B.L. cannot be left alone anymore, and they had to remove his bedroom door. *Id*. at 3.

Petitioner stated, "Because of his inability to communicate, and because of the periods of alone-time that were previously built-in to B.L.'s schedule, it is entirely possible that he underwent a seizure a home without anyone noticing." *Id*. at 3. B.L.'s early seizures were less noticeable, and it is possible that B.L. had subtle seizures while at school that were not witnessed because he was often left alone while the teachers and aides attended to the other special needs children under their care. *Id*. at 3-4. Petitioner added, "Because of what I have described above, there is no doubt in

my mind that B.L. might have experienced a seizure without any witnesses in the period between his shot on November 24, 2010 and the first-witnessed seizure on November 29, 2010." *Id*. at 4.

Petitioner submitted another affidavit after the hearing that stated that there is no seizure history known in any of B.L.'s paternal or maternal blood relatives. Pet. Ex. 43 at 1. This was in response to my request for clarification of the medical records, which at various times and in various places state that petitioner reported that a grandfather, grandmother, or both had a history of seizures.

IV. B.L.'s Educational Records

B.L.'s educational records were not filed in this matter until petitioner was ordered to do so following the entitlement hearing. Therefore, the experts did not have the benefit of these records. At no time after the submission of these records did either party request the opportunity to have their experts review and comment on the records. The records discuss B.L.'s preexisting autism and intellectual disability and the individual education plans ("IEPs") which were developed for him.

At a case conference held in October of 2008, B.L.'s teachers documented that, although B.L. was nine years old, he functioned at a preschool level in math and language arts, and was at 51% for functional skills. Pet. Ex. 41 at 35. His areas of strength were in number sense, reading recognition, and physical skills (76%). *Id*. His areas of weakness were in computation, writing application, and social-emotional skills (22%). *Id*.

At a case conference held in March of 2010, following a change of schools from Mary Bryan Elementary School to Arlington Elementary School, it was noted that the petitioner had received custody of B.L., and that the family would be moving over the weekend. Pet. Ex. 41 at 80-87. B.L.'s disabilities were noted to have a significant impact on both his academic achievement and functional performances. He needed functional academics and life skills. *Id*. at 82. B.L. was able to say "hi" and a few simple words, and his self-care skills had improved greatly. *Id*. at 86. He liked school and would stay with a routine, but had trouble with transitions. *Id*. He would not run from a group. He would not look before crossing the road. *Id*. He liked electronics; he found comfort in TV, and liked to watch the news and the weather channel. *Id*.

In November of 2010, prior to B.L.'s HPV vaccination, a Case Conference Committee Report was generated revising B.L.'s IEP due to his transfer back to Mary Bryan Elementary School. Pet. Ex. 41 at 72-79. B.L. was noted to have autism as well as a communication disorder, which prevented him from experiencing success in the general education classroom. *Id*. at 73. He required a modified curriculum and more adaptations to make progress than what was available in the general education classroom or pull-out setting. *Id*. B.L. needed functional academic, communication, and life skills. *Id*. at 74. B.L.'s disability required special transportation. *Id*. at 77. He was to be placed in 5th grade in the intermediate CIP (Comprehensive Intervention Program) *Id*. at 77, 78. He was using the Touch Math Program to learn addition and subtraction and using the Handwriting Without Tears Program to assist in writing his first and last name. *Id*. at 79.

Six months later, on May 22, 2011, B.L.'s progress notes from school showed that he had shown an "incredible explosion of communication." Pet. Ex. 41 at 18. He was saying many words and would visually pay attention to the speaker's mouth when they were teaching him to produce sounds. *Id*. He would also grab the speaker's mouth when he wanted them to teach him. *Id*. B.L. showed significant improvement in understanding that written words could be used for communicating his desires, as well as through the use of his Alphasmart typewriter. *Id*. He was described as "well on his way to becoming an active communicator in his environments." *Id*. There was no IQ test submitted. There is no indication that an IQ test was ever performed.

V. The Experts

A. Petitioner's Expert: Marcel Kinsbourne

Petitioner's expert is Dr. Marcel Kinsbourne. Dr. Kinsbourne graduated from Oxford University in England with a B.M.B.Ch., the equivalent of an American M.D., and a D.M., the equivalent of a Ph.D., in neuropsychology.[18] Tr. 6-7; Pet. Ex. 17 at 1. Neuropsychology is the study of abnormal behaviors caused by brain disease; neuropsychologists look at the neurological underpinnings of cognitive and emotional disturbances, including autism. Tr. 7. Dr. Kinsbourne began practicing as a pediatric neurologist and neuropsychologist when he came to the United States in 1964. Tr. 12. His last hospital-based neurology practice was in 1992; he has since retired from the active practice of neurology. Tr. 15-16. However, he continues to teach at the Boston University Medical School in the field of behavior and neuropsychology. Tr. 13. Dr. Kinsbourne is known as a pioneer in the field of neuropsychology and recently won a lifetime achievement award from the International Neuropsychology Society. Tr. 9. He is the co-editor of a textbook on epilepsy and has published "about a dozen" articles on autism. Tr. 9, 16.

B. Respondent's Expert: Shlomo Shinnar

Respondent's expert is Dr. Shlomo Shinnar. Dr. Shinnar received an M.D. as well as a Ph.D. in neurophysiology from Albert Einstein College of Medicine ("Einstein"), where he is a professor of neurology, pediatrics, and epidemiology and population health. Resp. Ex. F at 1-2; Tr. 83. He has been the Hyman Climenko Professor of Neuroscience Research at Einstein since 2002. *Id*. at 2. Dr. Shinnar has served as an attending physician in neurology and pediatrics at Montefiore Medical Center since 1993, and as the director of the Comprehensive Epilepsy Management Center, a collaboration between Einstein and Montefiore Medical Center, since 1986. *Id*. He is board certified in pediatrics, psychiatry, and neurology, with special qualifications in child neurology and epilepsy. *Id*.; Tr. 84. He holds multiple NIH grants for the study of seizures; about two-thirds of his patients have epilepsy, and many have comorbidities which include intellectual disability, autism, and learning disabilities. Tr. 85.

[18] According to Dr. Kinsbourne, there are two kinds of neuropsychologists, clinical and experimental. Clinical psychologists primarily treat patients. He is an experimental neuropsychologist; he understands the test results but does not perform the testing. Tr. 19.

VI. Legal Framework

The Vaccine Act provides two avenues for petitioners to receive compensation. First, a petitioner may demonstrate a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the provided time period. § 11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); *see* § 13(a)(1)(B). Second, where the alleged injury is not listed on the Vaccine Injury Table, a petitioner may demonstrate an "off-Table" injury, which requires that the petitioner "prove by a preponderance of the evidence that the vaccine at issue caused the injury." *Capizzano*, 440 F.3d at 1320; *see* § 11(c)(1)(C)(ii).

To prove causation for an "off-Table" injury, petitioner must satisfy the three-pronged test established in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). *Althen* requires that petitioner show by preponderant evidence that the vaccination caused his injury "by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* at 1278. A petitioner need not show that the vaccination was the sole cause, or even the predominant cause, of the alleged injury; showing that the vaccination was a "substantial factor" and a "but for" cause of the injury is sufficient for recovery. *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006); *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999).[19] Causation is determined on a case-by-case basis, with "no hard and fast *per se* scientific or medical rules." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Petitioner is not required to identify "specific biological mechanisms" to establish causation, nor are they required to present "epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities." *Capizzano*, 440 F.3d at 1325 (quoting *Althen*, 418 F.3d at 1280). "[C]lose calls regarding causation are resolved in favor of injured claimants." *Althen*, 418 F.3d at 1280. Once a petitioner has proven causation by preponderant evidence, "the burden then shifts to the respondent to show by a preponderance of the evidence that the injury is due to factors unrelated to the administration of the vaccine." *Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs.*, 717 F.3d 1363, 1367 (Fed. Cir. 2013) (citing § 13(a)(1)(B)).

The process for making factual determinations in Vaccine Program cases begins with analyzing the medical records, which are required to be filed with the petition. § 11(c)(2). Medical records created contemporaneously with the events they describe are presumed to be accurate and "complete" such that they present all relevant information on a patient's health problems. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). In making contemporaneous reports, "accuracy has an extra premium" given that the "proper treatment hang[s] in the balance." *Id.* Contemporaneous medical records that are clear, consistent, and complete warrant substantial weight "as trustworthy evidence." *Id*. Indeed, "where later testimony conflicts with earlier contemporaneous documents, courts generally give the contemporaneous documentation more weight." *Campbell ex rel. Campbell v. Sec'y of Health & Human Servs.*, 69

[19] The Vaccine Act also requires petitioners to show by preponderant evidence that the "residual effects or complications" of the alleged vaccine-related injury lasted for more than six months. § 11(c)(1)(D)(i). It is undisputed that this six-month requirement is satisfied in this case.

Fed. Cl. 775, 779 (2006); *see United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1948). But petitioners can support their claim with oral testimony if it is credible and consistent with the medical records. *See, e.g.*, *Stevenson ex rel. Stevenson v. Sec'y of Health & Human Servs.*, No. 90-2127V, 1994 WL 808592, at *7 (Fed. Cl. Spec. Mstr. June 27, 1994) (crediting the testimony of a fact witness whose "memory was sound" and "recollections were consistent with the other factual evidence"). In short, "the record as a whole" must be considered. § 13(a).

Furthermore, establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of his or her claim. *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). The Supreme Court's opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), requires that courts determine the reliability of an expert opinion before it may be considered as evidence. "In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Id*. at 590 (citation omitted). Thus, for Vaccine Act claims, a "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010). The *Daubert* factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). And nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder ex rel. Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 743 (2009) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)).

Finally, although this decision discusses many but not all of the literature in detail, the undersigned reviewed and considered all of the medical records and literature submitted in this matter. *See Moriarty ex rel. Moriarty v. Sec'y of Health & Human Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though [s]he does not explicitly reference such evidence in h[er] decision."); *Simanski v. Sec'y of Health & Human Servs.*, 115 Fed. Cl. 407, 436 (2014) ("[A] Special Master is 'not required to discuss every piece of evidence or testimony in her decision.'" (citation omitted)), *aff'd*, 601 F. App'x 982 (Fed. Cir. 2015).

VII. Discussion

Because petitioner does not allege an injury listed on the Vaccine Injury Table, his claim is classified as "off-Table." As noted above, for petitioner to prevail on an "off-Table" claim, he must show by preponderant evidence that B.L.'s injury resulted from the vaccination at issue. *Capizzano*, 440 F.3d at 1320. Doing so shifts the burden to respondent to show that the injury was caused by factors unrelated to the vaccination. *Deribeaux*, 717 F.3d at 1367.

1. *Althen* Prong I: Reputable Medical Theory

The first *Althen* prong requires petitioner to provide a "reputable medical theory" demonstrating that the vaccines received *can* cause the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citation omitted). To satisfy this prong, petitioner's "theory of causation must be supported by a 'reputable medical or scientific explanation.'" *Andreu ex rel. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009) (quoting *Althen*, 418 F.3d at 1278). This theory need only be "legally probable, not medically or scientifically certain." *Id.* at 1380 (emphasis omitted) (quoting *Knudsen*, 35 F.3d at 548). Nevertheless, "petitioners [must] proffer trustworthy testimony from experts who can find support for their theories in medical literature." *LaLonde v. Sec'y of Health & Human Servs.*, 746 F.3d 1334, 1341 (Fed. Cir. 2014). In this case, petitioner has not offered a reputable medical theory of causation that the HPV vaccine caused B.L.'s seizure.

i. Autism, seizures and epilepsy

Autism is a severe and devastating condition that is part of the broad spectrum of pervasive developmental disorders. Pet. Ex. 21[20] at 1. Autism is characterized by marked impairment in social skills, verbal communication, and behavioral and cognitive function. *Id*. Abnormalities in language development, intellectual disability, and epilepsy are frequent problems in the clinical profile of patients with autism. *Id*.

Dr. Kinsbourne submits that, although the neurobiological basis for autism is poorly understood, research supports the view that genetic, environmental, neurological, and immunological factors contribute to the development of autism. Pet. Ex. 29[21] at 1. Several studies of peripheral blood of those with autism show various abnormalities such as T-cell dysfunction, autoantibody production, and increased proinflammatory cytokines. *Id*. at 1-2. This suggests an immune dysfunction as a mechanism in the pathogenesis of autism.

Dr. Shinnar submits that a child who regresses and loses his language at around 18 months of age tends to be more severely autistic. Tr. 91-92. "Intellectual disability" is the current term for what used to be called mental retardation. Intellectual disability is different than autism; a person can be autistic and highly intelligent. Tr. 92. About 70% of children with autism also have intellectual disability. Tr. 92-93.

A seizure is defined as a transient occurrence of signs and/or symptoms due to abnormal, excessive or synchronous neuronal activity in the brain. Pet. Ex. 23[22] at 1. About 8% of the

[20] Carlos A. Pardo et al., *Immunity, neuroglia and neuroinflammation in autism*, 17 INT REV PSYCHIATRY 6: 485-95 (2005), filed as "Pet. Ex. 21."

[21] Diana L. Vargas et al., *Neuroglial Activation and Neuroinflammation in the Brain of Patients with Autism*, 57 ANN. NEUROL 1: 67-81 (2005), filed as "Pet. Ex. 29."

[22] Kiarash Riazi et al., *Contributions of peripheral inflammation to seizure susceptibility: Cytokines and brain excitability*, 89 EPILEPSY RES 34-42 (2010), filed as "Pet. Ex. 23."

population have at least one seizure in their lifetime. *Id*. Multiple seizures occurring in a 24 hour period is considered a single event. Resp. Ex. H[23] at 2.

Seizures lasting more than 30 minutes occur in approximately 11 to 12% of children and adults who present with their first unprovoked[24] seizure. Resp. Ex. E at 4; *see also* Resp. Ex. L at 6;[25] Resp. Ex. M at 4.[26] People with chronic neurological problems – i.e., history of stroke, cerebral palsy, autism, intellectual disability – are not only more likely to have seizures, but more likely to have prolonged seizures. Once a person has had a prolonged seizure, the chance of additional seizures is high. Tr. 99-101, 120; Resp. Ex. N.[27]

Epilepsy is considered one of the most common neurological disorders worldwide. Pet. Ex. 23 at 1. Epilepsy occurs when a person has a chronically low seizure threshold which results in spontaneous, recurrent seizures. *Id*. According to Dr. Shinnar, epilepsy is characterized by two or more unprovoked seizures separated by more than 24 hours. Resp. Ex. E at 4; *see also* Resp. Ex. H at 2. Changes in an individual's propensity for a seizure likely precede the onset of an epileptic syndrome. Pet. Ex. 23 at 1. The peak incidence for developing epilepsy is in the first two decades of life and again in the elderly. Resp. Ex. E at 4. Approximately one third of individuals with epilepsy do not respond to medication. Pet. Ex. 30[28] at 1.

An association between autism and epilepsy has long been recognized. About 22 to 30% of children with autism spectrum disorders develop seizures with no specific underlying pathology, and no obvious or classic EEG changes. Pet. Ex. 27[29] at 1. The rate of seizures in people with autism spectrum disorder is about ten times higher than the general population. *Id*. Epilepsy is commonly reported to occur in 12% of children with autism spectrum disorders, reaching 26% by

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[23] International League Against Epilepsy, *Guidelines for Epidemiologic Studies on Epilepsy*, 34 EPILEPSIA 4: 592-96 (1993), filed as "Resp. Ex. H."

[24] A provoked seizure is one that is the result of a trauma, low blood sugar, low blood sodium, high fever, or alcohol or drug abuse. Tr. 99-100. An unprovoked seizure is one that is not closely associated with a concurrent illness, fever, or acute brain injury. *See Pediatric Neurology: Principles & Practice* 981 (Swaiman, Ashwal, & Ferriero eds., 4th ed. 2006).

[25] Shlomo Shinnar et al., *The Risk of Seizure Recurrence after a First Unprovoked Afebrile Seizure in Childhood: An Extended Follow-up*, 98 PEDIATRICS 2: 216-25 (1996), filed as "Resp. Ex. L."

[26] W. Allen Hauser et al., *Seizure Recurrence after a First Unprovoked Seizure*, 307 N ENGL J MED 9: 522-28 (1992), filed as "Resp. Ex. M."

[27] Shlomo Shinnar et al., *Recurrent Status Epilepticus in Children*, 31 ANN NEUROL 6: 598-604 (1992), filed as "Resp. Ex. N."

[28] Annamaria Vezzani et al., *The role of inflammation in epilepsy*, 7 NAT REV NEUROL 31-40 (2011), filed as "Pet. Ex. 30."

[29] Theoharis C. Theoharides and Bodi Zhang, *Neuro-inflammation, blood-brain barrier, seizures and autism*, 8 J NEUROINFLAMMATION 168: 1-5 (2011), filed as "Pet. Ex. 27."

adolescence. Resp. Ex. K[30] at 9. Seizures usually begin after 10 years of age. Resp. Ex. D[31] at 2, 4. Autistic children with speech and language difficulties have the highest risk of epilepsy, most likely due to an underlying brain dysfunction. Resp. Ex. I[32] at 6.

ii. The opinions of the experts on Prong I

The experts agree that there is a markedly higher incidence of epilepsy in autism than in the general population. Petitioner submitted Bolton, *Epilepsy in autism: Features and correlates,* which showed a 22% incidence of epilepsy in a series of 150 people with autism, in contrast to the general population figure of 0.6%. Pet. Ex. 11 at 374; *see also* Pet. Ex. 18, Resp. Ex. D. The mean age of onset for epilepsy is 13.3 years, with the majority beginning around age 10. Pet. Ex. 18 at 4; Resp. Ex. D at 4.

a. Petitioner's expert, Dr. Kinsbourne

To explain B.L.'s development of seizures, Dr. Kinsbourne posits that there is an increase in the excitation-inhibition ratio in the autistic brain, caused by neurons firing which leads to neuroinflammation and a lowered seizure threshold. Tr. 30, 34-35, 38-39; Pet. Ex. 11 at 374-75. Neuroinflammation occurs when the brain's immune system is activated. Tr. 34. Studies of EEGs of autistic children who do not have epilepsy still showed epileptogenic activity at the subclinical level, indicating that children with autism have the potential for seizures, like a "ticking clock." Tr. 37. The "tipping point" could be an event that causes a secretion of proinflammatory cytokines. Tr. 36-37. In Dr. Kinsbourne's opinion, the HPV vaccine can act as that event.

According to Dr. Kinsbourne, under baseline conditions, microglial cells in the brain release cytokines, but when exposed to stressors such as acute injury, neurodegeneration, or psychological stressors, the amount of cytokines released increases. Pet. Ex. 11 at 375; Tr. 46. In the autistic brain, the microglia are primed and "morphologically similar to activated microglia, but do not appear to produce appreciable levels of inflammatory cytokines in this state. They are, however, hyper responsive to secondary stimuli and can produce an exaggerated cytokine response when further provoked." *Id*. According to Dr. Kinsbourne, studies have found microglial activation in autistic brains, which "supports the view that innate immune responses are present in the cortical and subcortical regions and that a state of chronic activation and reactivity may be involved" in autism. Pet. Ex. 29 at 11-12.

Dr. Kinsbourne explained that, in general, a vaccine activates the innate immune system, which then activates the adaptive immune system to generate long lasting immunity. Tr. 44. The

[30] Emma W. Viscidi et al., *Clinical Characteristics of Children with Autism Spectrum Disorder and Co-Occurring Epilepsy*, 8 PLOS ONE 7: 1-11 (2013), filed as "Resp. Ex. K."

[31] Patrick F. Bolton et al., *Epilepsy in autism: features and correlates*, 198 BR J PSYCH 289-94 (2011), filed as "Resp. Ex. D," and "Pet. Ex. 18."

[32] Roberto F. Tuchman et al., *Autistic and Dysphasic. II: Epilepsy*, 88 PEDIATRICS 6: 1219-25 (1991), filed as "Resp. Ex. I."

brain is insulated from the rest of the body by the blood-brain barrier ("BBB") which keeps out substances that could cause damage; however, the BBB is "rather imperfect" and can allow inflammatory cells to seep in. *Id*. Therefore, it could allow the substances in the HPV vaccine to cross the BBB into the brain. *Id*. Pathogens or self-antigens that cross the BBB can evoke innate and adaptive immune responses in the central nervous system ("CNS"). Pet. Ex. 30 at 2. This activates the microglia, astrocytes, neurons, BBB endothelial cells, and peripheral immune cells, which produce proinflammatory and anti-inflammatory molecules that can contribute to brain inflammation and result in a seizure. *Id*.

According to Dr. Kinsbourne, the HPV vaccine contains virus-like particles ("VLPs") consisting of viral structural proteins. Pet. Ex. 11 at 375. When overexpressed, the VLPs spontaneously self-assemble into highly immunogenic particles that are antigenically indistinguishable from infectious virus or subviral particles. *Id*.; Pet. Ex. 25[33] at 1. According to Dr. Kinsbourne, studies show that the HPV vaccine can induce an immune response that is at least as great as that following infection. Tr. 47-48; Pet. Ex. 25 at 5; Pet. Ex. 26[34] at 4. Therefore, in Dr. Kinsbourne's opinion, the VLPs in the HPV vaccine could cross the BBB and activate an immune response in the brain. In this case, the HPV vaccine would serve as a secondary stimulus to an already-primed autistic brain, inducing a vigorous peripheral immune stimulation capable of generating a central change in neural excitability, culminating in seizure activity.

In support of his theory, Dr. Kinsbourne cited to the Pinto study, stating that Pinto showed that the VLPs in the HPV vaccine bind strongly to dendritic cells and induce a maturation response characterized by the expression of co-stimulatory molecules and production of the cytokines IL-12, TNF-alpha, and IL-6, which have been implicated in the development of CNS inflammatory responses. Pet. Ex. 11 at 376; Pet. Ex. 22.[35]

Dr. Kinsbourne also relied upon an article by Riazi to show that toxin injected into young animals induced inflammation and could alter seizure susceptibility long term. Tr. 128; Pet. Ex. 23.[36]

Dr. Kinsbourne further submitted that, because the HPV vaccine was not introduced until 2006, relevant research is sparse. In his opinion, there are no epidemiological studies with the statistical power to detect rare events attributable to the HPV vaccine. Pet. Ex. 11 at 375. Accordingly, it is appropriate to rely on case reports; Dr. Kinsbourne cited to several reports from

[33] Judith F. Smith et al., *Evolution of type-specific immunoassays to evaluate the functional immune response to Gardasil*, 4 HUM VACCINES 2: 134-42 (2008), filed as "Pet. Ex. 25."

[34] Margaret Stanley, *HPV – immune response to infection and vaccination*, 5 INFECT AGENTS CANCER 19: 1-6 (2010), filed as "Pet. Ex. 26."

[35] Ligia A. Pinto et al., *HPV-16 L1 VLP vaccine elicits a broad-spectrum of cytokine responses in whole blood*, 23 VACCINE 3555-64 (2005), filed as "Pet. Ex. 22."

[36] *Supra*, n.22.

other countries that show neurological side effects of the HPV vaccines, Cervarix and Gardasil.[37] *Id*.; Pet. Ex. 28[38] at 5. He added that there have been no studies on the effects of the HPV vaccine on the autistic population, as it is unlikely that many autistic people would have received the HPV vaccine. Tr. 50-51, 61. In Dr. Kinsbourne's opinion, the epidemiological studies that do exist are not useful, because they did not study a population with a lowered seizure threshold. Tr. 51. He added that he had no dispute with any of the epidemiological studies that Dr. Shinnar relied on, he just felt that none of them were helpful because children like B.L. were not part of the population studied. Tr. 61.

Dr. Kinsbourne concluded that the inflammatory property of the HPV vaccine was well equipped to provoke or, in this case, to amplify, the existing neuroinflammation and was a likely candidate in further activating an already overexcited autistic brain producing seizures. Pet. Ex. 11 at 376.

b. Respondent's expert, Dr. Shinnar

Dr. Shinnar disagreed with Dr. Kinsbourne's theory that the HPV vaccine can cause seizures. In Dr. Shinnar's opinion, severe autism, intellectual disability and inability to speak are all caused by chronic encephalopathy, which means the brain is not working correctly. Tr. 102-03. When a child has both autism and intellectual disability, he will also have neurological abnormality and an increased risk of developing prolonged seizures. Tr. 120; Resp. Ex. E at 8; *see also* Resp. Ex. N, O, P. Therefore, when these children develop epilepsy, it is attributed to autism, and while a majority will not have seizures, they share commonalities with a lot of the children who will. Tr. 173.

According to Dr. Shinnar, "[N]euroinflammation" is a loose term, and the topic of neuroinflammation in the autistic brain is controversial. Tr. 123, 140. According to Dr. Shinnar, seizures cause a release of cytokines, and inflammation is implied in people with many seizures. Tr. 123. However, there is no clear data that inflammation is causally related to autism or the onset of epilepsy. *Id*. Dr. Shinnar stated that studies of patients with chronic epilepsy show evidence of inflammatory markers, but it is unclear which came first, the inflammatory marker or the seizure. *Id*. By way of example, Dr. Shinnar stated that IL-1 beta is a cytokine that can cause fever and provoke seizures in some people, but simply being exposed to something that produces neuroinflammation does not mean a person will have seizures. Tr. 140-41, 178-79.

According to Dr. Shinnar, autism and epilepsy have a common genetic basis. The same brain abnormality/dysfunction or mechanism that causes the development of severe autism, intellectual disability and one to become nonverbal at an early age causes the development of

[37] The adverse reactions referred to as nervous system and psychiatric disorders included headache, syncope, convulsions, dizziness, hypoesthesia, paresthesia, lethargy, migraine, tremors, somnolence, loss of consciousness, dysarthria, hallucinations, and insomnia. Pet. Ex. 28 at 5.

[38] Lucija Tomljenovic & Christopher A. Shaw, *Human papillomavirus (HPV) vaccine policy and evidence-based medicine: Are they at odds?*, ANN MED 1-12 (2011), filed as "Pet. Ex. 28."

seizures in the second decade in life, not an outside factor. Tr. 115-16; Resp. Ex. EE.[39] Dr. Shinnar relied on the NINDS Epilepsy and Autism Workshop Report, which discussed and summarized the biological relationships between autism and epilepsy. He stated that, while the causes of autism, intellectual disability, and epilepsy are complex and not completely understood, scientists currently believe that they "'may result from the same pathophysiologic mechanisms that lead to abnormal synaptic plasticity and excitatory/inhibitory imbalance in the developing brain.'" Tr. 115-16; Resp. Ex. DD at 2, citing Resp. Ex. EE. "There are multiple complex mechanisms involved but they all have in common increased neuronal excitability due to either changes in the individual cells or disruptions in the network properties. The increased neuronal excitability is thought to be the shared pathophysiological basis for the known association of epilepsy and autism spectrum disorders." Resp. Ex. DD at 2. Dr. Shinnar added, "Environmental and immunological factors may also play a role but are less well understood." *Id*.

Dr. Shinnar was questioned about the following statement contained in the NINDS study and whether that statement supported Dr. Kinsbourne's opinion on neuroinflammation and causation: "Immunological risk factors common to both ASD and epilepsy include those with neuroinflammatory components. Studies have demonstrated increased activation of microglial and astroglial as well as differential expression of cytokines in the brains of individuals with ASD or those with epilepsy." Tr. 118; Resp. Ex. EE at 2. Dr. Shinnar responded that the focus of the workshop was on the events early in life, what persists in the brain thereafter and understanding the underlying mechanisms leading to epilepsy and cytokine expression, not neuroinflammation or what causes acute seizures. Tr. 118.

Dr. Shinnar added that a large body of reliable literature establishes a high rate of seizures and epilepsy, especially in the second decade of life, in children with autism. This rate is particularly high in those with associated intellectual disability. These children are also at increased risk for status epilepticus. In contrast, there is no established association between the HPV vaccine and seizures or epilepsy. Resp. Ex. BB at 3.

In support of this opinion, Dr. Shinnar pointed to the Maski (Resp. Ex. J[40]) and Viscidi (Resp. Ex. K[41]) studies, which show that children with autism alone who were followed through adolescence have a 10 to 15% increase in epilepsy; those with both autism and intellectual disability have a cumulative rate of 30 to 40% increase in epilepsy compared to the general population, who have a 0.5 to 1% rate of developing epilepsy. Tr. 111-12; Resp. Ex. E at 4, 8. The increased risk of seizure onset in early adolescence for those with autism, as well as all syndromes significant for developmental disability, is due to an underlying susceptibility for seizures and is part of the long term outcome of these children without any need for external factors, triggers, or immune mechanisms. Tr. 114-15, 172; Resp. Ex. E at 5, 7-8.

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[39] Roberto Tuchman et al., *NINDS epilepsy and autism spectrum disorders workshop report*, 81 NEUROLOGY 1630-36 (2013), filed as "Resp. Ex. EE."

[40] Kiran P. Maski et al., *Common neurological co-morbidities in autism spectrum disorders*, 23 CURR OPIN PEDIATR 609-15 (2011), filed as "Resp. Ex. J."

[41] *Supra*, n.30.

Dr. Shinnar pointed to the IOM report, which lists both autism and intellectual disability as conferring a high risk of developing epilepsy. Resp. Ex. BB at 4; Resp. Ex. G. According to Dr. Shinnar, even in a completely non-verbal autistic child who is brilliant, the risk of epilepsy is tenfold the normal population. Tr. 153. People with chronic neurological problems – old stroke, cerebral palsy, autism, and intellectual disability – are not only more likely to have seizures, but more likely to have prolonged seizures. Tr. 120; Resp. Ex. N. According to Dr. Shinnar, once someone has had a prolonged seizure, the chance of the additional seizures is high. *Id*. Prolonged seizures lasting more than 30 minutes, known as status epilepticus, are not uncommon. Resp. Ex. BB at 2. Status epilepticus occurs in 10 to 12% of patients who present with their first unprovoked seizure, and is most common in children who are otherwise not neurologically normal. *Id.* The severity of the epilepsy is consistent with that seen in children with autism and intellectual disability. *Id*. Additionally, children who are neurologically abnormal have a much higher rate of intractable seizures than children who are neurologically normal, and fewer than half of neurologically abnormal children have epilepsy that is fully controlled with medication. *Id.*; *see also* Resp. Ex. X, Y, Z, AA.

In addressing Dr. Kinsbourne's mechanism of injury, Dr. Shinnar stated that there is no proof of an association between HPV vaccine and seizures based on any of the studies submitted or the IOM report. Resp. Ex. E at 7. Dr. Shinnar agreed that HPV vaccine activates an immune response and acknowledged that autoimmune diseases that arise in genetically predisposed individuals require an environmental factor, sparking the debate of whether vaccines can activate an autoimmune disease. *Id*. at 6. But, he stated, "'Autoimmunity is a feature of the normal healthy immune system. There is little doubt that laboratory measurable signs of autoimmunity can associate with infection and might occasionally appear after vaccination. It is comforting to appreciate that the immune system has evolved sufficient fail-safe mechanisms to ensure that these signs rarely develop into clinical disease.'" Resp. Ex. R. Dr. Shinnar submitted that producing laboratory evidence of cytokine responses after vaccination does not demonstrate that the vaccine causes adverse events. Resp. Ex. E at 6. He further stated that the "safety profile of [the HPV vaccine] is excellent. In the authoritative Institute of Medicine report on Adverse Effects of Vaccines there is a paucity of ANY neurological consequences from this vaccine and NO mention of seizures." *Id*.

Dr. Shinnar further disagreed with Dr. Kinsbourne's opinion that HPV can cause seizures, stating that there is no data to suggest that the causes of seizures in the general population of children is any different than the causes of seizures for autistic children merely because they have a lower seizure threshold. Tr. 130-31. According to Dr. Shinnar, for an autistic child to suffer a seizure from an external factor, you would have to show that the external factor actually causes seizures. Tr. 131-32. HPV is not an acute infectious disease that presents with fever and acute symptoms; it is a subclinical infection that is associated with a higher risk of cervical cancer later in life, not with seizures. Tr. 164-65. Dr. Shinnar admitted that he is not an infectious disease doctor, but as a neurologist and board certified pediatrician who assesses the causes of seizures in children, HPV infection is not a factor that doctors look at for adolescents who present with new onset seizures. Tr. 165.

Dr. Shinnar addressed the Pinto study relied upon by Dr. Kinsbourne in support of his theory in this case, pointing out that Pinto studied the immune response to the HPV vaccine, not

inflammation or adverse reactions to the vaccine. Tr. 126. Dr. Shinnar explained that HPV VLPs were put into blood samples taken from volunteers, some who received the HPV vaccine and some who did not, to determine if they mounted the appropriate response. Tr. 124-25. Pinto looked at the IL-10, IL-1 beta, IL-8, IL-6, IL-2, and interferon reactions in the white blood cells to assess for responses to the vaccine and to identify the correlates of protection. Tr. 125-26; Pet. Ex. 22 at 4. Pinto then studied the immune response in the blood samples when re-exposed to the antigen, not adverse reactions to the vaccine. Tr. 125-26. The study showed an increase in cytokines, which should occur if the vaccine is effective; it did not show a correlation to any inflammatory reaction or clinical manifestations of seizure. Tr. 127. Pinto showed that the HPV vaccine activates an immune response and, as it is designed to do, produces memory, so that, upon re-exposure to the antigen, the immune system remembers it. Tr. 155. This, Dr. Shinnar explained, is the difference between autoimmunity and autoimmune disease. Autoimmunity is a feature of the normal and healthy immune system. Tr. 127; Resp. Ex. R[42] at 7.

Dr. Shinnar further pointed out that Pinto did not study the latency period of the immune response, but rather sustained response, which is the goal of vaccines. Tr. 128. Specifically, Pinto measured the response for efficacy after two months, six months, and seven months. *Id*. According to Dr. Shinnar, if you interpret the study to mean adverse reactions rather than protection efficacy, you would have to accept that seizures could occur one day, two days, five years, or thirty years after vaccination because of the evidence of sustained response. *Id*.

On cross examination, petitioner's counsel pressed Dr. Shinnar on the Pinto findings, arguing that after receipt of the HPV vaccine, the increase in various cytokines suggested an adverse reaction potential to the vaccine, particularly if it were a second vaccine. Tr. 157-60. Dr. Shinnar disagreed pointing out that it was blood samples that were studied at zero, two, and seven months post-vaccination, with statistically insignificant results. Tr. 160. It was only when the blood samples were challenged with the actual virus did it become statistically meaningful, which suggested memory, not the potential for an adverse reaction. *Id*. Petitioner's counsel countered, blaming those findings on the medium not containing any viral particles. *Id*. Dr. Shinnar responded that B.L. did not receive viral particles either; he received antigens to the viral particles. Tr. 160-61. Despite petitioner's counsel's attempts to get Dr. Shinnar to agree that Pinto could be interpreted to show an adverse reaction to HPV vaccine, Dr. Shinnar refused, explaining that the study showed that when viral particles were injected into blood samples, there was some elevation in cytokines, which was promising for the efficacy of the vaccine, not a screening for adverse reactions. Tr. 161-63. Additionally, Dr. Shinnar pointed out that Pinto did not revaccinate any of the individuals; the virus was injected into blood samples taken from vaccinated individuals. Tr. 162-63.

Ultimately, Dr. Kinsbourne agreed that Pinto studied blood samples of vaccinated people against two other groups where the blood samples were stimulated with additional virus-like particles, and it was in that setting that the cytokines were elevated. Tr. 63. Dr. Kinsbourne conceded that the study was not looking for the mechanism of injury or adverse event, but rather the mechanism of how the vaccine caused immunity. *Id*. Dr. Kinsbourne admitted that he used Pinto only as an observation that the vaccine is particularly potent in stimulating proinflammatory

[42] David C. Wraith et al., *Vaccination and autoimmune disease: what is the evidence?*, 362 LANCET 1659-66 (2003), filed as "Resp. Ex. R."

cytokines. Tr. 64. Dr. Kinsbourne also agreed that the testing was done two months and six months later, not two days or two weeks later. *Id.* Dr. Kinsbourne added that, if he could have found an article that was more specific to the time frame, he would have used it. *Id*. Dr. Kinsbourne also agreed that the Pinto study did not include autistic children. *Id*.

Dr. Shinnar also addressed the Riazi study relied upon by Dr. Kinsbourne, stating that he had no argument with this as a "review" article and agreed that children with autism have increased susceptibility to seizures. Tr. 129. However, Dr. Shinnar pointed out that in the Riazi study, a toxin was injected into animals and when the toxin reached peak levels, it lowered the seizure threshold. But when the toxin disappeared, so did the response. Tr. 145. Dr. Shinnar submitted that the Riazi study had no relevance to this case, and did not address autism. *Id*.

Dr. Shinnar agreed with Dr. Kinsbourne that, while no studies of the HPV vaccine specifically make reference to autistic children, the findings of the studies that exist are relevant to everyone since they are studies of the general population, which would include those who are autistic. Tr. 130, 183-84, 186-88. Dr. Shinnar cited to several large population studies, to show that there was no data of a seizure signal from the HPV vaccine. Tr. 186. In a study of 997,585 girls in Denmark and Sweden, 296,826 received a total of 696,420 doses of HPV vaccine, with no increased risk for autoimmune or neurological adverse events reported. Tr. 132-33; Resp. Ex. T.[43] In a Canadian study following 691,994 doses of HPV vaccine, the overall adverse event rate was "very low."[44] Tr. 134; Resp. Ex. U.[45] A study utilizing Vaccine Data SafetyLink, which contains data from seven large managed healthcare organizations, found no increased risk of seizures in those receiving HPV vaccine versus those who did not. Tr. 134-35; Resp. Ex. V.[46] According to Dr. Shinnar, these studies do not conclude that HPV vaccine does not cause seizures in normal children; they conclude that it does not cause seizures regardless of the population. Tr. 183-84. Dr. Shinnar added that autism occurs in one in 80 children, so a study of close to a million girls, of whom 300,000 received about 700,000 HPV doses, is a good indicator of the level of adverse reactions in the general population. Tr. 131-32; Resp. Ex. T.

Dr. Shinnar concluded that the studies look at populations at large without reference to whether they are normal, autistic or anything else. Tr. 187-88. Dr. Shinnar agreed with Dr. Kinsbourne that many of the studies of HPV vaccine are old and reflective of adolescent teenage girls not boys, but added that boys have a slightly higher seizure risk only because they engage in activities leading to head trauma. Tr. 186, 190.

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[43] Lisen Arnheim-Dahlstrom et al., *Autoimmune, neurological, and venous thromboembolic adverse events after immunization of adolescent girls with quadrivalent human papillomavirus vaccine in Denmark and Sweden: a cohort study*, BMJ 1-11 (2013), filed as "Resp. Ex. T."

[44] Dr. Shinnar admitted that two cases of seizures were reported but only details on one were provided. Resp. Ex. E at 7.

[45] Tara Harris et al., *Adverse events following immunization in Ontario's female school-based HPV program*, 32 VACCINE 1061-66 (2014).

[46] Julianne Gee et al., *Monitoring the safety of quadrivalent human papillomavirus vaccine: Findings from the Vaccine Safety Datalink*, 29 VACCINE 8279-84 (2011), filed as "Resp. Ex. V."

I asked Dr. Shinnar to explain the findings in *Syncope and Seizures following human papillomarvirus vaccination: a retrospective case series*,[47] which concluded that syncope and syncopal seizures occurred after the quadrivalent HPV vaccination. Resp. Ex. C at 1. Dr. Shinnar explained that syncope is a vasovagal episode, which occurs when a change in heartrate causes a temporary lack of profusion to the brain, resulting in fainting, followed by a return to normal function. Tr. 194. Some people experience brief shaking, which looks like a convulsion, resulting in the name "syncopal seizures." *Id*. In the U.S., is it referred to as "convulsive syncope." Tr. 194, 196. According to Dr. Shinnar, syncope is "not rare" with any injection; it also happens during blood draws. Tr. 195. The outcome of the syncope article was a warning for practitioners to put vaccine recipients in a chair so that they do not injure themselves if they pass out. *Id*. Dr. Shinnar added that syncope typically occurs immediately or within a few minutes of a vaccination, not 24 hours later and certainly not 5 days later. Tr. 196.

iii. Evaluation of the evidence

Under *Althen* Prong I, petitioner bears the burden of providing a plausible biologic theory which explains how the vaccine could have caused the alleged injury. Dr. Kinsbourne proffered the theory that the autistic brain is primed for inflammation and only needs a secondary stimulus, in this case, the HPV vaccine, to cause an exaggerated cytokine response resulting in seizures. Pet. Ex. 11 at 375; Tr. 46. While petitioner's theory need only be legally probable, "when a petitioner travels the plausibility route to causation-in-fact, he should endeavor to buttress his argument with more factors than just a plausible mechanism and a literal temporal relationship." *Pafford v. Sec'y of Health & Human Servs*., 64 Fed. Cl. 19, 31 (2005), *aff'd*, 451 F.3d 1352 (2006). In this case, Dr. Kinsbourne was unable to substantiate his theory with reliable scientific or medical evidence. To support his assertion that the HPV vaccine was capable of triggering an exaggerated cytokine response, he relied on the Pinto study only to concede that Pinto showed that the HPV vaccine was effective in inducing a sustained immune response to the antigen, not adverse reaction. Similarly, to support his assertion that the HPV vaccine could lower the seizure threshold, Dr. Kinsbourne proffered the Riazi study, which showed that the introduction of a toxin could lower an animal's seizure threshold. However, this effect only lasted while the toxin was still present in the body; it did not have a long term effect. The only evidence in support of a correlation between the HPV vaccine and seizures were case reports based solely upon temporal association which connected the HPV vaccine to a wide variety of adverse reactions. *See* Pet. Ex. 28 at 5. Dr. Kinsbourne admitted that he relied on Pinto because it was the best that he could find.

Epidemiological evidence is not required for a theory to be plausible, but "it should be obvious to petitioner a scientific theory that lacks any empirical support will have limited persuasive force." *Caves v. Sec'y of Health & Human Servs*., 100 Fed. Cl. 119, 134 (2011), *aff'd*, 463 Fed. App'x. 932 (2012). Indeed, Dr. Kinsbourne ultimately admitted that he had no proof for this theory in this case, but argued that the issue here was susceptibility, not causation. A special master is entitled to require some indicia of reliability to support an expert's theory; Dr. Kinsbourne was unable to provide evidence to support a "sound and reliable" medical theory. Accordingly, petitioner has failed to satisfy his burden under prong I.

[47] Nigel W. Crawford et al., *Syncope and seizures following human papillomavirus vaccination: a retrospective case series*, 194 MED J AUST 1: 16-18 (2011), filed as "Resp. Ex. C."

2. *Althen* Prong Two: Logical Sequence of Cause and Effect

The second *Althen* prong requires proof of a "logical sequence of cause and effect." *Capizzano*, 440 F.3d at 1326 (quoting *Althen*, 418 F.3d at 1278). In other words, even if the vaccinations can cause the injury, petitioner must show "that it did so in [this] particular case." *Hodges v. Sec'y of Health & Human Servs.*, 9 F.3d 958, 962 n.4 (Fed. Cir. 1993) (citation omitted). "A reputable medical or scientific explanation must support this logical sequence of cause and effect," *id.* at 961 (citation omitted), and "treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury," *Paluck v. Sec'y of Health & Human Servs.*, 786 F.3d 1373, 1385 (Fed. Cir. 2015) (quoting *Andreu*, 569 F.3d at 1375). Petitioner is not, however, required "to eliminate alternative causes as part of establishing [their] prima facie case." *Doe v. Sec'y of Health & Human Servs.*, 601 F.3d 1349, 1357-58 (Fed. Cir. 2010); *see Walther v. Sec'y of Health & Human Servs.*, 485 F.3d 1146, 1152 (Fed. Cir. 2007) (holding that a "petitioner does not bear the burden of eliminating alternative independent potential causes").

Petitioner contends that he has established entitlement to compensation for B.L.'s allegedly vaccine-induced seizure disorder by a preponderance of the evidence. Pet. Post-Trial Brief at 12. According to petitioner, "Factors that increase susceptibility to disease alone cannot cause disease." Therefore, he argues that the HPV vaccine was the trigger that pushed B.L.'s autistic brain "over the edge to disease." *Id*. at 2.

i. The experts

Dr. Kinsbourne opined that "[i]t is medically reasonable to suppose that it was the [HPV] vaccination that precipitated the seizure disorder in [B.L.'s] particular case." Pet. Ex. 32 at 3. Dr. Kinsbourne's theory that B.L. had neuroinflammation by virtue of being autistic, and therefore a lowered seizure threshold to the extent that the HPV vaccine triggered his seizure five days later, is unsupported by the facts or literature in this case.

Dr. Kinsbourne offered a theory of susceptibility; he cited statistics that children with autism are 20 to 25% more likely to have seizures in early adolescence than the general population. Tr. 60. A majority of autistic children with epilepsy experience onset at around 10 years old, but four out of five autistic children will negotiate this age without seizures. Pet. Ex. 11 at 374. In most cases, the trigger is unknown. Tr. 60. According to Dr. Kinsbourne, "we are left with the claim that autism causes epilepsy except when it does not." Pet. Ex. 32 at 2.

B.L. was severely autistic and at maximal risk of onset of epilepsy at the time of his vaccination. Pet. Ex. 11 at 374. Dr. Kinsbourne opined that the combination of B.L.'s autism and the HPV vaccine contributed significantly to his development of epilepsy. Tr. 21. However, he also admitted that epidemiology cannot tell us what caused B.L to become epileptic, or why he developed epilepsy when he did. Pet. Ex. 32 at 2. Whether B.L. would have become epileptic absent the vaccination is speculative and cannot be resolved by applying epidemiological group data to a single individual. *Id*. Dr. Kinsbourne conceded that if B.L. had not had an HPV vaccine but had developed seizures during that timeframe, the trigger would have been unknown. Tr. 60. Therefore, Dr. Kinsbourne could not say what triggered B.L.'s seizures, if anything at all.

According to Dr. Shinnar, B.L. was neurologically abnormal by virtue of having autism and intellectual disability, which long preceded his receipt of an HPV vaccine; therefore, he was at increased risk for prolonged seizures. Tr. 90, 120; Resp. Ex. BB at 1. Dr. Shinnar stated that B.L. developed epilepsy at age 11, which is consistent with the peak in seizures during the second decade of life for children with autism and intellectual disability, and as supported by medical literature. Statistically, the risk was greater than 40% for seizures at this age to develop. Resp. Ex. BB at 2-4. B.L. presented with a prolonged seizure, which accounts for 10 to 15% of new-onset seizures. Tr. 120. In contrast, there is no established association between the HPV vaccine and seizures or epilepsy. Resp. Ex. BB at 4.

Dr. Shinnar pointed out that development of seizures later in adolescents is not unique to autism. Children with other congenital errors in brain development also develop seizures later on. "The accepted theory is that the networks around the lesion mature over time and as the connectivity increase, seizures are more likely to occur. This is also a known phenomenon following brain insults such as febrile status epilepticus in children where the epilepsy may occur many years later." Resp. Ex. DD at 3; *see also* Resp. Ex. GG at 3.

According to Dr. Shinnar, B.L.'s severe autism and intellectual disability were the sole cause of development of seizures. In Dr. Shinnar's opinion, no insult was required to provoke B.L.'s seizure. Tr. 120; Resp. Ex. N, O, P. There is "no reason to postulate a theoretical and not plausible rare event when, in fact, cases like [B.L.] who develop epilepsy at this age without a history of a vaccine given a few days earlier are well recognized…" Resp. Ex. DD at 3. Dr. Kinsbourne had no disagreement with Dr. Shinnar's opinions and conceded that if B.L. had not had an HPV vaccine but developed seizures during this timeframe, the trigger would have been unknown. Tr. 60. Dr. Kinsbourne could not say what triggered B.L.'s seizures, if anything at all. B.L. was reportedly behaving normally after the HPV vaccination and had no neurological symptoms over the five day period after his HPV vaccination. His treating physicians classified his seizures as unprovoked and of unknown cause. Pet. Ex. 4 at 186, 188.

B.L.'s medical records indicate that he received multiple vaccines over the seven month period prior to the November 2010 HPV vaccine, all without event. Pet. Ex. 12 at 2-3. Dr. Kinsbourne admitted to having no explanation as to why B.L. had no reaction to the HPV, DTaP, and meningococcal vaccinations that he received on September 22, 2010. Tr. 57. He stated, "The state of the brain itself fractionates, and there has to be some convergence between defense in the brain, which we don't yet understand, and the challenge of the vaccination to actually release the epileptogenic effect of the vaccination, given before and given after, it won't do that." Tr. 80-81. According to Dr. Kinsbourne, sometimes a child will react to the first dose of a vaccine but not react to the second dose, but he cannot explain why. Tr. 81. He further acknowledged that B.L. was behaving normally after the vaccination and had no neurological symptoms over the Thanksgiving holiday. Tr. 58. B.L. was described as his "usual self" the following Monday, when he got ready for school and got on the bus. *Id.*

Dr. Shinnar also noted that B.L. had no reaction to his prior vaccinations, and that the first report of B.L. being groggy the morning after his vaccine came in the form of an affidavit several years later. Tr. 97. This detail is absent in the medical records. *Id.* Therefore, Dr. Shinnar gave no clinical significance to this statement, stating that B.L. could have had a variety of reasons to be

groggy in the morning, including sleep disturbance, which is common for autistic children and specifically for B.L.[48] Tr. 97-98.

Though the doctors who treated B.L. listed the HPV vaccine as having been received several days prior to the onset of his seizures, they classified his seizures as unprovoked and of unknown cause. Pet. Ex. 4 at 186, 188. Only Dr. Sokol commented that she "looked it up and found a high rate of seizures with the vaccine." *Id*. at 190. According to Dr. Shinnar, the record did not contain an explanation for what Dr. Sokol meant, or what she looked up, since there is no literature linking HPV vaccine to seizures, and the vast amount of literature is to the contrary. Tr. 110-11. He stated that Dr. Sokol was making "a reference without a reference." *Id*.

Dr. Shinnar and Dr. Kinsbourne agreed that the EEGs done on B.L. were indicative of patterns seen after a seizure and medication to control a seizure. Tr. 74-77, 102-04; Pet. Ex. 4 at 206. No EEGs were done on B.L. that were not post-seizure. Dr. Shinnar submitted that the presence of spikes on the EEG identified that this child had susceptibility seizures, but added that this was a known factor due to his autism and intellectual disability. Tr. 106. If an EEG was done unrelated to a seizure, about 50% of children with autism and intellectual disability would have normal EEGs, but about one-third of children would show slowing. Tr. 170. An EEG shows chronic encephalopathy as slowing. Tr. 102-03, 105-06. According to Dr. Shinnar, though the slowing on B.L's EEG did not distinguish between acute and chronic encephalopathy, the slowing of the occipital dominant rhythm was suggestive of chronic encephalopathy. Tr. 107. Dr. Shinnar and Dr. Kinsbourne agreed that B.L.'s EEGs do not show permanent injury, but more likely a brain that is chronically dysfunctional. Tr. 79-80, 154.

The statements of B.L.'s parents were telling. According to his parents, B.L. may very well have been having seizures for some time before his vaccination that went unnoticed due to the subtlety of the seizures and the amount of "alone time" built into B.L.'s schedule.[49] Ms. Domangue stated, "I realized that before I started watching him so closely, B.L. likely suffered seizures that no one even noticed, because he is non-communicative and was often left alone for stretches of time." Pet. Ex. 35 at 2; Tr. 239. It was only after counsel's prompting that that Ms. Domangue added that she meant to say after the vaccination. Similarly, petitioner stated in his affidavit, that B.L.'s early seizures were less noticeable and even at school it is possible that he had subtle seizures without anyone seeing because he was often left alone while the teachers and aides attended to the other special needs children under their care. Pet. Ex. 34 at 3-4. "Because of what I have described above, there is no doubt in my mind that B.L. might have experienced a seizure without any witnesses in the period between his shot on November 24, 2010 and the first-witnessed

[48] Both petitioner's counsel and Dr. Kinsbourne apparently placed little significance on this statement as evident in petitioner's counsel's questioning of Dr. Shinnar, in which he asked, "So, with regard to his first vaccination, so it – you agree with Dr. Kinsbourne that there is no significance with the sleepiness and grogginess after the first vaccine that was articulated in the affidavits. You agree with that don't you?" Tr. 168.

[49] The production of B.L.'s school records as well as the testimony of Ms. Domangue occurred after the experts in this case had rendered their opinions and testified; therefore, neither expert commented on this information.

seizure on November 29, 2010." *Id*. at 4. It is interesting to note that after B.L. was started on seizure medication in the spring of 2011, *see* Pet. Ex. 4 at 152, he displayed an "incredible explosion of communication." Pet. Ex. 41 at 18. The marked improvement that B.L. experienced in communication and learning potential after being medicated for seizures in the spring of 2011 suggests that he may have been having subtle seizures prior to November of 2010 and the receipt of the subject HPV vaccine.

The experts agreed that this case turns on seizure susceptibility for a severely autistic, nonverbal, intellectually disabled eleven year old child. The literature on autism and seizures submitted by both sides confirms that B.L. was at a critical age for the development of seizures by virtue of his autism, intellectual disability, and nonverbal status.[50] However, the literature does not support any triggers for the onset of seizures in this population; the seizures are characterized as unprovoked, and a trigger, if any, is generally unknown. Dr. Shinnar added, "… there is no reason to postulate a theoretical and not plausible rare event when, in fact cases like [B.L.] with no history of a vaccine given a few days earlier are well recognized and are seen all the time...a strong family history of epilepsy…further increase[ed] [B.L.'s] risk of developing epilepsy independent of his autism." Resp. Ex. E at 8.

ii. Evaluation

In sum, the experts agree, and the medical records support, that B.L. is severely autistic, nonverbal, and intellectually disabled. The experts agree, and the literature supports, that there is a high rate of epilepsy in the autistic population in the first two decades of life. The experts agree, and the literature supports, that the age of onset for seizures in this population is between 10 and 13 years of age; B.L. was 11 years old when he had his first witnessed seizure.

Petitioner asserts that the HPV vaccine caused B.L.'s seizures and that there is no alternative explanation for B.L.'s seizures. Dr. Kinsbourne admitted that there was no epidemiology to support what caused B.L to become epileptic, or why he did when he did, but stated, "Autism is clearly a susceptibility factor for seizure activity…in already seizure prone autistic individuals, [the HPV vaccine] would be a more potent risk factor for seizures than it is in the general population." Pet. Ex. 32 at 2. However, if petitioner cannot prove that the HPV vaccine is capable of causing seizures, petitioner cannot prove that the HPV vaccine caused B.L.'s seizures. *See Harris v. Sec'y of Health & Human Servs.*, No. 10-322V, 2014 WL 3159377, at *23 (Fed. Cl. Spec. Mstr. June 10, 2014), *mot. rev. denied*, No. 10-322V (Fed. Cl. Sept. 23, 2014). Petitioner must offer more than B.L.'s "susceptibility" to seizures in order to prove that the HPV vaccine specifically triggered his development of epilepsy. Moreover, although "the Vaccine Act does not require petitioner to bear the burden of eliminating alternative causes where the other evidence of causation is sufficient to establish a prima facie case," a petitioner "may be required to eliminate potential alternative causes where the petitioner's other evidence on causation is insufficient." *Walther v. Sec'y of Health and Human Servs*. 485 F. 3d. 1146, 1149-50 (Fed. Cir. 2007)(citing *Pafford*, 451 F. 3d. at 1359). As reflected in his medical records and the literature, B.L.'s severe autism, language deficits, level of intellectual disability, and apparent neurological abnormalities

[50] B.L.'s school records filed after the hearing confirm that B.L. was functioning at a preschool level. *See generally*, Pet. Ex. 42.

alone were sufficient to cause his development of epilepsy. Petitioner failed to provide evidence to support a finding that HPV vaccine could cause seizures, or that it was more likely the cause or even a significant factor in B.L.'s seizures.

Petitioner has failed to provide preponderant evidence that the HPV vaccine was the cause or trigger of B.L.'s seizures and therefore has failed to sustain his burden under prong II.

3. *Althen* Prong Three: Temporal Relationship

To satisfy the third *Althen* prong, petitioner must establish a "proximate temporal relationship" between the vaccination and the alleged injury. *Althen,* 418 F.3d at 1281. This "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan,* 539 F.3d at 1352. Typically, "a petitioner's failure to satisfy the proximate temporal relationship prong is due to the fact that onset was too late after the administration of a vaccine for the vaccine to be the cause." *Id.* However, "cases in which onset is too soon" also fail this prong; "in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked." *Id.*; *see also Locane v. Sec'y of Health & Human Servs.*, 685 F.3d 1375, 1381 (Fed. Cir. 2012) ("[If] the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness.").

B.L. suffered a seizure five days after his second (third according to the records) HPV vaccination. Dr. Kinsbourne submits that five days is an acceptable time frame for the onset of seizures following HPV vaccination. He relied on the Pinto study stating that HPV vaccine generates high levels of cytokines that stay for "quite a while," certainly longer than five days, and up to seven months post-vaccination. Tr. 48-49; Pet. Ex. 22. However, he conceded on cross-examination that the Pinto study did not look at adverse effects of the vaccine, but rather immune response to the vaccine, adding that if there had been an article more specific to the time frame than the Pinto article, he would have used it. Tr. 64.

Dr. Kinsbourne also submitted that B.L.'s immune system would have retained memory cells from the first HPV vaccination, resulting in an enhanced immune response following a second HPV vaccine.[51] This enhanced immune response further increased B.L.'s susceptibility to seizures. Tr. 67. Dr. Shinnar disagreed, stating that in a person with a reduced seizure threshold, the latency period between a putative insult and a seizure would be shorter, and there was simply no basis for the five day interval between vaccination and seizure. Tr. 129-30.

Petitioner was unable to offer any support for his assertion that five days was an appropriate temporal interval between HPV vaccination and seizure. Dr. Kinsbourne admitted that there is no established time frame for adverse neurological reactions following HPV vaccination.

Dr. Shinnar submitted that there was no evidence that HPV vaccines can cause seizures and no time frame established for any adverse events following HPV vaccine. Resp. Ex. E. at 7. In comparison, Dr. Shinnar stated that medically acceptable time frames have been established for

[51] According to the medical records, this was the third HPV vaccine. *See* Pet. Ex. 12 at 2.

seizures within 72 hours of DTaP vaccination and within seven to ten days of MMR vaccination associated with fever. B.L. did not have a fever in the five days following his HPV vaccination and was admittedly his "usual self."

The evidence in this case shows that B.L. suffered his first recognized seizure five days after his second (or third, as the records reflect) HPV vaccination. But "a proximate temporal association alone does not suffice to show a causal link between the vaccination and the injury." *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144 (Fed. Cir. 1992). Furthermore, the experts in this case agreed that B.L. had a reduced seizure threshold due to his autism and intellectual disability. Dr. Shinnar submitted that the latency period between a putative insult and a seizure would be shorter for someone with a reduced seizure threshold. Tr. 129. Therefore, there is simply no basis for a five day interval between vaccination and seizure. Tr. 129-30.

Petitioner has failed to offer preponderant evidence that five days between HPV vaccination and seizure, in a child who did not suffer from a fever or any adverse reaction following receipt of the vaccine, is a medically acceptable time frame.

Accordingly, petitioner has failed to sustain his burden under prong III.

IV. Conclusion

There is no doubt that B.L. and his family have suffered greatly in dealing with his limitations and need for continuous care. However, despite sincere empathy for B.L. and his family, my decision must reflect a thorough analysis of the evidence and the application of the law based upon probative weight and persuasiveness. For this reason, the undersigned finds that petitioner has not established entitlement to compensation and his petition must be dismissed. In the absence of a timely filed motion for review pursuant to Vaccine Rule 23, the clerk is directed to enter judgment consistent with this decision.

IT IS SO ORDERED.

s/ Mindy Michaels Roth
Mindy Michaels Roth
Special Master