In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

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EILISE MORIARTY, a minor,	*	
by her parents and natural guardians,	*	No. 03-2876V
MARIE LOUISE and STEPHEN	*	
MORIARTY,	*	Special Master Christian J. Moran
	*	
Petitioners,	*	Filed: August 15, 2014
	*	
v.	*	Entitlement; measles, mumps, rubella
	*	("MMR") vaccine; autoimmune
SECRETARY OF HEALTH	*	epileptic encephalopathy.
AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
* *		

Clifford J. Shoemaker, Shoemaker, Gentry & Knickelbein, Vienna, VA, for petitioners;
Alexis B. Babcock, United States Dep't of Justice, Washington, DC, for respondent.

PUBLISHED DECISION DENYING COMPENSATION[1]

Marie Louise and Stephen Moriarty alleged that measles, mumps, rubella ("MMR") vaccine caused their daughter, Eilise, to develop seizures, encephalopathy, and a decline in cognitive and motor functions. Am. Pet. at 2.

[1] The E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002), requires that the Court post this decision on its website. Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

The Moriartys seek compensation pursuant to the National Childhood Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10 through 34 (2006). In support of their petition, the Moriartys rely upon the testimony of Yuval Shafrir, a board-certified pediatric neurologist.

Dr. Shafrir's opinion was opposed by respondent's expert, John MacDonald, who is also a pediatric neurologist. On May 6, 2013, a hearing was held in which the Moriartys, Eilise's brother (Harris), Dr. Shafrir, and Dr. MacDonald testified.

Because the Moriartys did not prove that the MMR vaccine administered on January 2, 2001 could cause Eilise's injury and did not provide a logical sequence of cause and effect linking Eilise's vaccination to the onset of her injuries, the Moriartys did not meet their statutory burden. Thus, they are not entitled to compensation.

I. Background

Because the parties relied upon Dr. Shafrir and Dr. MacDonald to explain the significance of the events in Eilise's life, their qualifications are discussed below in section A. Their comments on Eilise's history are presented in Section B, below.

A. Brief Biographies of Testifying Witnesses

1. Dr. Shafrir

Dr. Shafrir attended medical school in Israel and graduated in 1982. Exhibit 38 at 3. After graduation, he spent two and a half years in pediatric residency. He moved to the United States and continued to study pediatrics at North Shore University Hospital in New York from February 1986 through June 1988. Next, Dr. Shafrir went to Washington University in St. Louis to complete a pediatric neurology fellowship, which he finished in June 1991. He continued to Miami Children's Hospital to complete an epilepsy fellowship. Id.

Dr. Shafrir is board-certified in psychiatry and neurology with a special competence in child neurology and in clinical neurophysiology. Exhibit 38 at 4. Currently, Dr. Shafrir works in private practice as a pediatric neurologist in Baltimore, MD. Id. Dr. Shafrir also works in academia as an assistant professor for the Department of Pediatrics at the University of Maryland School of Medicine,

and also teaches residents at Sinai Hospital. Id. He describes himself as an "epitologist." Tr. 145.

2. Dr. MacDonald

Dr. MacDonald studied medicine at the University of Michigan. Exhibit A at 1. He stayed in Ann Arbor after graduation in 1970 to study pediatrics. Id. After next serving in the Navy, Dr. MacDonald completed a child neurology fellowship at the University of Miami in 1977. Id. He then spent 30 years as a private practitioner in Minneapolis. Tr. 220.

Dr. MacDonald is board-certified in psychiatry and neurology with a special competence in child neurology. Exhibit A at 2. He has worked in academia for the past 10 years, and currently holds an appointment in the Department of Neurology at the University of Minnesota. Tr. 220; exhibit A at 1. Dr. MacDonald teaches pediatric neurology to pediatric residents, fellows, and neurology residents and supervises clinical rotations. Exhibit A at 10.

B. Medical History

The parties generally agree that the medical records created contemporaneously with the events they describe set forth Eilise's history accurately. Thus, there is relatively little dispute about the facts. The most prominent point of contention on factual matters concerns whether Eilise suffered a seizure on January 7, 2001. This issue is addressed and is resolved in section 2.a below.

1. Eilise's Health before her MMR Vaccination

Eilise was born in 1996. Exhibit 4 at 1; Tr. 19. Ms. Moriarty described Eilise as a "very energetic, motivated child," but Eilise also had trouble walking and talking from a young age. Tr. 19-20. The first record of Eilise's developmental delay was in June 1997, when Eilise was ten months old. Id. at 52. During this visit, Eilise's pediatrician, Dr. Vojisla Russo, noted that Eilise had delayed gross motor development. Exhibit 8 at 75. At two years old, Eilise was still not talking, and she was accordingly referred to Children's National Medical Center ("Children's") for a developmental evaluation. Id. at 76.

On August 26, 1999, when Eilise was three, Dr. Susan Berman evaluated Eilise. Exhibit 8 at 112-14. Dr. Berman described Eilise as a "slow walker" because she did not start walking until the age of 21 months. Id. During her evaluation, Eilise was able to walk up and down stairs, run, jump, and climb. Id. However, because Eilise could not balance on one foot, Dr. Berman did not complete a gross motor skills evaluation. Id. at 113. He concluded that Eilise was "at least in the 24 to 27 month age range in terms of gross motor skills." Id. Her fine motor skills were in the 18 month range. Id. Eilise had diminished muscular tone in all of her extremities, but more in her upper extremities than lower. Id.

Ms. Moriarty expressed her concern about Eilise's language development to Dr. Berman. Exhibit 8 at 113. Eilise's vocabulary consisted of only approximately ten words, and most of her speech was unintelligible. Id. Ultimately, Dr. Berman concluded that Eilise's speech and language skills were in the 18 to 24 month range. Id.

After the evaluation, Dr. Berman diagnosed Eilise with hypotonia and developmental delay. Exhibit 8 at 113. According to Dr. Shafrir, a child with developmental delay is the same as a child with static encephalopathy. Tr. 185 ("when you see a child with developmental delay[,] you say that they have static encephalopathy"). Dr. Berman also noted that the department of physical medicine and rehabilitation at Children's had followed Eilise's older sister, Mairin, who was diagnosed with cerebral hypotonia and learning disabilities. Id. at 112.[2]

Dr. Berman recommended a hearing test to determine whether Eilise's language delay was not "secondary to hearing impairment." Exhibit 8 at 113. She also recommended that Eilise begin occupational therapy once a week for at least twelve weeks to address "the same visual motor issues that her sister had." Id.

On November 15, 1999, Eilise was found to have normal hearing. Exhibit 8 at 118. After a subsequent speech and language evaluation on November 24, 1999,

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[2] Dr. Shafrir believes that Mairin's medical history is significant because she also had delayed walking and delayed speaking. Dr. Shafrir opined that Eilise and her sister "probably have the same cause of their static encephalopathy, which is likely genetic." Tr. 163-64. Although he was speculating, he added that in his view the medical records support the possibility. Id.

Eilise was diagnosed as having a moderate receptive language disorder and a severe expressive language disorder, and her speech skills were said to be "severely impaired." Id. at 116. The examiner recommended that Eilise attend speech therapy sessions. Exhibit 27 at 29.

In addition to numerous evaluations, Eilise had several surgeries as a young child. In April 1999, she had surgery to correct exotropia in her left eye, with similar surgery to correct the same defect in her right eye the next year. Exhibit 8 at 110, 112. In March 2000, Eilise's tonsils and adenoids were removed. Exhibit 49 at 1. Eilise's sister, Mairin, also had a tonsillectomy when she was around Eilise's age. Before surgery, Mairin was developmentally delayed, but after surgery, Mairin improved dramatically. Tr. 118-19, 121-22, 298. Ms. Moriarty testified that after the surgery, Eilise had never "[spoken] so clearly or engage[d] and [paid] such close attention to anything." Tr. 21. She added that Eilise's "whole demeanor was more confident" after her surgery. Tr. 81.

On May 1 and May 24, 2000, Eilise went to the Devonshire Center to be evaluated for a special education preschool program. Exhibit 27 at 9. To assess her cognitive functioning, Eilise took the Bayley Scales of Infant Development – Second Edition. Exhibit 27 at 12. Eilise's performance resulted in an overall cognitive age equivalent of 20 months. Id. The assessment team warned that "[h]er performance should be interpreted cautiously as it was affected by her limited expressive language, hypotonia, and ocular difficulties." Id. at 17.

To assess her speech and language skills, Eilise took several tests. On the Peabody Picture Vocabulary Test – Revised (Form L), she earned a score matching that of a two year old, a "very significant delay." Exhibit 27 at 16. The Preschool Language Scale – 3 revealed a "severe receptive and expressive language delay." Id. Her pragmatic communication skills also were "very significantly delayed" and her articulation skills were "severely delayed." Id.

After reviewing Eilise's assessments, the Fairfax County school system approved Eilise for special education services. Exhibit 27 at 38-44. On June 30, 2000, Eilise underwent an IEP. Tr. 60; exhibit 27 at 198-201. The IEP report described Eilise as having a "normal activity level" but also as "having difficulty fully participating in the preschool environment." Exhibit 27 at 37. The team recommended that Eilise receive "adult guidance and modeling" for developing fine motor skills, interacting and playing with peers, and for communicating more effectively. Id.

Eilise started a preschool program in fall 2000. Tr. 23. She continued to improve in her development and was "very chatty," according to Ms. Moriarty. Id. A progress report in October 2000 showed that Eilise was making improvements, particularly after focused therapy to improve fine motor and speech skills. Exhibit 31 at 13-15. Dr. MacDonald attributed Eilise's progress to the fact that she was receiving therapy during that time. Tr. 227. Dr. Shafrir doubts that Eilise was completely normal after the surgeries, but that she "definitely improved dramatically." Tr. 185.

2. Eilise's Health from the Date of Vaccination until the End of January 2001

The school required Eilise to have certain vaccinations before returning to school in January 2001. Exhibit 51 at 2. Thus, on January 2, 2001, at Dr. Russo's office, Eilise received the second dose of the MMR vaccine. Exhibit 8 at 77, 134; Tr. 135. Although Dr. Russo also gave Eilise a dose of the DTaP and IPV vaccines on the same occasion, the Moriartys' claim and Dr. Shafrir's opinion are based upon the MMR vaccine.

a) Episode on January 7, 2001, and Following Weeks

The Moriartys allege that Eilise suffered a seizure on January 7, 2001. Pet'rs' Posthr'g Br., filed Sept. 25, 2013, at 2. The basis is a report from Harris, Eilise's older brother, who provided an affidavit (exhibit 47) and testified. The Secretary has some questions about Harris's account because a medical record was not created contemporaneously. See Resp't's Posthr'g Br., filed Nov. 25, 2013, at 16-17.

According to Harris, on Sunday, January 7, 2001, Eilise and he stayed at home alone while the rest of the family attended Catholic Mass. Tr. 25-26. While watching television, he witnessed Eilise as her back "arched into the couch," her head "thrust back," her eyes "rolled back," and her left side jerked "very strangely, almost in a rhythmic pattern" for about 45 seconds. Tr. 6. Eilise was disoriented and dazed after the episode, so Harris put Eilise to bed and then called their parents. Tr. 6-7, 10-11. Although Harris did not know it on that day, he now believes, after witnessing many other seizures, that what he witnessed was Eilise having a seizure. Tr. 7. According to Mr. and Ms. Moriarty, Eilise was feverish and lethargic the night of January 7, 2001. Tr. 27, 121; see also Tr. 12.

Harris's testimony raises two questions. First, did anything happen to Eilise, and, second, if something unusual did occur, was it a seizure? Dr. Shafrir believes that this episode was a seizure, constituting the onset of Eilise's epileptic encephalopathy. Exhibit 37 at 2; Tr. 148. Dr. MacDonald stated that he agreed "there was probably an event" on January 7, 2001, but that he "would not characterize it as unequivocally a seizure." Tr. 229; see also exhibit B at 3 (Dr. MacDonald's report stating that he could not accept Harris's report "to a reasonable degree of medical certainty").

Here, strong evidence supports a finding that Eilise behaved unusually during the evening of January 7, 2001. Less than three weeks later, when Eilise was in Inova Fairfax Hospital following an unquestioned seizure, Harris told one of Eilise's doctors about what he saw. Exhibit 7 at 162. Harris's report to Dr. Elgin was made to facilitate his sister's treatment and was not made in the context of litigation. Consequently, Harris's account has sufficient indicia of reliability to be accepted. See Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

The ensuing question is: was this behavior was a seizure? The evidence preponderates in favor of finding it was. First, in the years between this episode and his appearance in court, Harris has learned how Eilise acts during a seizure. Second, Dr. Shafrir, someone with medical training, accepted Harris's description of Eilise's behavior and characterized her as suffering a seizure. Third, the contrary position taken by Dr. MacDonald seems to be a consequence of an overly demanding burden of proof. Under the simpler more-likely-than-not evidentiary standard, the Moriartys have established that on January 7, 2001, Eilise suffered a seizure.[3]

On the next day, January 8, 2001, Eilise went to school, but returned home early. Later that afternoon, Eilise was running a fever. Tr. 28. The following day, Ms. Moriarty took Eilise to see Dr. R. A. Comunale. Id.; exhibit 10 at 2. The

[3] Although Dr. MacDonald disagreed, he stated that even if it were a seizure, he still believed that Eilise did not have autoimmune epileptic encephalopathy. Tr. 245-46, 273. Whether Eilise suffered from an autoimmune epileptic encephalopathy is discussed in section V below.

doctor noted that Eilise's only symptom was a fever and he prescribed an antibiotic, Zithromax. Tr. 29; exhibit 10 at 2.[4] Dr. MacDonald assumed that Eilise was being treated for a "viral type illness," but he was not sure because Dr. Comunale prescribed an antibiotic, which likely would not have helped a viral illness. Tr. 228, 262.

Over the next two weeks, Eilise continued to attend school, but she was "glassy and tired and lethargic and put herself to bed." Tr. 28. Ms. Moriarty described Eilise as "under the weather and not sure how or why." Tr. 69. Eilise did not go to the doctor during this period. See id. Commenting on this two week period, Dr. MacDonald stated that Eilise was apparently eating well because she was gaining weight and she did not appear to be seriously ill. Tr. 228.

b) Seizure on January 23, 2001, and Associated Hospitalizations

On January 23, 2001, Eilise had a seizure at school and was taken in an ambulance to Columbia Reston Hospital ("Reston"). Exhibit 17 at 2-3. The Emergency Department record indicated that Eilise "had a grand mal seizure at school consisting of arching back of head [and] rolling back of eyes and tonic clonic movement of extremities." Exhibit 24 at 3. Her seizure lasted several minutes. Id. at 6. As part of the "history of present illness," the doctor noted that Eilise had no cough or cold. Id. at 3. Overall, she was described as alert, active, and in no acute distress. Exhibit 24 at 6; see also Tr. 232.[5] Eilise's CT scan was normal. Exhibit 8 at 106. Dr. MacDonald believes that these descriptions are inconsistent with a diagnosis of acute encephalopathy. Tr. 232 ("a child who comes in [to the emergency room] and doesn't wake up, has focal neurological signs, signs of intracranial pressure, other signs that would point me to more than a seizure.").

[4] Dr. Comunale's report did not memorialize Eilise having any seizure-like behaviors the evening before.

[5] Despite the doctor's description of Eilise as alert, active, and in no acute distress, Dr. Shafrir opined that she was encephalopathic. Tr. 169-70.

On January 24, 2001, Ms. Moriarty and a nurse witnessed Eilise having a left-sided focal seizure lasting approximately 40 seconds. Exhibit 24 at 45; Tr. 30. Eilise was transferred to Inova Fairfax Hospital ("Fairfax") later that day. Exhibit 24 at 46.

A pediatric neurologist, Virginia Elgin, saw Eilise while she was at Fairfax. Exhibit 7 at 169-71. Dr. Elgin noted that Eilise had another focal seizure lasting approximately two minutes involving left side jerking. Id. Harris and Ms. Moriarty both witnessed Eilise having the seizure. Tr. 32. While they were at the hospital, Harris spoke with Dr. Elgin about the episode on January 7, 2001. Id. Dr. Elgin made a note, stating that Harris witnessed Eilise's first seizure while they were watching TV. Exhibit 7 at 162. Dr. Elgin assessed Eilise as "[a]lert, fussy, [and] cranky" and able to "follow simple commands" but having "limited" cooperation. Id. at 171; see also id. at 163. Ultimately, Dr. Elgin diagnosed Eilise with new onset seizures. Id. at 164.

On January 25, 2001, Eilise had a seizure that lasted for approximately 75 seconds, consisting of left-sided focal activity. Exhibit 7 at 161. Eilise initially was given Cerebyz, Ativan, and Dilantin. Id. at 161, 169. She later started Tegretol and Cerebyz was discontinued. Id. Her dose of Tegretol was "gradually increased after she was seizure free for 24 hours." Id. at 161.

Eilise had images of her brain taken while she was at Fairfax. Exhibit 7 at 185-89. The images from her brain MRI only showed "a moderate degree of inflammatory change in the paranasal sinuses." Id. at 189.

Eilise also had an EEG. The test administrator indicated that Eilise was in "the drowsy, light sleep state" when the EEG was taken. Exhibit 7 at 188. The EEG had a single burst of spike and high voltage slow activity symmetrically. Id. at 187. The doctors believed that her EEG was consistent with the clinical diagnosis of epilepsy. Id. at 185-88. Dr. Shafrir believes that EEG report was "supportive of a diagnosis of encephalopathy" but "not diagnostic." Tr. 202. Dr. MacDonald discussed two problems with the EEG report. Tr. 234. First, he asserted that reading EEGs before the patient is an adult is a subjective exercise. Id. Second, he opined that drowsiness creates slowing on an EEG and Eilise was likely drowsy when the EEG was taken. Id. Dr. MacDonald believed that the EEG confirmed an epilepsy, but nothing more. Tr. 277.

Eilise continued to have seizures for the next two days and her medications were adjusted accordingly. See, e.g., exhibit 7 at 175, 183. On January 27, 2001, Dr. T. Watkin saw Eilise, and noted that she was "still encephalopathic but improving." Id. at 178. Dr. Shafrir believes that Eilise was encephalopathic at the time of her admission to Fairfax, even though the medical records do not mention "acute distress" because "many patients go in and out of a state of encephalopathy." Tr. 170. However, Dr. MacDonald attributed her behavior to side effects of her medication, high doses of Dilatin as well as Ativan. Dr. MacDonald questioned how well Eilise, a small child, was sleeping while on those medications. Tr. 233.

Eilise was discharged on January 28, 2001, after her seizures had been controlled. Exhibit 21 at 55-56; Tr. 33. Upon discharge, Dr. Elgin noted that Eilise had a "new onset of seizure disorder," exhibit 21 at 56, and "there seem to be no precipitating factors causing the seizures," including that Eilise had no illnesses recently. Exhibit 7 at 160.

On January 30, 2001, Eilise went to Johns Hopkins Medical Center and saw Dr. Eileen Vining. Exhibit 4 at 18-20. In her report, Dr. Vining commented that Eilise had recently recovered from an upper respiratory infection. Id. at 18.[6] Dr. Vining reviewed Eilise's MRI and EEGs from Fairfax Hospital, noting that the nature of Eilise's seizures was unclear. Id. at 19. She emphasized that the nature of her seizures was particularly important for prescribing the correct medication. Id. Tegretol would help if Eilise were having complex partial seizures, but it could worsen her symptoms if her seizures were "poly spike and wave." Id. In her assessment, Dr. Vining noted that Eilise had new onset of seizure with unknown etiology. Id. at 19. Dr. Vining recommended close monitoring and maintaining her current anti-seizure medications. Later, Ms. Moriarty corrected an inaccuracy in the original medical history, adding that Harris did tell his parents about Eilise's episode on January 7, 2001. Tr. 73, 75; exhibit 4 at 9, 18 (note dated April 19, 2003).

[6] Dr. Vining's reference to a recent upper respiratory infection is inconsistent with the Reston Hospital record stating that Eilise had not had a cough or cold. Exhibit 24 at 3.

3. Additional Seizures and Hospitalizations: March through June 2001

On March 18, 2001, Eilise was readmitted to Fairfax after exacerbation of her seizures. Exhibit 7 at 130; exhibit 8 at 98. Ms. Moriarty reported that Eilise's seizure activity was focused on the right side. The doctor noted that Eilise had a history of partial and partial complex seizures. Exhibit 8 at 98. Dr. Elgin attributed the increased seizure activity due to auto-induction of liver enzymes and "increased leptic clearance." Exhibit 7 at 132. Because Eilise had not been responding to changing doses of Tegretol, Dr. Elgin started Eilise on Carbatrol, a slow-release anticonvulsant. Exhibit 7 at 69. Eilise did not have seizures overnight, and was discharged. Id. at 132.

In response to "drop attacks," on March 23, 2001, Eilise went back to Fairfax and saw Dr. Elgin. Exhibit 8 at 96; exhibit 21 at 40. Although Eilise appeared to show improvement in the partial seizures, Ms. Moriarty reported that during Eilise's recent episodes, she had a tendency to drop her head suddenly and sometimes to collapse altogether. Exhibit 8 at 96. Overall, Dr. Elgin believed that Eilise was improving, but she noted concern "regarding the possibility of additional seizure types which had not manifest[ed] previously." Id. In particular, Dr. Elgin was concerned about a "Lennox-Gastaut syndrome or some variant form thereof." Id. Dr. Shafrir credited Dr. Elgin's words as "clearly describ[ing] the development of the epileptic encephalopathy." Exhibit 37 at 2. [7]

Eilise continued to have seizures. On March 26, 2001, Eilise again was admitted to Fairfax. Exhibit 7 at 66, 69. Ms. Moriarty reported that Eilise had experienced more than 20 episodes of acute onset seizures since discharge three days prior. During these seizures, Eilise would fall to the floor. Id. at 66. There was no clear evidence of myoclonic seizures, however. Id.

Ms. Moriarty also reported that Eilise was experiencing expressive language regression. Exhibit 7 at 66. Dr. MacDonald believed that when Eilise began

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[7] Dr. Shafrir described epileptic encephalopathy as progressive in nature. Tr. 186 ("Typically [a patient has] a seizure then another one and increasing frequency, increasing severity, and finally they have full-blown epileptic encephalopathy.").

having daily seizures, she was recovering from both the seizures and Todd's paralysis.[8] Tr. 241. In addition, she was on multiple medications with side effects. Together, these likely led to transient changes in Eilise's cognitive ability, but not a decline in her overall abilities, because her test scores before and after the vaccination were "pretty much stable." Tr. 242; see Tr. 275. Dr. MacDonald added that seizures interfere with the ability of the brain to function rather than cause damage. Tr. 250. Eilise was diagnosed with mild to moderate speech delay, intermittent right hemiparesis, and decreased right nasolabial fold. Exhibit 7 at 70.

Eilise had more images taken. She had an EEG on March 27, 2001, which was consistent with clinical seizure disorder. Exhibit 7 at 85. The EEG was abnormal because of the prominent bilateral spike, poly spike, and slow wave activity. Exhibit 7 at 85; see Tr. 200. It also indicated an evolving disorder. Tr. 280. Eilise was discharged on March 28, 2001. Exhibit 7 at 80.

Dr. Elgin also ordered an MRI scan, which yielded normal results, including "mild to moderate membrane thickening involving a few paranasal sinuses." Exhibit 21 at 59, 62. Dr. Shafrir added that this condition would not contribute to encephalopathy. Tr. 206-07 ("Take every child on the street with a cold and nasal discharge, and they will have the same thing on the MRI.")

Mr. and Ms. Moriarty decided to take Eilise to Johns Hopkins Hospital to enroll her in the ketogenic diet program. Exhibit 51 at 5. However, there was a wait list and she was not able to see the doctors until June 2001. Id.

In the meantime, on April 19, 2001, the school system administered a psychological assessment to determine Eilise's continuing eligibility for special education services. Exhibit 27 at 94. She was four years and seven months old at the time of assessment. Id. at 95. During the evaluation, Eilise was administered the Stanford Binet Intelligence Scale: Fourth Edition, scoring in the first percentile in verbal comprehension, nonverbal reasoning, and overall. Id. She was completing only two-word sentences. Id.

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[8] Todd's paralysis is the loss or impairment of motor function in part due to the lesion of the neural or muscular mechanism. Dorland's Illustrated Medical Dictionary 1933, 1378 (32nd ed. 2012).

One month later, on May 10 and May 23, a speech clinician evaluated Eilise's speech and language to determine her continued eligibility for special education services. Exhibit 27 at 117-18. Testing indicated that Eilise had severe delays in receptive and expressive language, and her quality of speech was slurred. Id. at 119. Eilise was using three to five words, gestures, and pointing to communicate. Id.

In her June 2001 preschool progress report, Eilise's teacher, Ms. Dulong, commented on Eilise's communication and cognition. Exhibit 27 at 126. Ms. Dulong indicated that Eilise was capable of speaking in sentences, but on most occasions, she did not. Id. She also mentioned that Eilise had a limited vocabulary. Id. Eilise earned a score of 29 months on receptive language and 30 months on expressive language after taking the Battelle Development Inventory. Id.

On June 6, 2001, Eilise was admitted to Johns Hopkins Hospital for intractable seizures and to begin a ketogenic diet. Exhibit 8 at 89.[9] She was discharged four days later. Id. The attending physician noted that Eilise tolerated the diet well, and had only a "few little very brief seizures" on the day of discharge. Id. at 90. Eilise was still taking Depakote. Id.

4. After Eilise Started Ketogenic Diet

Eilise returned to Johns Hopkins for a follow-up examination on September 25, 2001. Exhibit 4 at 14. She was reportedly seizure-free after beginning the diet "except for [three] incidents." Id. Ms. Moriarty explained that the diet was very strict and sometimes difficult for her to follow. Tr. 41. In July 2001, Ms. Moriarty misread one of the items on an ingredient list and Eilise had a seizure. Id. In general, Eilise's talking and language structure improved since she started the diet. Exhibit 4 at 14.

On January 15, 2002, Eilise went to Johns Hopkins for a six-month follow up visit. She saw Dr. James Rubenstein for her appointment. Exhibit 4 at 12. By

[9] According to Dr. Shafrir, Johns Hopkins is "by far the leading ketogenic diet place in the country and probably in the world." Tr. 151.

this time, Eilise was no longer taking any seizure medications. Id.[10] Eilise's last seizure occurred on October 12, 2001. Id. Dr. Rubenstein's diagnosis, after the visit, was that Eilise had intractable seizures of unknown etiology, which were successfully treated with the ketogenic diet. Id. at 13. Dr. Rubenstein recommended occupational therapy, physical therapy, and speech therapy for Eilise. Id.

Eilise was a "super-responder" to the ketogenic diet with respect to her seizure disorder. Exhibit 4 at 9 (report of Dr. Eric Kossof). After one year on the diet, Eilise began developing kidney stones, but had been seizure free for eight months. Id. at 11. Her EEG on July 23, 2002, was essentially normal. Id. at 10. Mr. and Ms. Moriarty wanted Eilise to be seizure free for two years before tapering off the diet. Id. at 9. Eilise finally began to taper off the diet in October 2003, finishing in winter 2005. Id. at 2, 6-7. During her October 2003 appointment and again in October 2005, Dr. Rubenstein indicated that Eilise's problems or diagnoses were "1. Static encephalopathy of unknown etiology" and "2. Intractable atonic seizures, resolved with ketogenic diet." Id. at 2-3, 6-7.

Dr. Shafrir proposed that the ketogenic diet was an effective anti-epileptic medication or treatment for Eilise because the diet stopped the seizures, and the stopped seizures helped with her epileptic encephalopathy, but did not reverse the injury. Tr. 189. He commented that doctors do not have a theory for why some seizure patients, like Eilise, respond well to a ketogenic diet. Tr. 188. Dr. MacDonald attributed Eilise's success to the ketogenic diet's effect on Eilise's metabolism, suggesting that Eilise's problem was actually a metabolic disorder. Tr. 284.

On July 21 and July 29, 2004, Eilise went to Dr. Rachna Varia for a psychoeducational evaluation. Exhibit 18 at 74-83. Her test results showed deficits in language, attention, memory, sensorimotor, and visual-spatial skills. Id. at 81. Dr. Varia's report noted that Eilise had a "medically acknowledged MMR

[10] During the hearing, Dr. Shafrir was asked whether he had ever been able to take his epileptic encephalopathy patients off medication. He said no, but conditioned his answer, saying that this is not a common situation. Tr. 196. He was answering the question based on his experience with "one, two, maybe three patients." Id.

reaction, Lennox Gasto [sic], which led to complex partial seizures and brain damage." Exhibit 18 at 74.

On August 31, 2004, Eilise underwent an audiological and occupational therapy evaluation. Exhibit 18 at 57. The examiners noted that Eilise had made progress in auditory processing and sensory integration functions in "the past two years," but recommended that Eilise continue at least two hours a week of speech and occupational therapy. Id. at 60-61.

On February 22, 2005, Eilise had another occupational therapy evaluation at Georgetown University Hospital. Exhibit 18 at 42. The examiner found that Eilise was at risk for further developmental delay if she did not receive direct occupational therapy services. Id. The examiner noted that Eilise's "medical team attributed her seizures to a reaction to her MMR injection." Id.

During Eilise's developmental speech and language evaluation on April 28, 2005, the clinician indicated that Eilise presented an "expressive/receptive language delay as a result of seizure activity prompted by an adverse reaction to an MMR vaccine in January 2001." Exhibit 18 at 62. She also stated that the seizures "caused regression of development and loss of all language ability." Id. The clinician suggested that Eilise continue speech therapy sessions to improve her deficits. Id. at 63.

At the time of the hearing, Eilise was 17 years old and would have normally been a junior in high school. Tr. 46. However, she was reading at an "easy fifth grade level." Id. Her math skills and her cursive handwriting were at a third grade level. Id. She was being home-schooled and attended physical therapy and special education sessions. Tr. 48. According to her mother, Eilise has been making progress and "she's learning faster all the time." Id.

II. Procedural History

Acting through their attorney, the Moriartys filed a petition on December 31, 2003. In this original petition, they alleged that vaccines caused Eilise to suffer autism. Their designation led to this case being grouped and stayed with other cases involving autism.

After special masters issued decisions in the lead cases of the autism omnibus proceeding, the special master to whom this case was assigned ordered

the Moriartys to file an amended petition. The amended petition no longer referred to autism. Eilise does not have autism. Tr. 244. Instead, the Moriartys claimed that she suffered a "seizure disorder and encephalopathy." Am. Pet., filed July 14, 2011, ¶ 12.

Nearly eight years after the original petition was filed, the Moriartys filed the initial set of medical records on August 15, 2011. Another set was submitted on October 14, 2011.

The Secretary reviewed this material and concluded that the evidence did not support an award of compensation. To the Secretary, the notations of treating doctors associating Eilise's MMR vaccination with her subsequent neurological problems were not persuasive. The Secretary also noted that the Moriartys had not presented the report of an expert discussing causation. Resp't's Rep't, filed Jan. 13, 2012, at 16-17.

After the Moriartys filed two more sets of records, the parties obtained reports from experts. The petitioners submitted a report from Yuval Shafrir, M.D. and his curriculum vitae. Exhibits 35-36. The respondent countered with a report from John MacDonald, M.D., his curriculum vitae, and articles. Exhibits A-B.

By a March 1, 2013 order, the special master set the case for hearing on May 6, 2013. She also set a deadline of April 5, 2013, for the submission of any medical literature and a deadline of April 22, 2013, for the submission of various other documents such as briefs. On March 26, 2013, the case was reassigned to another special master.

The parties complied with the March 1, 2013 order. The Moriartys filed a second report from Dr. Shafrir, exhibit 37, on April 3, 2013, and additional medical records a few days later. The Secretary responded by filing a second report from Dr. MacDonald, exhibit C, on April 22, 2013. On April 22, 2013, both parties also filed briefs.

The hearing was held on May 6, 2013. Five witnesses testified. Three witnesses testified about Eilise's medical history: Harris Moriarty (her brother), Marie Louise Moriarty (her mother), and Stephen Moriarty (her father). The other two witnesses were Dr. Shafrir and Dr. MacDonald.

The then-assigned special master set a schedule for submitting briefs. Order, filed July 17, 2013. In the midst of this process, the term of service for this special master ended and the case was re-assigned to the undersigned. The undersigned issued an order directing both parties to state whether they wanted a second hearing. The Moriartys stated that they do "not believe that conducting another hearing, rather than the Special Master simply relying on the evidence as submitted, is necessary and therefore respectfully decline[] to request a new hearing." Pet'rs' Status Rep't, filed Oct. 8, 2013. The Secretary also declined an opportunity for another hearing. Resp't's Status Rep't, filed Oct. 25, 2013.

Consequently, the parties submitted their briefs. With the submission of the Moriartys' reply brief, the case is ready for adjudication.

III. Standards for Adjudication

The elements of the Moriartys' case are set forth in the often cited passage from the Federal Circuit's decision in Althen: "(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." Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). The burden of proof is preponderance of the evidence. Id.

IV. Theory

The first element of petitioners' case has been described as a "can it?" question which asks whether the vaccine could cause the alleged injury. See Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1356 (Fed. Cir. 2006) (affirming special master's use of "can cause" and "did cause" as consistent with the Althen test); Veryzer v. Sec'y of Health & Human Servs., 100 Fed. Cl. 344, 352 (2011) (describing the first prong of Althen as presenting the question of general causation). The theory that the Moriartys are advancing to connect the MMR vaccination to Eilise's condition has evolved throughout the litigation. After the submission of all the evidence (written medical records and oral testimony), the Moriartys claim that the measles vaccine "triggered an immune-mediated reaction in [Eilise's] body that led to an epileptic encephalopathy." Pet'rs' Posthr'g Br. at

6. Thus, this theory will be evaluated in this decision.[11] The specific mechanism is the production of antibodies against measles that attack the brain. Tr. 159.[12]

In Dr. Shafrir's opinion, the measles vaccine can cause various adverse reactions. Manifestations of an adverse reaction include acute disseminated encephalomyelitis ("ADEM") and cerebral ataxia. Tr. 159, 180. Another type of manifestation along this spectrum, according to Dr. Shafrir, is an epileptic encephalopathy. Tr. 159.

Dr. Shafrir has a sound basis for saying vaccines can cause ADEM. Many cases have made that finding.[13] However, petitioners failed to demonstrate how the measles vaccine would cause an autoimmune epileptic encephalopathy.

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[11] Dr. Shafrir's first report, exhibit 35, recites information about Eilise's medical history for the first seven pages of the eight page report. On the final page, Dr. Shafrir asserts that Eilise suffered an encephalopathy within the time period associated with measles vaccine on the Vaccine Injury Table. But, otherwise, Dr. Shafrir's first report fails to present any theory explaining how any vaccine can cause an encephalopathy. The Moriartys are not pursuing an on-Table claim. Pet'rs' Posthr'g Br. at 2-3.

In his second report, exhibit 37, Dr. Shafrir discusses a connection between measles vaccination and encephalopathy. He chiefly relies upon the National Childhood Encephalopathy Study (NCES) and also discusses other articles. Although he mentioned the diphtheria-tetanus-pertussis vaccine briefly, his opinion is that "Eilise's epileptic encephalopathy sits within the spectrum of MMR vaccine encephalopathy." Exhibit 37 at 4; accord Tr. 169.

[12] Dr. Shafrir rejected two other possible mechanisms – a direct invasion of the brain by the measles virus and a dormant infection. Tr. 157-59, 207-09.

[13] Special masters have found that various vaccines are linked to ADEM. See Daniels v. Sec'y of Health & Human Servs., No. 07-462V, 2012 WL 763175 (Fed. Cl. Spec. Mstr. Feb. 16, 2012) (awarding compensation for ADEM linked to a flu vaccine); Brown v. Sec'y of Health & Human Servs., No. 09-426V, 2011 WL 5029865 (Fed. Cl. Spec. Mstr. Sept. 30, 2011) (awarding compensation for ADEM linked to a flu vaccine); Hawkins v. Sec'y of Health & Human Servs., 99-450V, 2009 WL 711931 (Fed. Cl. Spec. Mstr. Feb. 27, 2009) (awarding compensation for ADEM linked to a hepatitis B vaccine); Banks v. Sec'y of Health & Human Servs., No. 02-0738V, 2007 WL 2296047 (Fed. Cl. Spec. Mstr. July 20, 2007) (awarding compensation for ADEM linked to an MMR vaccine); Camerlin ex rel. Camerlin v. Sec'y of Health & Human Servs., No. 99-615V, 2003 WL 22853070 (Fed. Cl. Spec. Mstr. Oct. 29, 2003) (awarding compensation, finding that HiB vaccine was a substantial factor related to ADEM); Kuperus ex

Petitioners elicited very little testimony about the basis for Dr. Shafrir's opinion that the measles vaccine can cause an epileptic encephalopathy. Their direct examination on this topic was covered in approximately three transcript pages. Tr. 158-60; see also Pet'rs' Posthr'g Br. at 6-10 (citing only these three pages from direct examination for petitioners' prong one argument). It is difficult to find such a cursory presentation persuasive. See La Londe v. Sec'y of Health & Human Servs., 110 Fed. Cl. 184, 201 (2013) (the petitioner's expert "could not back up his hypothesis with a reliable medical or scientific explanation. . . . [The special master] quite properly required petitioner to carry her burden to bring forward a reliable medical or scientific explanation"), aff'd, 746 F.3d 1334, 1340 (Fed. Cir. 2014); Langland v. Sec'y of Health & Human Servs., 109 Fed. Cl. 421, 441 (2013) ("the Special Master did not commit a legal error by requiring a sufficiently-detailed explanation of how" a vaccine can cause a disease); Taylor v. Sec'y of Health & Human Servs., 108 Fed. Cl. 807, 819 (2013) ("the mere existence" of expert testimony about a theory "is insufficient to satisfy the burden of showing a 'persuasive' medical theory --- this theory must also preponderate").

Although Dr. Shafrir had cited various articles in support of his opinion in his second report, exhibit 37, petitioners did not elicit testimony from Dr. Shafrir about these articles as part of the direct examination.[14] When an expert does not explain the relevance of the article, a special master is not required to interpret the study without the benefit of an expert's guidance. Moberly v. Sec'y of Health & Human Servs., 85 Fed. Cl. 571, 598 (2009), aff'd, 592 F.3d 1315 (Fed. Cir. 2010).

The lack of direct testimony from Dr. Shafrir was ameliorated to some extent because the Secretary and the presiding special master inquired about a few of the articles that Dr. Shafrir cited. Tr. 174-83, 202. During cross-examination, the Secretary questioned Dr. Shafrir about the Pampiglione article, exhibit 42 (G. Pampiglione et al., Transient Cerebral Changes After Vaccination Against

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rel. Kuperus v. Sec'y of Health & Human Servs., No. 01-0060V, 2003 WL 22912885 (Fed. Cl. Spec. Mstr. Oct. 23, 2003) (awarding compensation for ADEM linked to DTaP vaccine).

[14] The Moriartys did ask Dr. Shafrir about the Pampiglione and Gibbs articles in the rebuttal phase. Tr. 305-06.

Measles, 298 (7714) Lancet 5 (1971)); Tr. 176-82, and the Gibbs article, exhibit 44 (Frederic A. Gibbs and Ira M. Rosenthal, Electroencephalopathy in Natural and Attenuated Measles, 103 Am J of Diseases of Children 395 (1962)); Tr. 182-83.

In the Pampiglione study, eight children received an injection of live attenuated measles vaccine, Beckenham 31 strain, and were observed with a control group of three children for a total of three weeks after vaccination. Exhibit 42 at 2.[15] The researchers established a baseline for EEGs, taking two or three for each child prior to vaccination. Id. Each child then underwent an EEG four times after vaccination: once on the date of vaccination, then seven, nine, and fourteen days after vaccination. Id. The researchers found EEG changes in six of the eight vaccinated children, but no EEG changes in the control group. Id. at 3. The EEG changes were characterized as "fairly uniform." Id. (the researchers noted that "on no occasion did spikes or complex waves form"). All EEG changes disappeared within fourteen days after vaccination. Id. The researchers concluded that EEG changes after vaccination were more common than previously suggested, and that the reversible changes have a time relationship to the date of vaccination. Id. at 4. However, they also noted that different types of live attenuated vaccines may relate to the incidence and severity of EEG changes.

When asked about the relevance of the Pampiglione study, Dr. Shafrir explained that he "just wanted to show that there was a very viable, well-supported possibility that the measles vaccination will cause EEG changes" and sometimes will lead to epileptic encephalopathy. Tr. 179.[16]

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[15] The Secretary pointed out that Pampiglione studied a different strain of the measles vaccine than Eilise received. Tr. 179.

[16] Dr. Shafrir further explained that he included the Pampiglione study to demonstrate how healthy children can develop a neurological disease when they are exposed to neurological change, such as a vaccine or infection. Tr. 181-82. The reason some otherwise healthy children develop neurological change is because there is "something peculiar about them . . . [such as] acute cerebellar ataxia." Tr. 181. He attributed the cause of acute cerebellar ataxia mostly to chicken pox. Tr. 180. However, Dr. Shafrir seems to have digressed because Eilise only initially had ataxia, and she did not have chicken pox. Tr. 181.

Dr. MacDonald discussed the outdated eight-channel EEG method used in the Pampiglione article. Tr. 248. Dr. MacDonald explained that this method limits the reader's "ability to interpret the EEG, but given who was reading them they did the best they [could]." Id. On rebuttal, Dr. Shafrir indicated that the eight-channel EEG has the same information as a 32-channel or 64-channel EEG, but the reader has to look at the brain from more directions. Tr. 305.

The Secretary's counsel also asked Dr. Shafrir about the Gibbs article. Tr. 182-84; see also exhibit 44 (Gibbs & Rosenthal (1962)). In this study from 1962, Gibbs and Rosenthal sought to determine whether children vaccinated with attenuated measles virus developed EEG abnormalities similar to those seen in untreated (no gammaglobulin received) measles cases. The authors first screened for natural immunity to the measles virus and identified 28 nonimmune children. Of this group, 15 were classified as having normal health and the remaining 13 had either metabolic or neurologic diseases. Exhibit 44 at 4. Each child was vaccinated with attenuated measles virus then monitored by EEG twice, once directly following vaccination, and again 9-13 days later. Id.

Six of the children with histories of metabolic or neurologic disease had abnormal initial EEGs with unchanged readings 9-13 days later. Id. at 5. Of the remaining twenty-two children (15 normal health, 7 with disease history), all had normal initial EEGs and only one child's EEG changed after vaccination. Id. This child was of normal health but had developed a respiratory infection two days after vaccination, and the observed EEG changes were attributed to this intercurrent infection. Id. The child underwent another EEG one month later, which was normal. Id. Although the authors noted that the measles vaccine could not be completely ruled out as the cause of the child's abnormal EEG, they found the most likely cause to be the intercurrent infection and concluded that encephalitis from attenuated measles vaccine was "extremely unlikely." Id. at 7.

Dr. MacDonald made the same remarks about the eight-channel EEG method, which was also used in the Gibbs study. Tr. 248. Respondent argues that the medical literature cited by petitioners does not support their case. Resp't's Posthr'g Br. at 14-15.

The Gibbs article does not support Dr. Shafrir's previous point from the Pampiglione article discussion. The one child in the Gibbs study did not have cerebellar ataxia or other preexisting neurologic disease. Tr. 183. Additionally,

when Dr. Shafrir was asked if "the abnormal, slow activity would quickly subside and the EEG [would] revert back to normal," he answered, "Yes." Id.

These two articles do not establish the reliability of Dr. Shafrir's theory. The Pampiglione study did not support Dr. Shafrir's reasoning because the children did not develop epileptic encephalopathy and the children's EEG changes disappeared after 14 days. The Gibbs article did not appear relevant to Dr. Shafrir's opinion of Eilise's condition because the study indicated that the EEG changes were due to intercurrent illness rather than vaccination.

After the Secretary challenged Dr. Shafrir, the Moriartys did relatively little to rehabilitate his opinion by demonstrating its reliability. Rather, in their reply, the Moriartys appear to be relying upon testimony from the Secretary's expert, Dr. MacDonald. Pet'rs' Posthr'g Reply Br., filed Feb. 3, 2014, at 5. While the Moriartys argue that Dr. MacDonald "conceded the plausibility of Dr. Shafrir's theories," Pet'rs' Reply at 5, the Moriartys exaggerated the consequence of Dr. MacDonald's "concession." Dr. MacDonald did not say that Dr. Shafrir's theories were "plausible." When asked whether the measles vaccine can cause an encephalopathy resulting in epilepsy, Dr. MacDonald testified "it's possible." Tr. 272. There's a difference between "possibility" and "plausibility." Additionally, even if Dr. MacDonald had said Dr. Shafrir's theory was "plausible," this testimony would not get the petitioners very far. The petitioners' burden is to demonstrate the probability, not just the plausibility, of the theory. Bast v. Sec'y of Health & Human Servs., No. 01-565V, 2014 WL 3719188, at *28 (Fed. Cl. July 8, 2014) ("[N]ot excluding a *possibility* is far from conceding a probability. The preponderance of the evidence standard requires more than proof of a mere possibility."); Doe v. Sec'y of Health & Human Servs., 19 Cl. Ct. 439, 450 (1990) ("[A]n assertion that something is 'highly possible' does not rise to the level necessary to establish causation by a preponderance of the evidence[.]"); see also Moberly, 592 F.3d at 1322. In fact, Dr. MacDonald ultimately testified that there is no evidence to support the conclusion that the MMR vaccine can cause autoimmune epileptic encephalopathy. Tr. 223, 246, 260, 273-74.

Rather than relying on the Secretary's expert, petitioners would have been more persuasive if they had developed Dr. Shafrir's medical theory. But, Dr. Shafrir was unpersuasive. Consequently, petitioners failed to demonstrate that the MMR vaccine can cause an autoimmune epileptic encephalopathy, and failed to meet Althen prong 1.

V. Logical Sequence

The second element is to establish by preponderant evidence "a logical sequence of cause and effect" showing that the MMR vaccine did in fact cause Eilise's autoimmune epileptic encephalopathy. Althen, 418 F.3d at 1274. A logical presentation from petitioners would entail showing that Eilise's response to the MMR vaccine was consistent with the theory Dr. Shafrir articulated. See Hibbard v. Sec'y of Health & Human Servs., 698 F.3d 1355, 1364 (Fed. Cir. 2012); Dodd v. Sec'y of Health & Human Servs., 114 Fed. Cl. 43, 52-57 (2013); La Londe, 110 Fed. Cl. at 205. Another aspect of proof on this element is to consider the views of treating doctors. Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006) ("[T]reating 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.'")

The Moriartys' presentation on this point was spotty. In their direct examination of Dr. Shafrir, they asked relatively few questions about why he believed that the MMR vaccine specifically caused Eilise's epileptic encephalopathy. See Tr. 161. Later, the presiding special master asked Dr. Shafrir to elaborate. He explained that the basis for his finding a logical sequence of cause and effect was that: (a) the literature demonstrates that MMR vaccine can cause an encephalopathy, and (b) he did not identify any other cause for Eilise's condition. Tr. 216-17.

This reasoning is not adequate. As Dr. MacDonald noted, it would be illogical to find that because the cause of Eilise's problems has not been identified, the cause must be the vaccine. Tr. 244; see also Caves v. Sec'y of Health & Human Servs., 100 Fed. Cl. 119, 140-41 (2011) (explaining that the ruling out of other potentially known causes of a condition does not necessarily mean the vaccine caused the condition), aff'd, 463 Fed. Appx. 932 (Fed. Cir. 2012). More importantly, the Federal Circuit has consistently rejected reasoning based upon the postulates of "the vaccine can cause" a particular condition and "no other cause has been found." Hibbard, 698 F.3d at 1365-66 (Fed Cir. 2012); accord Moberly, 592 F.3d at 1323; Althen, 418 F.3d at 1278.

The gaps in the Moriartys' evidence are also reflected in their brief. Most of their argument regarding Althen prong 2 is devoted to explaining that Eilise suffers from an epileptic encephalopathy. The remainder of this section of their brief discusses the progression of Eilise's epileptic encephalopathy. While these aspects

are important, the Moriartys skip past the most important issue --- what caused the epileptic encephalopathy in the first place. See Pet'rs' Posthr'g Br. at 10-12.

The Moriartys' problem stems, in part, from the vagueness in Dr. Shafrir's theory for how the MMR vaccine can cause an epileptic encephalopathy. As described in the preceding section, the Moriartys maintain that Eilise epileptic encephalopathy was "immune-mediated." Pet'rs' Posthr'g Br. at 6. As also discussed in the preceding section, the Moriartys presented thin support for the theory that the MMR vaccine can cause an autoimmune epileptic encephalopathy. Hence, the Moriartys failed to meet their burden of proof on the first Althen prong.

Even if there were persuasive evidence that a vaccine can cause an autoimmune epileptic encephalopathy, petitioners are required to establish that Eilise suffered an autoimmune epileptic encephalopathy. See Hibbard, 698 F.3d at 1364, Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339, 1345 (Fed. Cir. 2010) (stating "a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case"). Dr. Shafrir identified few, if any, solid bases for his conclusion that Eilise suffered from an epileptic encephalopathy that was autoimmune in origin. He stated that "no specific clinical signs" are associated with autoimmune epileptic encephalopathy Tr. 214, 216. Instead, Dr. Shafrir was relying upon his "clinical experience" and the sequence of events in which the vaccination preceded Eilise's January 7, 2001 seizure. Tr. 214.

Dr. MacDonald, by contrast, testified that Eilise's presentation did not resemble an autoimmune epileptic encephalopathy. Tr. 293. These patients most commonly present with "lethargy, behavioral issues, confusion, speech loss, aphasia, a whole host of cognitive problems, balance problems, hemiparesis." Tr. 290. Additionally, objective evidence of an autoimmune encephalopathy may include brain swelling on an MRI scan, lateral and focal neurological damage, elevated white cells, and changes in gammaglobulin levels. Tr. 291. An autoimmune process that affects the brain is likely to be visible on an MRI. The MRI would be grossly abnormal and the EEG would show "total disorganization." Tr. 290. Seizures stemming from an autoimmune process would not be sporadic. Tr. 287.

As to whether Eilise suffered from an autoimmune epileptic encephalopathy, Dr. MacDonald was more persuasive than Dr. Shafrir. First, although Dr. Shafrir relied on his clinical experience, he admitted he was referring to only a few

patients. Tr. 193-96. Second, it is unusual for a disease not to have any typical clinical symptoms as Dr. Shafrir asserted. Dr. MacDonald was more credible when he provided a list of clinical signs and diagnostic assessments. Dr. MacDonald's persuasiveness on this topic was enhanced by the lack of contradiction from Dr. Shafrir. With respect to Eilise's clinical presentation, Dr. MacDonald stated he did not "know of any clinical scenario that [he] could accept where [there is] an ongoing autoimmune process that's damaging the brain" where there is a history of "a day and a half of fever and then two weeks with nothing." Tr. 260. Dr. MacDonald disagreed with the assertion that Eilise had autoimmune epileptic encephalopathy because in his experience, patients are "desperately sick" if they have immune-mediated encephalopathies that result in seizures. Tr. 276. Additionally, Dr. MacDonald's suggestion that an autoimmune process is likely to cause changes on neuroimaging studies rings true. See Ricci v. Sec'y of Health & Human Servs., No. 99-524V, 2011 WL 2260391, at *8-10 (Fed. Cl. Spec. Mstr. May 16, 2011), mot. for review denied, 101 Fed. Cl. 385 (2011). Dr. Shafrir, on the other hand, essentially identifies no criteria, and ultimately, his opinion that Eilise suffered from an autoimmune epileptic encephalopathy is not persuasive.

Moreover, Eilise's treating doctors did not identify her problem as autoimmune in origin. If they thought she was having an autoimmune reaction, then the proper course, according to Dr. Shafrir, would have been to prescribe intravenous immunoglobulin or steroids. But, the doctors did not, as Dr. Shafrir conceded. Tr. 215-16, 219. Dr. MacDonald's assessment of how Eilise's doctors would have responded was similar. In his view, Eilise's treating doctors did not think that her condition was autoimmune related because, at a minimum, they would have done a spinal tap. Tr. 272. The treatment ordered by Eilise's doctors, although not dispositive, tends to support Dr. MacDonald's opinion that Eilise did not suffer an autoimmune disorder. See Capizzano, 440 F.3d at 1326 (favoring views of treating doctors).

Finally, how the treating doctors viewed Eilise when they were treating her in 2001 makes relying upon later occasional statements linking the MMR vaccination to the onset of Eilise's seizure disorder problematic. Examples include Dr. Varia's report from 2004, exhibit 18 at 74 (stating Eilise had a "medically acknowledged MMR reaction, Lennox [Gastaut]), an occupational therapist's report from 2005, exhibit 18 at 42 (stating Eilise's "medical team attributed her seizures to a reaction to her MMR injection), and a speech pathologist's report from 2005, exhibit 18 at 62 (indicating that Eilise presented with an "expressive/receptive language delay as a result of seizure activity prompted by an

adverse reaction to an MMR vaccine in January 2001"). These passages occur in the parts of the reports giving Eilise's remote history. Presumably, the source of information for this material was Ms. Moriarty. While Ms. Moriarty may genuinely believe that the doctors attributed Eilise's seizure disorder to an adverse reaction to the MMR vaccine, she has not identified any record from a doctor directly. Regardless of the sincerity of Ms. Moriarty's belief, her views about causation are not persuasive because she is not a medical doctor. See 42 U.S.C. § 300aa—13 (stating the special master may not find in favor of the petitioner "based on the claims of a petitioner alone, unsubstantiated by medical records or medical opinion").

In short, although Dr. Shafrir claimed Eilise suffered an epileptic encephalopathy that was immune-mediated, he did not explain the basis for his opinion. Dr. Shafrir, for example, failed to list any clinical symptoms for an immune-mediated epileptic encephalopathy. In contrast, Dr. MacDonald provided an unrebutted list of symptoms and diagnostic signs most of which Eilise did not start experiencing in January 2001, when the alleged autoimmune epileptic encephalopathy began. Consequently, the Moriartys failed to demonstrate an autoimmune basis for Eilise's epileptic encephalopathy. Since Dr. Shafrir's theory proposes the MMR vaccine would cause an autoimmune reaction leading to epileptic encephalopathy, the petitioners' case is not logical. Eilise's presentation does not match Dr. Shafrir's theory. Therefore, they necessarily failed to establish Althen prong 2.

VI. Timing

In addition to presenting a reliable medical theory explaining how the MMR vaccine can cause an autoimmune epileptic encephalopathy and a logical sequence of cause and effect between Eilise's MMR vaccination and her autoimmune epileptic encephalopathy, the Moriartys must also show that Eilise's first manifestation of autoimmune epileptic encephalopathy occurred in a medically appropriate timeframe to infer causation. Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008). To satisfy the third Althen prong, the petitioners' burden is to present "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." Bazan, 539 F.3d at 1352; accord Shapiro v. Sec'y of Health & Human Servs., 101 Fed. Cl. 532, 542-43 (2011), reconsideration denied after remand, 105 Fed. Cl. 353 (2012), aff'd without opinion, 503 Fed. App'x 952 (Fed. Cir. 2013).

For the first aspect of the third prong of Althen, Dr. Shafrir relies upon the NCES. The NCES detected an increased risk that a person who received an MMR vaccine would develop an encephalopathy between 7-14 days after vaccination. Exhibit 39 at 29; Tr. 152-53. Dr. Shafrir shortened the anticipated interval because Eilise's MMR vaccination was actually a booster dose. For a booster dose, Dr. Shafrir expected any reaction (adverse or not) would be "faster . . . and stronger." Tr. 154.[17] Dr. MacDonald agreed that the second exposure to an antigen may produce a sooner reaction. Tr. 286.

For the second aspect of the third prong of Althen, the Moriartys maintain that Eilise started manifesting her epileptic encephalopathy on January 7, 2001, the day her brother witnessed Eilise moving unusually while watching television. Pet'rs' Posthr'g Br. at 13; Pet'rs' Posthr'g Reply Br., filed Feb. 3, 2014, at 2-3. Since Eilise received the MMR vaccine on January 2, 2001, exhibit 8 at 77, the interval between vaccination and onset is five days. The Moriartys also point out that since Eilise received her vaccination early on January 2, 2001, and her episode happened late on January 7, 2001, the interval is nearly six days. Pet'rs' Posthr'g Br. at 13.

The Secretary's primary argument on prong 3 is to question whether Eilise started having neurologic problems on January 7, 2001. Resp't's Posthr'g Br. at 16-18. As explained in the Facts, Dr. Shafrir and Dr. MacDonald dispute whether Eilise's episode on January 7, 2001 was a seizure.[18] And, as also discussed above, preponderant evidence established that Eilise did have a seizure on January 7, 2001.

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[17] According to petitioners, a stronger and faster response is part of the anamnestic response. Pet'rs' Posthr'g Br. at 13 n.10. While petitioners are probably correct, they should be mindful that assertions of counsel are not evidence. See United States Philips Corp. v. Windmere Corp., 861 F.2d 695, 707 (Fed. Cir. 1988).

[18] If Eilise did not manifest her epileptic encephalopathy on January 7, 2001, then her initial manifestation would be when she had a seizure on January 23, 2001. Exhibit 17 at 3. Under this scenario, the latency between vaccination and onset is 22 days.

The Moriartys did not present any basis for lengthening the longer interval found in the NCES, which was 15 days. Dr. Shafrir actually acknowledged that if Eilise did not have a seizure on January 7, 2001, then it would be difficult to establish a connection between the MMR vaccination and her epileptic encephalopathy. Tr. 187.

Whether petitioners met their burden of demonstrating a proximate temporal relationship between the date of vaccination and onset of symptoms is a close question. However, close calls are to be construed in the petitioners' favor. Althen, 418 F.3d at 1280. Although the Moriartys met their burden on this prong, establishing temporal association is not sufficient to establish causation in fact. Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992).

VII. Alternative Cause

For the reasons explained in the preceding sections, the Moriartys have not established Althen prongs 1 and 2. When petitioners fail to carry their burden, the Secretary is not required to present an alternative expression for the vaccinee's injury. Bazan, 539 F.3d at 1352. Nevertheless, the Secretary has proposed a reason for Eilise's neurologic problems and developmental delays – a deficiency in her ability to transport glucose. The specific medical term for this condition is glucose transporter I deficiency syndrome ("GLUT1"). See exhibit B (Dr. MacDonald's report) at 4 (proposing this diagnosis).

In addition to Dr. MacDonald's report, the Secretary submitted medical articles demonstrating that children with GLUT1 may suffer from developmental delay and seizures. The medical articles also stated people with this problem may benefit from the ketogenic diet because the brain substitutes ketones for glucose as an alternative energy source. Exhibit B, tab 7 (Jörg Klepper, Glucose transporter deficiency syndrome (GLUT1DS) and the ketogenic diet, 49 (Supp. 8) Epilepsia 46 (2008)) at 1.

Dr. Shafrir did not challenge the basic premise that GLUT1 may cause developmental delays. See Tr. 148-50, 188, 309. Instead, Dr. Shafrir questioned the conclusion that Eilise had GLUT1. He noted that none of Eilise's treating doctors proposed GLUT1 deficiency. Tr. 151.

Dr. MacDonald relied upon Eilise's medical history to support the possibility that Emily suffers from GLUT1. In his view, Eilise's developmental problems before and after the vaccination reflect one continual process that was apparent at a very early age. Tr. 242-46. In addition, Eilise improved dramatically after starting the ketogenic diet. This rapid improvement suggests that the underlying cause of Eilise's problems may have been metabolic. Tr. 236-37, 283.

Dr. Shafrir disagreed. He pointed out that after Eilise stopped the ketogenic diet, she did not deteriorate. In Dr. Shafrir's opinion, if the introduction of ketones stopped seizures, then the removal of ketones should lead to seizures. Tr. 188. Without referencing any specific articles, Dr. MacDonald maintained that some recent studies have presented examples of children who improved on the ketogenic diet and remained improved after leaving the diet years later. Tr. 237.

Ultimately, this debate is largely academic. The best evidence about whether Eilise suffers from GLUT1 is genetic and metabolic testing that was not performed in this case. See Tr. 151 (Dr. Shafrir noting that the doctors at Johns Hopkins did not request this testing), 238 (Dr. MacDonald stating that if Eilise were his patient he would suggest genetic testing). Although Dr. MacDonald proposed genetic testing in his September 19, 2012 report, exhibit B at 4, the Secretary did not formally request testing. In addition, as noted at beginning of this section, the alternative factor analysis is required only after petitioners otherwise demonstrate that the vaccine caused some harm. Because the Moriartys have not made this showing, further analysis of GLUT1 is not needed.[19]

VIII. Conclusion

Before her MMR vaccine, Eilise had developmental delay that was improving with therapy. On January 2, 2001, Eilise received her MMR vaccine. She developed seizures that started five to six days after the vaccine, and her seizures continued sporadically, until she started the ketogenic diet in June 2001.

Eilise's parents alleged that MMR vaccine can cause epileptic encephalopathy through an autoimmune process. However, the Moriartys' proof was not persuasive on this point, and they did not establish Eilise suffered an autoimmune disorder. Thus, the Moriartys are not entitled to compensation.

The Clerk's Office is instructed to issue judgment in accord with this decision.

IT IS SO ORDERED.

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[19] This outcome is consistent with the parties' briefing in that their submissions after the hearing did not discuss GLUT1.

s/ Christian J. Moran
Christian J. Moran
Special Master