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 23, 2016
	*	
v.	*	Entitlement; measles, mumps, rubella
	*	("MMR") vaccine; autoimmune
SECRETARY OF HEALTH	*	epileptic encephalopathy; decision on
AND HUMAN SERVICES,	*	remand.
	*	
Respondent.	*	
* *		

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

PUBLISHED DECISION ON REMAND DENYING COMPENSATION[1]

Marie Louise and Stephen Moriarty allege that the 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. The Moriartys seek compensation pursuant to the National Childhood Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10 through 34 (2012). Their

[1] The E-Government Act, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services), 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.

claim was denied, first by the undersigned special master, 2014 WL 4387582 (Aug. 15, 2014), and then by a judge of the Court of Federal Claims, 120 Fed. Cl. 102 (2015). However, the Federal Circuit vacated the August 15, 2014 decision, ordering reconsideration of the evidence. No. 2015-5072, 2016 WL 1358616, at *10 (Fed. Cir. Apr. 6, 2016).

In accord with the Federal Circuit's order, the undersigned has re-reviewed all the evidence after remand. This re-evaluation changes one aspect of the August 15, 2014 decision. While that decision had found that the Moriartys had not established that the MMR vaccine can cause an epileptic encephalopathy, this decision changes course. The Weibel article supports this finding.

However, a re-review of the record has not identified any persuasive basis for altering the outcome for another element of the Moriartys' case. Federal Circuit precedent indicates that even after the Moriartys present a persuasive case for the first Althen prong, to prevail on the second Althen prong, the Moriartys must establish, by a preponderance of the evidence, that Eilise's epilepsy was autoimmune in origin. They have not made that showing. Therefore, the Moriartys are not entitled to compensation.

I. Procedural History

A. Office of Special Masters[2]

For approximately eight years, it appeared that the Moriartys were alleging that vaccines caused Eilise to suffer autism. By the end of this time, the case had been assigned to Special Master Vowell. Special Master Vowell oversaw the case's development, including the submission of medical records, affidavits, and expert reports. The Moriartys submitted a report from Yuval Shafrir, M.D. Exhibit 35. In response, the Secretary filed a report from John MacDonald, M.D. Exhibit B.

Special Master Vowell scheduled a hearing on May 6, 2013. Order, issued March 1, 2013. She also set a deadline of April 5, 2013, for the submission of any

[2] The August 15, 2014 decision sets forth the procedural events through that date in more detail.

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 Special Master Zane.

In accord with the March 1, 2013 order, the Moriartys filed another report from Dr. Shafrir. Exhibit 37. 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.

Special Master Zane presided at the hearing held on May 6, 2013. Dr. Shafrir and Dr. MacDonald testified. Three other witnesses testified about Eilise's medical history: Harris Moriarty (her brother), Marie Louise Moriarty (her mother), and Stephen Moriarty (her father). After the hearing, Special Master Zane set a schedule for submitting briefs. Order, issued July 17, 2013.

Special Master Zane's tenure as a special master ended before she decided this case. Thus, the case was re-assigned to the undersigned. Order, issued Sept. 23, 2013. Both parties declined an opportunity for a second hearing. Pet'rs' Status Rep., filed Oct. 8, 2013; Resp't's Status Rep., filed Oct. 25, 2013. Both parties filed briefs.

The undersigned issued a decision on August 15, 2014. Initially, the undersigned made a finding about when Eilise first started experiencing symptoms of a neurologic disorder. Although the undersigned had not observed Harris Moriarty testify, the undersigned credited his testimony that Eilise made abnormal movements on January 7, 2001, which was five days after her vaccination. 2014 WL 4387582, at *4. This finding, in turn, was the predicate for a determination that the Moriartys established an appropriate temporal relationship, the third of the three prongs from Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). Id. at *16-17.

However, the undersigned also found that the Moriartys had not established the first or second Althen prong. The first prong requires the petitioners to present "a medical theory causally connecting the vaccination and the injury." Althen, 418 F.3d at 1278. The undersigned found that the Moriartys were claiming that Eilise suffered from an autoimmune epilepsy. Thus, to prevail, the Moriartys must have

established a theory that connected the MMR vaccine to autoimmune epilepsy. The undersigned found that Dr. Shafrir presented little evidence about autoimmune epilepsy.[3] In this context, the undersigned discussed two articles in particular, one by Pampiglione and the other by Gibbs, because Dr. Shafrir appeared to discuss only those two articles in his testimony. Citing Moberly v. Sec'y of Health & Human Servs., 85 Fed. Cl. 571, 598 (2009), aff'd, 592 F.3d 1315 (Fed. Cir. 2010), the undersigned stated: "When an expert does not explain the relevance of any article, a special master is not required to interpret the study without the benefit of an expert's guidance." 2014 WL 4387582, at *11. The undersigned's analysis of Althen prong one concluded with an examination of whether Dr. MacDonald's testimony that "it's possible" that the measles vaccine can cause epilepsy satisfied the petitioners' burden. The undersigned concluded that the testimony about a possibility was not the same as testimony about a probability. Thus, the undersigned found that the Moriartys did not meet prong one.

For the second prong of Althen, the undersigned found that the Moriartys' evidence was "spotty." "Dr. Shafrir identified few, if any, solid bases for his conclusion that Eilise suffered from an epileptic encephalopathy that was autoimmune in origin." 2014 WL 4387582, at *14. The undersigned found that this lack of persuasiveness was a basis for finding that the Moriartys did not carry their burden as established in Hibbard v. Sec'y of Health & Human Servs., 698 F.3d 1355, 1364 (Fed. Cir. 2012) and Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339, 1345 (Fed. Cir. 2010).

Separately, the undersigned also noted that Dr. MacDonald had raised the possibility that Eilise's epilepsy was metabolic in origin because she improved when on the ketogenic diet.[4] The undersigned did not resolve this issue, however, because it was superfluous and because the parties did not brief the issue. 2014 WL 4387582, at *17.

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[3] The undersigned also found that Dr. Shafrir presented more evidence that the MMR vaccine can cause a disease other than the disease afflicting Eilise, acute disseminated encephalomyelitis ("ADEM"). 2014 WL 4387582, at *11.

[4] The ketogenic diet is a diet that contains a large amount of fat with minimal amounts of protein and carbohydrate, in order to produce ketosis. Dorland's Illustrated Medical Dictionary 516 (32nd ed. 2012); Tr. 42.

B. Court of Federal Claims

The Moriartys filed a motion for review of the August 15, 2014 decision, challenging the outcome with respect to the first and second Althen prongs.[5] For Althen prong one, the Moriartys made several intertwined arguments. They argued that an acknowledgement that the MMR vaccine has been found to cause ADEM was a sufficient basis for finding that the MMR vaccine can cause autoimmune epilepsy. Pet'rs' Mot. for Review, filed Sept. 15, 2014, at 12. They argued that the special master wrongly focused on a limited part of Dr. Shafrir's testimony and erred in the assessment of the Pampiglione and Gibbs articles. Id. at 13-16. They also argued that the special master wrongly required them to establish the probability of their theory and erroneously did not credit Dr. MacDonald's testimony regarding possibility. Id. at 17-18.[6]

For Althen prong two, the Moriartys argued that they are not required to provide "direct proof of the autoimmune basis for [Eilise's] encephalopathy." Because the special master had looked for evidence that Eilise's epilepsy was autoimmune in origin, the special master employed "an impermissible level of proof." Id. at 20.

The Secretary filed a response to the motion for review. With respect to prong one, the Secretary appears to have taken slightly inconsistent positions. At one point, the Secretary argued that the first prong of Althen "requires a plausible medical theory linking the MMR vaccination with the specific injury alleged." Resp't's Resp. to Pet'rs' Mot. for Rev., filed Oct. 17, 2014, at 11. But, at another place, the Secretary contended that "Petitioners' medical theory needed to be 'persuasive.'" Id. at 14, quoting Moberly v. Sec'y of Health & Human Servs., 592 F.3d at 1322. In any event, the Secretary maintained that the special master's decision reflected a "thorough consideration of Dr. Shafrir's testimony in its

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[5] The petitioners did not address the possibility of an alternative cause. The motion for review mentioned the ketogenic diet only in the context of reciting Eilise's medical history.

[6] With respect to prong one, the Moriartys stated that "the Special Master was critical of the Petitioners for not discussing the literature during direct examination." Id. at 15. However, the Moriartys did not specifically argue that the special master failed to comply with section 13(a).

entirety, as well as his consideration of the literature cited as supportive of it." Id. at 12. The Secretary also addressed Dr. MacDonald's testimony about "possible." Id. at 13.

For prong two, the Secretary argued that the special master was not arbitrary in finding that the petitioners had not established that Eilise suffered an autoimmune encephalopathy. Id. at 15, 17-19. As to the potential alternative cause, the Secretary, like the Moriartys, mentioned the ketogenic diet only as part of Eilise's medical history.

The Court denied the motion for review. For prong one, the "Special Master reasonably determined that Petitioners failed to offer a reliable theory as to how the MMR vaccine can cause autoimmune epileptic encephalopathy, and thus he did not act contrary to law in concluding that Petitioners failed to prove the first prong." 120 Fed. Cl. at 107. For prong two, the special master's "finding that Petitioners did not prove that Eilise suffered from an autoimmune disorder is reasonable: there is very little evidence in the record supporting Petitioners' assertion of an autoimmune reaction." Id.

C. Court of Appeals for the Federal Circuit

The Moriartys filed a timely notice of appeal of the judgment that they were not entitled to compensation. In the summary of the argument section of their brief, the Moriartys maintained that the special master required more evidence than was legally permissible. They also contended that although the special master was required to consider the record as a whole, the special master erred by giving "little or no weight . . . to expert evidence presented in filed expert reports, or live testimony that is not given during direct examination." Brief for Petitioners-Appellants at 13, Moriarty, Petitioners-Appellants, v. Sec'y of Health & Human Servs., Respondent-Appellee, No. 2015-5072, 2015 WL 4068153, at *12 (Fed. Cir. June 24, 2015).

The Moriartys further developed these arguments. With respect to the first prong, the Moriartys argued that the special master was wrong to require more than a plausible theory. Id. at 23-24. The Moriartys also stated that the special master wrongly disregarded articles that Dr. Shafrir had discussed in his reports. Id. at 27-29. With respect to the second prong, the Moriartys argued that the "Special Master here again requires more than is permissible. Eilise's burden is not and cannot be to demonstrate how vaccines directly affected her body. She cannot be

required to prove an 'autoimmune basis' for her encephalopathy." Id. at 40-41.[7] The Moriartys concluded by requesting a reversal and a remand for assessment of compensation. Id. at 45-46.

The Secretary filed a response. Her summary was the "special master properly evaluated all of the relevant evidence and determined that Eilise did not have the injury alleged, autoimmune epileptic encephalopathy, and that [the Moriartys] had not established a reliable theory causally connecting the MMR vaccine to the alleged injury." Brief for Respondent-Appellee at 11, Moriarty, Petitioners-Appellants, v. Sec'y of Health & Human Servs., Respondent-Appellee, No. 2015-5072, 2015 WL 4877160, at *10.

The Moriartys' reply brief generally recast the arguments from their opening brief, including the argument that the special master wrongly rejected literature that was not discussed in oral testimony. See Reply Br. for Petitioners-Appellants at 17-18, Moriarty, Petitioners-Appellants, v. Sec'y of Health & Human Servs., Respondent-Appellee, No. 2015-5072, 2015 WL 5086426, at *17 (Fed. Cir. Aug. 21, 2015)

The Federal Circuit agreed with the Moriartys' argument that the special master erred in not considering articles that Dr. Shafrir had not discussed in his oral testimony. The Federal Circuit held that the Vaccine Act requires the special master to consider the record as a whole. In particular, the special master should have addressed an article by Weibel, which was relevant to prong one. The Federal Circuit did not directly review the prong two analysis. Because of the error on prong one, the Federal Circuit vacated the underlying decision and remanded for additional adjudication.[8] Moriarty, 2016 WL 1358616, at *10.

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[7] The Moriartys also asked: "Is there any evidence that her seizures, encephalopathy and developmental delays were likely caused by an unrelated factor?" They answered their question by stating "There is none." Id. at 16.

[8] Additional details about the Federal Circuit's opinion will be discussed below.

D. Office of Special Masters on Remand

In due course, the case returned to the Office of Special Masters. Although the undersigned requested that the parties explore an informal resolution, the parties could not resolve their differences. Thus, they filed briefs in response to a June 14, 2016 order. Because the August 15, 2014 decision had found that the Moriartys had established the appropriate temporal relationship, which corresponds to the third Althen prong, the June 14, 2016 order directed the parties to address the remaining issues, including Althen prong one, Althen prong two, and alternative cause.

In response, the Moriartys argued that "Eilise fits the description in the Weibel article cited by the [Federal] Circuit." Pet'rs' Remand Br., filed July 11, 2016, at 8. The Moriartys also argued that Eilise fits diagnostic criteria found in three other articles, which had not been filed into the record. The lead authors are Zuliani, Suleiman, and Graus. Exhibit 55 (Luigi Zuliani et al., Central nervous system neuronal surface antibody associated syndromes: review and guidelines for recognition, 83(6) J. Neurol. Neurosurg. Psychiatry 638 (2012)), exhibit 56 (Jehan Suleiman et al., Autoimmune epilepsy in children: Case series and proposed guidelines for identification, 54 Epilepsia 1036 (2013)), exhibit 57 (Francesc Graus et al., A clinical approach to diagnosis of autoimmune encephalitis, 15 Lancet Neurol. 391 (2016)).

The Moriartys were ordered to file those articles and file a supplemental brief. They did on July 18, 2016, adding a fourth article by Hacohen. Exhibit 58 (Yael Hacohen et al., Paediatric autoimmune encephalopathies: clinical features, laboratory investigations and outcomes in patients with or without antibodies to known central nervous system autoantigens, 84 J. Neurol. Neurosurg. Psychiatry 748 (2013)). In a single brief filed on July 29, 2016, the Secretary answered the arguments that the Moriartys made.

For the Zuliani, Suleiman, Graus, and Hacohen articles, the Secretary protested gently: "The Federal Circuit did not countenance re-opening the record on remand, for the court admonished the Special Master to consider the whole record already before him. . . . New literature simply distracts from the discussion of the extensive record and literature already filed." The Secretary also noted that two of the newly filed articles had been published in 2012 (exhibit 55 and exhibit 58) and in one in March 2013 (exhibit 56), which was a few months before the hearing. Only exhibit 57 was published after the hearing. Resp't's Remand Br.,

filed July 29, 2016, at 7. However, the Secretary stopped short of actually filing a motion to strike.

In the absence of a formal request from the Secretary, the undersigned will not remove the newly submitted articles from the record. And, of course, given the Federal Circuit's opinion and instruction, the undersigned has reviewed and considered those articles because they are now part of the record. The undersigned's review of these newly filed records would have been facilitated if the parties had presented an expert's interpretation of those articles.

The significance of the Zuliani, Suleiman, Graus, and Hacohen articles is set forth below in the analysis section, which follows the review of Eilise's history.

II. Eilise's Medical History[9]

A. 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. Her pediatrician was concerned about developmental delays. Exhibit 8 at 75-76; see also id. at 112-14.

After a speech and language evaluation on November 24, 1999, 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.

On May 1 and 24, 2000, Eilise went to the Devonshire Center to be evaluated for a special education preschool program. Testing showed that Eilise

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[9] As a predicate to the August 15, 2014 decision, the undersigned reviewed Eilise's medical records. The August 15, 2014 decision recited the events that were relevant to the outcome of the case. 2014 WL 4387582, at *2-9. The opinions of the Court of Federal Claims and the Federal Circuit were relatively consistent about the medical history. See 120 Fed. Cl. at 104-05; 2016 WL 1358616, at *1-2. Additional details can be found in those earlier adjudications.

was delayed in various skills, including communication. Exhibit 27 at 9, 12-17. After reviewing Eilise's assessments, the Fairfax County school system approved Eilise for special education services. Id. at 38-44.

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 before the vaccinations, but that she "definitely improved dramatically." Tr. 185.

B. 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 a 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.

On January 7, 2001, according to the testimony of Eilise's brother, Harris, Eilise arched her back, rolled her eyes back, and jerked her left side. Tr. 6-7, 10-11. The August 15, 2014 decision credited Harris's testimony. It also credited Dr. Shafrir's opinion that this behavior constituted a seizure. 2014 WL 4387582, at *4.

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 doctor noted that Eilise's only symptom was a fever and he prescribed an antibiotic, Zithromax. Tr. 29; exhibit 10 at 2.[10] Dr. MacDonald assumed that

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

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.

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.[11] Eilise's CT scan was normal. Exhibit 8 at 106.

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

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[11] In discussing this record, Dr. MacDonald stated that the word "encephalopathy" has many different meanings. Tr. 232. Without specifically defining the term, Dr. MacDonald asserted that Eilise was not suffering an encephalopathy, despite having had a seizure. 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"). On the other hand, Dr. Shafrir opined that when Eilise was admitted to Fairfax Hospital the next day, she was encephalopathic. Dr. Shafrir also provided this testimony without defining the term "encephalopathic." Tr. 169-70.

approximately two minutes involving left side jerking. Id. 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 showed only "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." In this report, Dr. Watkin noted that Eilise had not had a seizure since 8:15 A.M. Dr. Watkin did not otherwise describe Eilise's condition. 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.

After her seizures had been controlled, Eilise was discharged on January 28, 2001. 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.[12] Dr. Vining reviewed Eilise's MRI and EEG 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.

C. 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. 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.

On March 22, 2001, the Fairfax County school system reevaluated Eilise's eligibility for special education services. In this context, it was reported that "Optimal medication has not been achieved. Absences have been frequent due to continued seizures and hospitalizations." Exhibit 27 at 74. The IEP committee recommended additional assessments.

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[12] 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.

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. 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.[13]

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 having daily seizures, she was recovering from both the seizures and Todd's paralysis.[14] 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; accord Tr. 275. Dr. MacDonald added that although "isolated seizures are probably not dangerous," the repetitive daily seizures that Eilise was experiencing can "incapacitate[]" a child. 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

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[13] 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").

[14] 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 at 1378.

activity. Exhibit 7 at 85; see Tr. 200. It also indicated an evolving disorder. Tr. 280.

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").

Eilise was discharged on March 28, 2001. Exhibit 7 at 80. Dr. Elgin's diagnosis at discharge was complex partial seizure disorder. Exhibit 7 at 65, 123.

On April 2, 2001, Ms. Moriarty brought Eilise to Chiropractic Healing Center in Vienna, Virginia. On the "Personal History" form, Ms. Moriarty stated that a chiropractor from Atlanta, Georgia, Lee Hammer, stated that Eilise should be seen as soon as possible.[15] Ms. Moriarty's chief complaint for Eilise was that she was having "seizures / evolving seizure syndrome [with] the possibility of Lennox Gastaut emerging." Exhibit 2 at 2. In response to a question about injury, Ms. Moriarty wrote: "(immunizations)?" Id. Eilise returned for manipulation eight times over the next five weeks. Id. at 6. The chiropractor's notes seem to include a referral to the National Vaccine Information Center in Vienna, Virginia, to a neurologist who specializes in nutrition in Naples, Florida, and to a chiropractor in Houston, Texas. Id. at 7.

Contemporaneously with the visits to the chiropractor, Ms. Moriarty had three appointments with a physical therapist, Lynne Ganz, in Reston, Virginia. Ms. Moriarty wrote the goal was to achieve "relief from seizures w/out medications." Exhibit 5 at 3.

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[15] The connection between the Moriartys, who live in northern Virginia, and Dr. Hammer is not readily apparent. A search of the website for the Georgia board of professional licensing maintained by the Secretary of State reveals that Lee Hammer did maintain a chiropractic license from 1997 through 2004. On May 14, 2004, the Georgia Board of Chiropractic Examiners issued a public reprimand to Dr. Hammer for paying people to refer victims of automobile accidents to him. http://verify.sos.ga.gov/verification/.

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.

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.[16] 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.

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

D. 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 this time, Eilise was no longer taking any seizure medications. Id.[17] Eilise's last seizure had 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. Dr. Rubenstein also suggested updating evaluations in advance of the next IEP meeting, which took place on May 14, 2002. Exhibit 27 at 177-93.

After being on the ketogenic diet for nearly two years, Eilise returned to Johns Hopkins for a checkup. With respect to her seizure disorder, Dr. Eric Kossoff characterized Eilise as a "super-responder." Exhibit 4 at 9 (report dated April 15, 2003). Although Eilise had developed kidney stones while on the ketogenic diet, she 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.

In October 2003, Dr. Rubenstein echoed Dr. Kossoff's positive assessment. Dr. Rubenstein stated: "She is having about as good a result from the diet as possible." Approximately one month earlier, Eilise, who was not taking any anti-seizure medications, had an episode of pneumonia that required hospitalization.

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[17] 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.

But, during this illness, Eilise did not experience any break through seizures, which Dr. Rubenstein characterized as "really excellent." Exhibit 4 at 6. Dr. Rubenstein also wrote "It seems both improbable and wonderful, but we have arrived at the point where Eilise is going to come off the diet. We are optimistic that she will remain seizure-free." Id. 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 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 stop in 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.

In April 2004, the Moriartys again reviewed Eilise's eligibility for special education services through Fairfax County. See exhibit 27 at 133-48. The Moriartys were not satisfied with the services that Fairfax County offered and requested an opportunity to obtain independent assessments. Id. at 238. On July 8, 2004, the school system approved the Moriartys' request for an independent "psychological assessment, education evaluation, and speech/language assessment at public expense." Id. at 241. Rachna Varia, Ph.D., agreed to perform the independent educational evaluation. Id. at 243.

Dr. Varia evaluated Eilise in three sessions – on July 21, July 29, and August 24, 2004. Exhibit 18 at 74-83.[18] On the Stanford-Binet IV, Eilise placed in the "mildly mentally retarded range of cognitive ability." Id. at 74-75. Other test results showed deficits in language, attention, memory, sensorimotor, and visual-spatial skills. Id. at 81. In the language, visual-spatial, and memory domains,

[18] Dr. Varia's report appears in at least two places in the record: exhibit 18 at 74-84 and exhibit 27 at 254-64. In those places, Dr. Varia has not indicated when she wrote her report. However, a letter from Fairfax County public schools indicated that it had not received Dr. Varia's report by the date of its letter, which was September 8, 2004. Exhibit 27 at 129.

Eilise scored less than the first percentile. Id. at 77.[19] Dr. Varia's report noted that Eilise had a "medically acknowledged MMR reaction, Lennox Gasto [sic], which led to complex partial seizures and brain damage." Exhibit 18 at 74.

Five days before Dr. Varia's last evaluation session with Eilise, on August 19, 2004, Stephanie Cave, a doctor who practices in Baton Rouge, Louisiana, examined Eilise. Exhibit 20 at 17.[20] In the history of present illness section, Dr. Cave has written, in part: "Reaction to MMR / 2001 – Sz. Also had DTaP, polio. Diarrhea became severe summer 2001. High temp immediately speechless. By August talking again. On ketogenic diet. 3 year – October – Sz free." Id. After this day's work up, Dr. Cave assigned four diagnoses: (1) seizure disorder, (2) IBS [probably irritable bowel syndrome], (3) nutritional deficiencies, and (4) food intolerance. Dr. Cave ordered an extensive set of tests including one for myelin basic protein. Exhibit 20 at 10. The results from these labs appear in exhibit 20. However, there does not appear to be a comprehensive assessment from Dr. Cave about the significance of the testing.

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[19] Dr. MacDonald compared the results from the testing in May 2000 (before the vaccination and before the seizures), to the results from testing in April 2001 (after vaccination and seizures but before ketogenic diet), to the results from testing in July 2004 (after the ketogenic diet stopped the seizures). He pointed out that in the Preschool Language Scale-3 test from 2001, Eilise scored in the first percentile. See exhibit 27 at 16. She also scored in the first percentile on the Stanford Binet in 2002. See exhibit 27 at 95. Finally, Eilise scored in the first percentile on some portions of the Neuropsychological Development Test for Children in 2004. See exhibit 18 at 77. Thus, in Dr. MacDonald's view, after the doctors stopped the seizures with the ketogenic diet, Eilise returned to her pre-vaccination baseline. Tr. 242. The Secretary relied upon this testimony to argue that "there is no evidence establishing that the MMR vaccination caused a significant change in Eilise's mental, physical, or other deficits." Resp't's Post-Hearing Br., filed Nov. 25, 2013, at 20-21.

The Moriartys' response is to argue that although Eilise was developmentally delayed before vaccination, Eilise probably would have followed the developmental course of her sister who "blossomed." Pet'rs' Post-Hearing Reply Brief, filed Feb. 3, 2014, at 8. Dr. Shafrir expressed this opinion. Tr. 162-65.

Overall, comparing Eilise's abilities before and after vaccination is difficult. Opinions from specialists in pediatric development who administer the tests Eilise took could have been informative.

[20] Ms. Moriarty took Eilise to see Dr. Cave because Dr. Cave had written a book called "What Your Doctor May or May Not Tell You about Childhood Vaccinations." Tr. 75.

Meanwhile, the Moriartys continued their pursuit of independent evaluations in support of their request for additional special education services from Fairfax County. For example, on September 10, 2004, the school system approved a speech / language evaluation at Building Blocks Therapy. Exhibit 27 at 244. This evaluation took place on September 11 and 24, 2004. Id. at 292. At this time, Eilise was attending a private school. Id.; see also exhibit 27 at 328 (report dated June 17, 2005, noting that Eilise was returning to Fairfax County Public Schools after a year of homeschooling). Through the remainder of the 2004-05 school year, Eilise periodically received therapy at Building Blocks. See exhibit 8 at 28-30.

In February and early March 2005, Eilise had three evaluations done at Georgetown University Hospital. On February 15, 2005, Amanda Kim conducted a physical therapy evaluation. Exhibit 26 at 43-47. On February 22, 2005, Julie Konisberg conducted an occupational therapy evaluation. Id. at 48-53. On March 5, 2005, Jennifer Recupero conducted a speech and language evaluation. Id. at 40-42. The beginning of the three reports is virtually identical. Ms. Kim, Ms. Konisberg, and Ms. Recupero each stated that Eilise's "medical team attributed her seizures to a reaction to her MMR injection."

On April 11, 2005, Eilise began having speech and language therapy at the George Washington University Speech and Hearing Center.[21] She attended two sessions before the clinic closed due to the end of the semester. At the beginning of her status report, Kristen Evans (the clinician) wrote: "Eilise Moriarty is a delightful eight year old girl who presents with 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.

[21] The report actually uses the date April 11, 2004, not 2005. However, the context indicates that 2004 was a typographical error.

In June 2005, the Fairfax County public school system again assessed Eilise's eligibility for special education services. It found that she was eligible. Exhibit 27 at 328.

Eilise was continuing to receive various therapies at Georgetown University. As part of this process, Georgetown required physicians to prescribe these services. See exhibit 18 at 16. On August 19, 2005, Dr. Rubenstein from Johns Hopkins prescribed two hours per week of individualized speech and language therapy. In this context, he used diagnosis code "345.01."[22] Exhibit 26 at 9.

On October 11, 2005, Dr. Rubenstein saw Eilise again. He repeated his earlier statement that Eilise was a "super responder" on the ketogenic diet. He noted that Ms. Moriarty had "engaged a physician in Louisiana who is a specialist in metabolic analysis in children with developmental and neurological disorders and she is now on what sounds like a partial gluten-free, casein-free diet." Dr. Rubenstein also recorded that Eilise has "continued in the OT, PT, and speech and language programs at Georgetown University Hospital and this is ongoing assistance for her and has played a great role in her developmental progress." Exhibit 8 at 18. Dr. Rubenstein wrote another referral for therapy, again listing diagnosis code "345.01." Id. at 32. About one month later, Dr. Russo also prescribed various therapies and used diagnosis code "742.9."[23] Id. at 35.

Another prescription for therapy came from Ewa Brandys, a doctor at Kennedy Krieger Institute on January 26, 2006. Dr. Brandys did not assign a code on this prescription. Exhibit 26 at 5.

Dr. Brandys dictated a more thorough report about the January 26, 2006 examination in a report transcribed on February 6, 2006. The history of present

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[22] The International Statistical Classification of Diseases ("ICD") billing code of 345.01 represents a diagnosis of "generalized nonconvulsive epilepsy, with intractable epilepsy." Centers for Medicare & Medicaid Services, ICD-9-CM Diagnosis and Procedure Codes: Abbreviated and Full Code Titles, available at https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/codes.html (last visited August 11, 2016).

[23] The billing code of 742.9 represents a diagnosis of "unspecified congenital anomaly of brain, spinal cord, and nervous system." Centers for Medicare & Medicaid Services, supra.

illness section of Dr. Brandys's report is more or less consistent with the recitation in the preceding paragraphs, except Dr. Brandys does not mention that Eilise's first seizures occurred shortly after a set of vaccinations in January 2001. Dr. Brandys recorded that in June 2001, Eilise "was started on [the] ketogenic diet to which she responded with complete cessation of seizures." Exhibit 8 at 13. In the "review of systems" portion, Dr. Brandys stated that Eilise's "mom reports that she was diagnosed with increased mercury level; however, I have no medical records to review in this regard." Id. at 14. After physical and neurologic exams, Dr. Brandys listed the following problems: "developmental delay, history of intractable seizures [status post] ketogenic diet intervention, speech dysfunction, resolving right hemiparesis, gait dysfunction, fine motor impairment, shoulder girdle weakness right more than left." Id. (capitalization changed without notation). Dr. Brandys's impression included: "Eilise has been recovering from encephalopathy and intractable seizures which responded well to [the] ketogenic diet." Id. Dr. Brandys recommended various therapies. She also noted "metabolic and genetic consultations may be indicated if not done previously." Id. at 15.

As recommended, therapy continued at Georgetown but with some problems. See exhibit 18 at 8-12, exhibit 26 at 16-22, exhibit 26 at 1 (form for Dr. Brandys's signature using diagnosis code 315.32[24]). In April 2006, occupational therapy at Georgetown ended. On June 21, 2006, the Moriartys withdrew Eilise from additional treatment for reasons that are not necessary to describe in this decision. Exhibit 18 at 16-18.

In July 2006, Great Plains Laboratory performed various tests on Eilise's blood and hair. E.g. exhibit 19 at 11, 22, 31-33. These labs had been ordered by Dr. Mary Megson. On August 9, 2006, Dr. Megson completed a report. Eilise's titers for measles, mumps, and rubella were positive, as expected. Dr. Megson also wrote: "Do not repeat vaccine." Dr. Megson recommended a series of supplements and other treatments, concluding "This child needs to be treated quite gently." Exhibit 19 at 10-11.

[24] The billing code of 315.32 represents a diagnosis of "mixed receptive-expressive language disorder." Centers for Medicare & Medicaid Services, supra.

Dr. Megson ordered another set of laboratory studies, which Quest Diagnostics performed in August 2006. See exhibit 19 at 2-8. On September 6, 2006, Dr. Megson wrote Eilise's "labs are all fine except her rubella antibody titer is too high to measure," and recommended treatment with supplements. Dr. Megson added "I think the 4 year old MMR overwhelmed her immune system." Exhibit 23 at 15.

On December 14, 2006, Eilise had her second visit at the Kennedy Krieger Institute.[25] The author of this report (presumably, Dr. Brandys) states that after the first visit to Kennedy Krieger, "Eilise was consulted by Dr. Mary Megson from Richmond, Virginia, and she will be started on chathration therapy [sic].[26] It has to be mentioned that previously she was believed to have mercury toxicity. Her mother reports that Eilise was also recently found to have a high titer of rubeola [sic, presumably, rubella]; however, I do not have detailed records in this regard." Exhibit 8 at 7. Dr. Brandys records that "Eilise has made progress in gross and fine motor skills."

She wrote one paragraph about the potential cause of Eilise's illness, but did not reach any firm conclusions. The report states:

> The etiology of Eilise's seizures, encephalopathy, and decline [in] cognitive and motor function is still not completely clear; however, the family and her providers believe that she was exposed to some heavy metal toxicity and may have some immune system dysfunction which her mom describes as a "reaction to a vaccination". I do not have her medical records to provide a more detailed comment on the nature of her developmental dysfunction.

Id. at 8.

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[25] Within exhibit 8, the report is not complete. The signature page is missing. Because the author compares Eilise's current skills with the examination about a year ago, it seems likely that the author is Dr. Brandys.

[26] The phrase "chelation therapy" was probably intended.

On March 1, 2007, Dr. Megson wrote a short note. It stated:

> Urine porphyrins.
> You may want to be more aggressive getting out mercury here.
> Send urine for metals on PCA Rx[27]
> We can discuss on phone consult or follow-up visit. It's sad to see the truth isn't it?

Exhibit 23 at 11. The pages in the record that follow Dr. Megson's report are results from testing performed by a laboratory in Paris, France, reporting levels of urinary porphyrins. Id. at 12-14.

According to Ms. Moriarty's affidavit, Amy Yasko conducted genetic tests in 2011. Exhibit 51 ¶ 42. Exhibits 29 and 50 are records from Dr. Yasko, whose letterhead identifies her as a Ph.D. and holistic health practitioner, among other things. The relevance of this material is not clear. Dr. Yasko wrote a workbook, published by the Neurological Research Institute called Autism: Pathways to Recovery A Parents' Guide to Using Nutrigenomics to Optimize Children's Health. Exhibit 26 at 44-113. But, Eilise does not have autism and no one has otherwise explained the significance of the testing Dr. Yasko ordered.

At the time of the hearing in 2013, Eilise was 17 years old and would have normally been a junior in high school. Tr. 46.[28] 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 homeschooled 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.

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[27] A district court in Oregon has since entered a permanent injunction against the Oregon company that manufactures PCA-RX, among other products, to cease all manufacturing and distribution. United States v. Cole, 84 F. Supp. 3d 1159, 1169 (D. Or. 2015).

[28] In the Secretary's most recent brief, she asserted that Eilise was an honors student. Resp't's Remand Br. at 11, citing Tr. 79, 163. However, this assertion appears to be a misinterpretation of Ms. Moriarty's and Dr. Shafrir's testimony, who were describing Eilise's sister.

After the Federal Circuit's remand, the Moriartys were ordered to file updated medical records. Some of these recently filed medical records actually described treatment that occurred years earlier. See, e.g., exhibit 54 at 31-32 (a September 21, 2010 response to a "head, neck, and facial pain questionnaire," listing at least four health care professionals treating Eilise). A June 9, 2016 record from Brendan Stack describes problems with Eilise's mouth and sleeping. Exhibit 54 at 39.

Eilise has been seeing Dr. Margaret Gennaro, who appears to practice holistic medicine, since May 2013. Exhibit 61, passim. In conjunction with visits to Dr. Gennaro, Eilise has been receiving occupational therapy. Exhibit 60, especially exhibit 60 at 92 (re-examination report).

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). In an en banc decision, the Federal Circuit characterized the Althen factors as pleading requirements. Cloer v. Sec'y of Health & Human Servs., 654 F.3d 1322, 1333 n.4 (Fed. Cir. 2011) (en banc).

The burden of proof is preponderance of the evidence. Althen, 418 F.3d at 1278. The burden of the proof standard differs from scientific certainty and "close calls regarding causation are resolved in favor of injured claimants." Id. at 1280.

IV. Analysis

Each of the three prongs will be assessed below. The analysis begins with the third Althen prong (timing) because that aspect was already resolved. For the remaining two Althen prongs, the analysis repeats any statements by the appellate tribunals, weighs the relevant evidence, and considers the parties' arguments before reaching a conclusion.

A. Timing

The August 15, 2014 decision credited Harris Moriarty's testimony that his sister behaved unusually on January 7, 2001. This finding of fact in the Moriartys' favor allowed Dr. Shafrir to opine that Eilise's seizures developed within the time expected by medical science. Thus, the Moriartys prevailed on prong 3. 2014 WL 4387582, at *17.

B. 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 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. The specific mechanism is the production of antibodies against measles that attack the brain. Tr. 159.

The August 15, 2014 decision found that the petitioners did not provide evidence that demonstrated the reliability of Dr. Shafrir's opinion. Although the decision discussed the two articles that Dr. Shafrir discussed most extensively in his oral testimony (Gibbs and Pampiglione), the decision did not discuss articles that Dr. Shafrir had cited in his written report. 2014 WL 4387582, at *11.

The Federal Circuit ruled that the Vaccine Act requires the special master to consider all articles that Dr. Shafrir had cited – even those that he had not discussed in his testimony. A notable example, according to the Federal Circuit, is the article by Weibel. Exhibit 41 (Robert E. Weibel et al., Acute Encephalopathy Followed by Permanent Brain Injury or Death Associated With Further Attenuated Measles Vaccines: A Review of Claims Submitted to the National Vaccine Injury Compensation Program, 101(3) Pediatrics 383–87 (1998) ("Weibel")). This article "constitutes relevant scientific evidence." Moriarty, 2016 WL 1358616, at *6.

All of the four authors of the Weibel article worked for the Department of Health and Human Services. Three of the four authors are doctors and the fourth is an attorney within the Office of General Counsel.

The researchers evaluated claims that were filed in the Vaccine Program. The researchers looked for cases in which children (a) received some form of the mumps – measles – rubella vaccine between April 1970 and March 1993, and (b) developed, within 15 days of the vaccination, an acute encephalopathy of undetermined cause. The diagnosis of acute encephalopathy required "significant brain impairment including behavior changes with a depressed level of consciousness, ataxia, or seizures." The researchers excluded cases in which there was an infectious, toxic, traumatic, or metabolic cause of the encephalopathy.

The researchers identified 48 cases. They determined the onset of the encephalopathy with reference to the vaccine with zero meaning an inception on the day of vaccination. The remaining cases were plotted across the remaining 15 days. They presented their results in Figure 1.

The researchers expected that if the vaccinations were not affecting the incidence of encephalopathy, then a random distribution of cases would be approximately three cases per day (48 ÷ 16 = 3). However, their analysis actually showed a clustering of onset at days eight and nine with 9 and 8 cases, respectively. From this statistically significant finding, the researchers concluded "the finding is evidence for a causal relationship between further attenuated measles vaccine, alone or in combination, and acute encephalopathy of undetermined cause, followed by permanent brain impairment or death."

The authors also discussed a possible limitation with their study: "a lack of background encephalopathic rates in unvaccinated children." They later mention that in the 23 years of vaccination between 1970 and 1993, approximately 75 million children received the measles vaccine. The 48 identified cases "may include some nonvaccine cases representing background rates." The researchers also questioned the accuracy of 48 cases, noting that some people may not have sought compensation but also acknowledging that "most serious cases temporally related to a vaccination have been captured."

As mentioned, the Federal Circuit described Weibel as "relevant scientific evidence." The Moriartys quote this language in arguing that the Federal Circuit "clearly determined that there is evidence to support the conclusions that the MMR

vaccine can cause autoimmune epileptic encephalopathy." Pet'rs' Remand Br., filed July 11, 2016, at 2.

In contrast, the Secretary argues that the Federal Circuit did not order the special master "to rule in a particular way." Resp't's Remand Br. at 1. The Secretary contends that the Weibel article is "merely a data point that should be analyzed and considered." Id. at 2. The Secretary suggests that Weibel may not be the best evidence because it is 20 years old and the Secretary may have presented evidence to rebut the findings in the Weibel article. Id.

A problem, however, is that the Secretary has not identified any evidence that actually rebuts the finding in the Weibel article. Although Dr. Shafrir had cited Weibel in his second report, Dr. MacDonald did not comment on Weibel in his responsive report. Exhibits 37, C. Furthermore, after Dr. Shafrir barely mentioned the Weibel article in his testimony,[29] the Secretary did not elicit any testimony from Dr. MacDonald during his direct testimony.

During the Moriartys' cross-examination of Dr. MacDonald, they raised the Weibel article. Dr. MacDonald conceded that the Weibel authors had "indicated that cases of encephalopathy after MMR vaccine were well recognized and could be attributed to the vaccine." Tr. 253.[30] Dr. MacDonald countered that "from a science standpoint[,] the evidence is weak." Id. He later elaborated that a flaw in the Weibel study was that the researchers accepted so many patients with so many different conditions that the underlying cause could be different. In addition, Dr. MacDonald questioned the confidence in drawing conclusions from only 48 cases. Tr. 255-56. Although the Moriartys called Dr. Shafrir to testify in rebuttal, they did not ask him about Dr. MacDonald's criticisms of the Weibel study. See Tr. 300-19.

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[29] Another review of the hearing transcript reveals that Dr. Shafrir mentioned the Weibel article twice. Tr. 180, 217. However, in both instances, the author's name is spelled as "Vibal."

[30] The Moriartys' counsel then asserts — and Dr. MacDonald agrees — that the authors considered incidents of encephalopathy as many as 30 days after vaccination. Tr. 253. However, this representation does not appear to be correct as the Weibel study was limited to 15 days after vaccination. Likewise, counsel asserted that there were 59 cases between 1-25 days after vaccination. The basis for counsel's assertion is not readily apparent.

In trying to assess the value of studies like Weibel, the undersigned has consulted the Federal Judicial Center's Reference Manual on Scientific Evidence. A relevant portion states that in epidemiologic studies, researchers compare subjects to controls. Michael D. Green et al., Reference Manual of Scientific Evidence, Reference Guide on Epidemiology, 556 (3d ed. 2011). Another relevant factor, according to these authors, is selection bias. Id. at 583-85.

From other cases, the undersigned has learned that the Institute of Medicine ("IOM") considered the Weibel article in its 2012 report. The IOM found that the Weibel article did not assist its analysis of whether the MMR vaccine causes seizures due to a lack of controls. However, the 2012 IOM report is not in the record.[31]

Thus, the record contains sufficient persuasive evidence that the MMR vaccine can cause an epileptic encephalopathy through an autoimmune process. In creating the Vaccine Program, Congress established a presumption that the MMR vaccine causes an encephalopathy (as that term was defined in the Vaccine Act) that arises within 15 days of the vaccination. 42 U.S.C. § 300aa-14 (1994); cf. Terran v. Sec'y of Health & Human Servs., 195 F.3d 1302, 1307-08 (Fed. Cir.

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[31] Special masters may take judicial notice of material found in medical textbooks even after a hearing. Hines v. Sec'y of Health & Human Servs., 940 F.2d 1518, 1526 (Fed. Cir. 1991). The usual practice is to introduce the material into the record and then allow the parties to comment on it. E.g. Davis v. Sec'y of Health & Human Servs., No. 07-451V, 2012 WL 1357501, at *13 (Fed. Cl. Spec. Mstr. March 20, 2012), mot. for rev. granted in part and denied in part, 105 Fed. Cl. 627 (2012); Ramsay v. Sec'y of Health & Human Servs., No. 07-786V, 2011 WL 2463532, at *21 (Fed. Cl. Spec. Mstr. May 27, 2011).

Here, although the undersigned mentions the 2012 IOM report, the undersigned exercises discretion not to submit it into evidence. The Secretary could have filed the 2012 IOM report earlier. See Rodriguez v. Sec'y of Health & Human Servs., 91 Fed. Cl. 453, 460-61 (2010) (declining to take judicial notice of material offered in support of a motion for review), aff'd, 632 F.3d 1381 (Fed. Cir. 2011). Even after remand, the Secretary did not submit the 2012 IOM report. Furthermore, the limited time available for remand (see Vaccine Rule 28(b)) suggests that the special master's introduction of an article at this time could burden the parties.

Consequently, because the 2012 IOM report is not an exhibit, the undersigned has not relied upon it in any way in deciding the Moriartys' case. In future cases, an expert relying upon the Weibel article can expect to be asked questions about the validity of the Weibel methodology and the 2012 IOM's assessment of the Weibel study.

2000) (discussing Table as enacted originally). Although the Department of Health and Human Services ("HHS") modified the Vaccine Table in 1995, HHS retained the presumptive causal connection between MMR vaccine and encephalopathy. 60 Fed. Reg. 7678, 7692 (Feb. 8, 1995). Using a broad definition of encephalopathy, epileptic encephalopathy is simply one form of encephalopathy. Citing the Table, the Secretary essentially concedes this same point, stating "Respondent does not contend that MMR does not cause encephalopathy." Resp't's Remand Br. at 11 n.9.

The final question, then, is whether the MMR vaccine can cause an epileptic encephalopathy through an autoimmune process. Here, the Weibel article completes the Moriartys' case. The authors in Weibel wrote that the cause of the acute encephalopathy that follows measles infection is "obscure, but may be suggestive of an autoimmune encephalopathy." Exhibit 41 at 383.

This finding that MMR vaccine can cause epileptic encephalopathy through an autoimmune process sheds little, if any, light on the question whether Eilise's epilepsy was autoimmune in nature. The answer to this question depends, in part, on the diagnostic criteria for autoimmune epilepsy and, in part, on the Eilise's signs and symptoms. The views of treating doctors as well as the opinions of doctors retained in this litigation may be helpful in understanding how Eilise does or does not fit the criteria for autoimmune epilepsy. This evidence is reviewed in the following section.

C. Logical Sequence

The remaining 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, 698 F.3d at 1364; Dodd v. Sec'y of Health & Human Servs., 114 Fed. Cl. 43, 52-57 (2013); LaLonde v. Sec'y of Health & Human Servs., 110 Fed. Cl. 184, 205 (2013), aff'd, 746 F.3d 1334 (Fed. Cir. 2014). 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.")

1. Background: Procedural History, Relevant Precedents, and Scope of Remand

The August 15, 2014 decision found that the Moriartys had not established a logical sequence connecting Eilise's epilepsy with the theory Dr. Shafrir had presented. As discussed in the prong one analysis, Dr. Shafrir opined that the MMR vaccine can cause epilepsy through an autoimmune process. However, according to the August 15, 2014 decision, the Moriartys had not established that Eilise's epilepsy was autoimmune in origin. For precedent that the Moriartys are required to establish the autoimmune origin of Eilise's epilepsy, the August 15, 2014 decision cited Broekelschen, 618 F.3d 1339, and Hibbard, 698 F.3d 1355. 2014 WL 4387582, at *14.

In Broekelschen, a divided panel of the Federal Circuit held that "it was appropriate in this case for the special master to first determine which injury was best supported by the evidence presented in the record before applying the Althen test." 618 F.3d at 1346. The dissenting opinion maintained that the issue of diagnosis should be part of the Althen analysis. 618 F.3d at 1352.

In Hibbard, the parties agreed that the petitioner suffered from dysfunction in her autonomic nervous system (dysautonomia) manifested as postural tachycardia syndrome (POTS). 698 F.3d at 1363. Her expert proposed a theory in which a vaccine, through a process of molecular mimicry, can damage autonomic nerves. Thus, the special master reasoned: for the petitioner to prevail on Althen prong 2, the petitioner must demonstrate that she suffered from an autonomic neuropathy. Id. at 1362; see also Hibbard v. Sec'y of Health & Human Servs., No. 07-446, 2011 WL 1766033, at *9 (Fed. Cl. Spec. Mstr. Apr. 12, 2011). On the motion for review, the Court of Federal Claims characterized the question of whether the petitioner suffered from an autonomic neuropathy as "the underpinning on which Ms. Hibbard's entire case hinges." 100 Fed. Cl. 742, 749 (2011).

The Federal Circuit in Hibbard also endorsed the structure of the special master's decision. "In light of her expert's theory of causation, which depended on a showing of autonomic neuropathy, it was plainly necessary for her to make that showing in order to satisfy the second of the Althen factors." 698 F.3d at 1364. The Federal Circuit also ruled that the special master's finding that Ms. Hibbard

failed to demonstrate that she suffered from an autonomic neuropathy was not arbitrary and capricious. Id. at 1368.

From this legal foundation, the August 15, 2014 decision reviewed the evidence that Eilise suffered from a type of epilepsy that was autoimmune. The decision found that their presentation was "spotty" and, ultimately, unpersuasive. 2014 WL 4387582, at *14.

On the motion for review, the Court of Federal Claims agreed. "[T]here is very little evidence in the record supporting Petitioners' assertion of an autoimmune reaction." Moriarty, 120 Fed. Cl. at 107. On appeal, the Moriartys argued that they "cannot be required to prove an 'autoimmune basis' for her encephalopathy." Brief of Petitioners-Appellants at 40-46, 2015 WL 4068153, at *40-44. However, they made this argument without discussing Hibbard, the case on which the August 15, 2014 decision primarily relied.

In its opinion in the pending case, the Federal Circuit did not discuss the prong two analysis separately and did not address Hibbard. See Moriarty, 2016 WL 1358616, at *10. However, some comments do bear on the issue of diagnosis.

In the context of discussing the Weibel article, which provides support for the finding that the MMR vaccine can cause an autoimmune epilepsy, the Federal Circuit stated that: "This article unmistakably talks about Eilise's injury." Id. at *6. The Moriartys quote this passage repeatedly. Pet'rs' Remand Br. at 3, 4, 5 n.7, 9; Pet'rs' Supp'l Remand Br., filed July 18, 2016, at 8. In another part of its opinion, the Federal Circuit stated the Weibel article "squarely addresses the same disease allegedly suffered by Eilise: autoimmune encephalopathy caused by administration of a measles vaccine." The Secretary cited this passage, emphasizing the word "allegedly." Resp't's Remand Br. at 2.

The Federal Circuit's statement that the Weibel article "unmistakably talks about Eilise's injury" is the foundation for the first of two arguments that the Moriartys make suggesting that the evaluation of prong 2 can be curtailed. They argue that the Federal Circuit "clearly determined that there is evidence to support the conclusion that . . . Eilise's injury is an autoimmune epileptic encephalopathy." Pet'r's Remand Br. at 2.

In other cases, the Federal Circuit has defined its scope of review. Ordinarily, the Federal Circuit does not find facts. Deribeaux v. Sec'y of Health &

Human Servs., 717 F.3d 1363, 1366 (Fed. Cir. 2013); Munn v. Sec'y of Health & Human Servs., 970 F.2d 863, 868-71 (Fed. Cir. 1992); but see Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1375 (Fed. Cir. 2009) (finding that petitioners were entitled to compensation). The Federal Circuit has also stated that when one of its opinions does not resolve an issue, that opinion does not establish precedent binding on other panels with respect to the unresolved issue. Boeing North Am. Inc. v. Roche, 298 F.3d 1274, 1282 (Fed. Cir. 2002).

With this understanding of Federal Circuit precedent, the undersigned interprets the Federal Circuit opinion as leaving the prong two analysis to the undersigned. At the end of the opinion, the Federal Circuit states: "We therefore vacate the decision below and remand to allow the special master to consider the entire record including the relevant medical and scientific evidence, such as Dr. Shafrir's second report and the articles cited therein." Moriarty, 2016 WL 1358616, at *10. Consistent with this directive, the undersigned will consider the parties' remaining arguments with respect to prong two.

The Moriartys' second argument in favor of a shortened analysis comes from Capizzano. In instructing special masters to give particular attention to the views of treating doctors, the Federal Circuit stated that: "if close temporal proximity, combined with the finding that hepatitis B vaccine can cause RA [rheumatoid arthritis], demonstrates that it is logical to conclude that the vaccine was the cause of the RA (the effect), then medical opinions to this effect are quite probative." 440 F.3d at 1326. However, it does not automatically follow that proving prong one and proving three necessarily leads to a conclusion that prong two is proved as well. On the next page of the Capizzano opinion, the Federal Circuit stated that:

> The second prong of the Althen III test is not without meaning. There may well be a circumstance where it is found that a vaccine can cause the injury at issue and where the injury was temporally proximate to the vaccination, but it is illogical to conclude that the injury was actually caused by the vaccine. A claimant could satisfy the first and third prongs without satisfying the second prong when medical records and medical opinions do not suggest that the vaccine caused the injury, or where the probability of coincidence or another

> cause prevents the claimant from proving that the vaccine caused the injury by preponderant evidence.

Id. at 1327.

As the Federal Circuit stated in Moberly, Althen itself stated: "'neither a mere showing of a proximate temporal relationship between vaccine and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation.'" Moberly, 592 F.3d at 1323, quoting Althen, 418 F.3d at 1278.

In Althen, the Federal Circuit indicated that "more" was required and Capizzano gives some insight into what might satisfy the "more" requirement — "medical opinions." If the medical opinions are persuasive on prong two, then the petitioners carry their burden. If the medical opinions are not persuasive on prong two, then the petitioners do not carry their burden. An emphasis on "medical opinions" is consistent with the Federal Circuit's opinion in the case at hand. The Federal Circuit stated that "in certain cases, a petitioner can prove a logical sequence of cause and effect between a vaccination and the injury (Althen prong two) with a physician's opinion to that effect where the petitioner has proved that the vaccination can cause the injury (Althen prong one) and that the vaccination and the injury have a close temporal proximity (Althen prong three). While we believe that this is one such case, we hesitate to determine that in the first instance." Thus, to prevail on prong two, the Moriartys are required to produce "a physician's opinion."[32]

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[32] The Federal Circuit's statement about a physician's opinion needs elaboration in two respects. First, the simple presentation of any physician's opinion does not satisfy a petitioner's burden of proof. It cannot be the case that the Moriartys prevail simply because Dr. Shafrir has testified that there is a logical sequence of cause and effect between the MMR vaccination and Eilise's injury. If that were the case, then petitioners would always prevail. Instead, the Secretary is permitted to introduce evidence to rebut the petitioners' evidence. Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1353 (Fed. Cir. 2008); see also Moberly, 592 F.3d at 1325 (indicating that special masters have the responsibility to weigh evidence for its persuasiveness).

Second, the source of the opinion does not necessarily have to be a physician. The Federal Circuit indicated that a special master erred in giving less weight to the opinion of a person who obtained a Ph.D. in immunology but not obtained a medical degree. Koehn v. Sec'y

(…continued)

A special master may award compensation when "medical records or medical opinions" substantiate the petitioner's claim. 42 U.S.C. § 300aa-13(a)(1). The search for preponderant evidence that shows that Eilise's condition was autoimmune in origin begins in section 2 with the "medical records." Section 3 analyzes the "medical opinions" from Doctors Shafrir and MacDonald, who were retained to provide opinions. Section 4 continues the examination of evidence with a consideration of medical articles about autoimmune epilepsy. Lastly, for sake of completeness, section 5 reviews any statements from medical professionals that relate, favorably or unfavorably, to the question of the MMR vaccine harming Eilise.

2. Medical Records regarding Autoimmune Epilepsy

On the question of diagnosis, treating doctors stand in a highly favorable position. Unlike doctors retained in litigation who review only paper records, the treating doctor observes, examines, and listens to the patient. Dr. Shafrir recognized that his review of "medical records does not put me in any position to second-guess the treating physicians, unless I see a striking inadequacy of the evaluation or clinical conclusions." Exhibit 37 at 6.

Here, none of Eilise's treating doctors diagnosed her with an autoimmune injury. The treating doctors did not order any testing to detect an autoimmune disease and did not offer any treatments for an autoimmune disease. The Moriartys concede these points explicitly. Pet'rs' Remand Br. at 8.

The Moriartys attempt to minimize these points by arguing that "at the time Eilise was first admitted to the hospital . . . the entire concept of antibody mediated autoimmune encephalopathy was not even known." Pet'rs' Remand Br. at 8. There are two problems with this explanation.

First, the argument is not sourced to any evidence. What is the basis for asserting that the doctors who treated Eilise in 2001 did not know about autoimmune epilepsy? Assertions of counsel are typically not credited. Moreover,

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of Health & Human Servs., 773 F.3d 1239, 1244 (Fed. Cir. 2014). Thus, this decision later assesses statements that non-physician health care providers made about the nature of Eilise's injury.

some evidence seems to contradict the assertion. The Weibel article, which was so critical in determining that MMR vaccine can cause autoimmune epilepsy, was published in a well-known journal, Pediatrics, in March 1998. It seems likely that some doctors who treated Eilise in 2001, especially doctors from Johns Hopkins, would read Pediatrics and be familiar with autoimmune epilepsy.[33]

Second, even if the Moriartys had presented persuasive evidence that autoimmune epilepsy had not been discovered until after 2001, this finding would only serve the limited purpose of explaining the lack of evidence. Because the Moriartys bear the burden of proof, they must come forward with affirmative evidence to make an assertion (that Eilise suffered an autoimmune reaction) more likely than not.

Along the same line, the Moriartys argue that Eilise meets the clinical criteria for a diagnosis of autoimmune epilepsy and that "there is no objective evidence in the medical records to show that she did *not* meet other criteria." Pet'rs' Supp'l Remand Br. at 3 (emphasis in original). In making this argument, the Moriartys overlook the significance of the ketogenic diet.

The ketogenic diet eliminated Eilise's seizures and, therefore, changed the course of her life. After Eilise had been following the ketogenic diet for about one year, Dr. Kossoff wrote: "Considering how significant Eilise's seizures were with as many as 40 drop seizures per day, and an EEG which showed spike wave discharges, it is pretty dramatic in terms of improvement." Exhibit 4 at 10 (report dated July 23, 2002). About one year later, Dr. Rubenstein's description was essentially the same: "she is having about as good a result from the diet as possible." Id. at 6 (report dated Oct. 27, 2003). The Moriartys agree that Eilise "responded so well to the ketogenic diet . . . that she did not require immunotherapy." Pet'rs' Supp'l Remand Br. at 3.

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[33] In another case, the undersigned credited testimony that autoimmune epilepsy started appearing in medical journals in 1987. Kenney v. Sec'y of Health & Human Servs., No. 11-363V, 2015 WL 10012991, at *8 (Fed. Cl. Spec. Mstr. Jan. 16, 2015); but see Lehner v. Sec'y of Health & Human Servs., 08-554V, 2015 WL 5443461, at *17 (Fed. Cl. Spec. Mstr. July 22, 2015) (autoimmune encephalitis was discovered in 2005-07). The disparate findings in Kenney and Lehner suggest that counsel's assertions that are not based upon evidence should be considered carefully.

Does Eilise's positive response to the ketogenic diet provide any information about the underlying cause of her seizures? Dr. Shafrir testified that doctors understand why the ketogenic diet works only in two situations: in patients with a glucose transporter deficiency 1 and in patients with a pyruvate dehydrogenase deficiency. Tr. 148-49.[34] Later, Dr. Shafrir asserted that: "We have no idea why the ketogenic diet helps her." Tr. 190.

However, Dr. MacDonald suggested that Eilise's dramatic improvement on the ketogenic diet suggested she had either a GLUT1 deficiency or a pyruvate dehydrogenase deficiency. Tr. 237. In response to the special master's questioning, Dr. MacDonald stated that people are considering changing the name from the ketogenic diet to the metabolic diet. The reason for this change is that diet changes "something metabolically." Tr. 283. One article, which was discussed in passing during the hearing, states that the ketogenic diet "provides alternative fuel to the brain." Exhibit B, tab 7 (Jörg Klepper, Glucose transporter deficiency syndrome (GLUT1DS) and the ketogenic diet, 49 (Supp. 8) Epilepsia 46 (2008)) at 46. Another article, about which there was no oral testimony but is part of the record, indicates that the ketogenic diet can be a successful treatment for children suffering from global developmental delay who have a metabolic disorder. Exhibit B, tab 4 (D.J. Michelson et al., Evidence Report: Genetic and metabolic testing on children with global developmental delay, 77 Neurology 1629 (2011)).

Whether Eilise truly suffers from a GLUT1 deficiency or a pyruvate dehydrogenase deficiency cannot be established conclusively with the existing record. A conclusive diagnosis for GLUT1 deficiency requires genetic testing that Eilise has not had. Dr. MacDonald readily acknowledged that he could not diagnose Eilise with this condition. Tr. 238. But, at this stage of the analysis, establishing that Eilise had a GLUT1 deficiency is not the Secretary's burden. See LaLonde v. Sec'y of Health & Human Servs., 746 F.3d 1334, 1340 (Fed. Cir. 2014). When the Secretary raises a potential alternative explanation for the injury, the special master may consider any evidence as part of the prong 2 analysis. Doe 11 v. Sec'y of Health & Human Servs., 601 F.3d 1149, 1357-58 (Fed. Cir. 2010).

[34] Dr. Shafrir further opined that Eilise did not have a GLUT1 or a pyruvate dehydrogenase deficiency. Tr. 149-51.

The important fact is that a positive response to the ketogenic diet may mean that Eilise's disorder could be metabolic as Dr. MacDonald proposed. Tr. 283. Dr. MacDonald was not the only doctor interested in exploring a metabolic basis for Eilise's condition as Dr. Brandys also proposed that Eilise have a metabolic consultation. Exhibit 8 at 15.[35] Furthermore, the Michelson article proposes the ketogenic diet as a treatment for children with metabolic disorders. Exhibit B, tab 4. And, even more importantly, there appears to be no persuasive evidence that the ketogenic diet is a typical treatment for autoimmune disorders. Dr. Shafrir did not present any persuasive testimony connecting a child's diet with the functioning of her immune system.[36]

Overall, the medical records tend not to support a finding that Eilise's epilepsy was autoimmune. The medical records are either silent (neutral) on the topic because no testing was conducted or point away from an autoimmune origin. Without any persuasive support in the medical records, the undersigned will consider the opinions from Dr. Shafrir and Dr. MacDonald.

3. Medical Opinions from Retained Experts about Whether Eilise's Epilepsy Was Autoimmune

To support their claim, the Moriartys presented the opinion of Dr. Shafrir. He asserted that the MMR vaccine caused Eilise to suffer an epileptic encephalopathy that was autoimmune in origin. Tr. 160. While Dr. MacDonald

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[35] While Eilise had some metabolic testing, neither Dr. Shafrir nor Dr. MacDonald explained whether the results of this testing was informative about a metabolic basis for Eilise's seizure disorder.

[36] Some literature states that children, whose seizures the ketogenic diet stopped, should remain on the ketogenic diet through adolescence. Exhibit B, tab 6 (Wilhelmina G. Leen et al., Glucose transporter-1 deficiency syndrome: the expanding clinical and genetic spectrum of a treatable disorder, 133 Brain 655 (2010)) at 667. Dr. Shafrir agreed. Tr. 151.

After being weaned from the ketogenic diet when she was between seven and nine years old, Eilise remained free of seizures. Exhibit 4 at 6-7; exhibit 8 at 18. Why Eilise maintained her seizure-free condition is an interesting question especially because when Ms. Moriarty made mistakes in Eilise's diet in the beginning, Eilise relapsed into seizures. See exhibit 4 at 14; Tr. 41.

agreed that Eilise suffered from epilepsy, Dr. MacDonald did not see a basis for concluding that Eilise's problem was autoimmune. See Tr. 260, 272.

On the topic of autoimmune reaction, Dr. Shafrir and Dr. MacDonald part company. When testifying experts disagree, their qualifications and their reasoning are useful in weighing their opinions. See Hennessey v. Sec'y of Health & Human Servs., No. 01-190V, 2009 WL 1709053, at *42 (Fed. Cl. Spec. Mstr. May 29, 2009), mot. for rev. denied, 91 Fed. Cl. 126 (2010).[37]

a) Qualifications

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 "epileptologist." Tr. 145.

In responding to the undersigned's question about qualifications, the Secretary noted that "Dr. Shafrir has been criticized in other recent decisions by special masters" and cited four cases issued in 2015 or 2016 plus a fifth case from 2008. See Resp't's Remand Br. at 13 n.13. In most of those cases, the child-vaccinee was suffering from an autism spectrum disorder, although the petitioners and Dr. Shafrir in those cases attempted to characterize the underlying disease as something other than autism.

[37] Another useful factor for evaluating expert testimony is the consistency of the opinions with the vaccinee's medical records. This factor was considered in section 2 above.

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.

Because the Secretary had cited cases in which special masters were critical of Dr. Shafrir, the undersigned attempted to balance the information by searching for similar cases with respect to Dr. MacDonald. In a 2005 decision, the chief special master had a mixed, but ultimately favorable, view of Dr. MacDonald. The decision criticized Dr. MacDonald for employing a standard for finding causation that was "too high." English v. Sec'y of Health & Human Servs., No. 01-61V, 2005 WL 3485963, at *15 (Fed. Cl. Spec. Mstr. Dec. 1, 2005). Yet, the decision also found that Dr. MacDonald was "a far more persuasive witness. Dr. MacDonald's testimony comported with the records [and] literature." Id. at *19. Other decisions have found Dr. MacDonald to be credible and persuasive. Bowman v. Sec'y of Health & Human Servs., No. 06-349V, 2008 WL 4442591, at *7 (Fed. Cl. Spec. Mstr. Aug. 29, 2008); Carter v. Sec'y of Health & Human Servs., No. 04-1500V, 2007 WL 415185, *14 n.18 (Fed. Cl. Spec. Mstr. Jan. 7, 2007). From these and other cases, Dr. MacDonald appears to have a reputation as a competent expert. In short, his work falls within the middle spectrum — neither highly praised nor sharply criticized.

For the issue of autoimmune epilepsy, the experts' qualifications and backgrounds are relatively close. Dr. Shafrir had a fellowship in epilepsy. Tr. 301. Seeing children with epilepsy appears to be a part of Dr. Shafrir's day-to-day practice. His testimony regarding Eilise's possible autoimmune epilepsy, therefore, appears to flow more consistently with his field of expertise than in the cases in which the child has autism. In this regard, many of the cases the Secretary cited regarding Dr. Shafrir are distinguishable. R.V. v. Sec'y of Health & Human Servs., No. 08-504, 2016 WL 3882519, at *19-20, *41 (Fed. Cl. Spec. Mstr. Feb. 19, 2016); Lehner v. Sec'y of Health & Human Servs., No. 08-554, 2015 WL

5443461, at *45-48 (Fed. Cl. Spec. Mstr. July 22, 2015); Wright v. Sec'y of Health & Human Servs., No. 12-423, 2015 WL 6665600, at *2 (Fed. Cl. Spec. Mstr. Sept. 21, 2015). It also would be incorrect to paint Dr. Shafrir with a broad brush because an independent review has located at least one instance in which a special master credited Dr. Shafrir's opinion. Price v. Sec'y of Health & Human Servs., No. 11-442V, 2015 WL 7423070 (Fed. Cl. Spec. Mstr. Oct. 29, 2015) (crediting Dr. Shafrir's opinion that seizures were connected to an anaphylactic reaction that followed vaccination).

In other words, the persuasiveness of Dr. Shafrir's opinion rises or falls based upon the evidence in this case. His performance in those other cases does not affect the outcome in this case.

Dr. MacDonald, too, has experience with epilepsy. He is also an associate professor of neurology with the associated responsibilities of teaching medical students about the best practices in that discipline.

Any differences between Dr. Shafrir and Dr. MacDonald are more like differences in degree, rather than differences in kind. Therefore, the basis for Dr. Shafrir's conclusion will be considered.

b) Dr. Shafrir's Reasoning

In proposing that Eilise's epilepsy was autoimmune in origin, Dr. Shafrir faces an uphill climb, although the path is not insurmountable. Eilise was treated by a series of doctors between 2001 and 2003. Dr. Shafrir has not suggested that the doctors' care of Eilise fell short of what he expected in any way. By 2003, the doctors' recommendation of the ketogenic diet and Ms. Moriarty's faithful following of that regime had stopped Eilise's seizures. Throughout this time, the doctors did not explore an immunologic basis of the seizures. Consequently, the doctors did not order tests that could show (or not show) an adverse reaction in Eilise's immune system.

The basis for Dr. Shafrir's conclusion that Eilise's epilepsy is autoimmune is muddled. On direct examination, the Moriartys asked relatively few questions about the evidence allegedly indicating that Eilise's epilepsy was autoimmune. See Tr. 159-61. In this context, Dr. Shafrir testified: "I think the conclusion is that we have the onset of encephalopathy at the right time and we have the mechanism that exists in other conditions, and we don't have any other obvious explanations

. . . for the encephalopathy." Tr. 160. This appears to be the crux of Dr. Shafrir's reasoning.

The special master attempted to clarify the evidence on which Dr. Shafrir was relying for his conclusion about an immune reaction. Because his answers were not responsive, she asked follow up questions. See Tr. 209-17. When asked for the diagnostic evidence that an immune response attacks the brain, Dr. Shafrir answered: "I mean, the most important thing is the temporal association and the clinical experience." Tr. 210; accord Tr. 216. When pressed to explain what the clinical signs are, Dr. Shafrir responded "There [are] no specific clinical signs." Tr. 216.

Dr. Shafrir also explained that detection of antibodies is difficult. In some cases, doctors "actually isolated the antibodies." Tr. 211. But, the detection of antibodies "depends [on] what kind of antibodies her body produced in response to the vaccination." Tr. 214. In "the vast majority of the cases that we call postinfectious encephalopathies, we make an assumption based on clinical experience and temporal association and that's it." Tr. 211-12 (emphasis added).

Dr. Shafrir recognized that when doctors suspect an adverse reaction in the immune system, the treatment is intravenous immunoglobulin (IVIG) or high dose steroids. Tr. 159, 216. However, Eilise was not treated with IVIG or high dose steroids. Tr. 219.

After Dr. Shafrir's initial testimony concluded, Dr. MacDonald added some information about epilepsies that are autoimmune in origin.[38] He stated that the

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[38] In some parts of his testimony, Dr. MacDonald described the symptoms of his patients who have suffered immune-mediated seizures. Dr. MacDonald stated that most of his patients have suffered from either lupus or another immune-based disease, such as acquired immune deficiency syndrome. Tr. 276, 279. The August 15, 2014 decision cited this testimony in the context of presenting information about how children with autoimmune epilepsy would present. 2014 WL 4387582, at *15. On appeal, they argued that the decision erred in not recognizing that Dr. MacDonald's description pertained only to patients with lupus or AIDS. Brief of Petitioners-Appellants at 34, 2015 WL 4068153, at *33.

Upon further review of the transcript, the undersigned recognizes the Moriartys' point that Dr. MacDonald may have been speaking about patients with lupus or AIDS specifically, and not about autoimmune epilepsies more generally. But see Tr. 294-95. However, even if Dr.

(…continued)

cases he sees tend to be severe. Tr. 252. In children with an immune mediated response to a vaccine, there is "usually a rather dramatic picture." Tr. 290. "The MRI scans can be grossly abnormal. The EEGs show a total disorganization of brain function." Clinical signs could include: "lethargy, behavioral issues, confusion, speech loss, aphasia, a whole host of cognitive problems, balance problems, hemiparesis." Id. Dr. MacDonald asserted that when doctors suspect an autoimmune process, they order a spinal tap. Dr. MacDonald reasoned that because the doctors did not order a spinal tap, then the doctors must not have considered an autoimmune process. Tr. 272. Dr. MacDonald also excluded an autoimmune process because, in his view, it would be "very, very unusual" for seizures to start on one day (for Eilise, January 7), have a gap in seizures in which the patient was functioning normally, then resume seizures weeks later (for Eilise, January 22). Tr. 292-93.

Dr. Shafrir had an opportunity to address Dr. MacDonald's testimony during a rebuttal phase. In response to a leading question from the Moriartys' attorney, Dr. Shafrir indicated that after one seizure an ongoing immune process can cause seizures later. Tr. 306. Dr. Shafrir also distinguished lupus-based seizures. He considered a more apt analogy was NMDAR antibody encephalitis. For NMDAR antibody encephalitis, the patient has a normal MRI and usually has a normal spinal tap. The key diagnostic factor is the presence of certain antibodies. Tr. 307-08. Patients with NMDAR often go into a coma, especially when they are not treated early. Tr. 311. These patients are not treated with the ketogenic diet. Tr. 313.

On this record, the undersigned found that the Moriartys had failed to establish, more likely than not, that Eilise's epilepsy was autoimmune. 2014 WL 4387582, at *14. In denying the motion for review, the Court of Federal Claims stated "there is very little evidence in the record supporting Petitioners' assertion of an autoimmune reaction." 120 Fed. Cl. at 107.

After remand from the Federal Circuit, the undersigned has reviewed the record again. The information about Eilise's medical history has been expanded in

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MacDonald's testimony on this point were not relevant, the problems with Dr. Shafrir's testimony persist.

non-significant respects. See exhibits 53-54, 59-61. The basis for Dr. Shafrir's opinion, as expressed in the transcript, has not changed.

In Moberly, the Federal Circuit considered reasoning similar to the reasoning Dr. Shafrir employed in this case. In Moberly, the petitioner alleged the diphtheria-pertussis-tetanus (DPT) vaccine caused her daughter, Molly, to suffer seizures. According to the Federal Circuit, the special master found DPT can cause seizures in some circumstances. 592 F.3d at 1323; see also 2005 WL 1793416, at *2-6 (discussing NCES and reasoning based on NCES); but see id. at *28 (announcing shift in the special master's analysis of the NCES). Likewise, in this decision, the undersigned is finding that the MMR vaccine can cause autoimmune epilepsy, a seizure disorder. The ensuing question in Moberly was: did persuasive evidence show that the DPT vaccine caused the seizure disorder in Molly Moberly?

The Federal Circuit stated:

> The evidence before the special master-other than the expert testimony from Dr. Kinsbourne-consisted in essence of the following: Molly was healthy before she received her second DPT vaccination; she suffered seizures within 36 hours of receiving the vaccine; DPT vaccine is capable of causing seizures and permanent brain damage; and no alternative cause of her condition has been identified. As the special master noted, the problem with that evidence is that it amounts at most to a showing of temporal association between a vaccination and a seizure, together with the absence of any other identified cause for the ultimate neurological injury.

592 F.3d at 1323. Quoting Althen, 418 F.3d at 1278, Moberly continued: "neither a mere showing of a proximate temporal relationship between vaccine and injury, nor a simplistic elimination of other potential causes of injury suffices, without more, to meet the burden of showing actual causation." 592 F.3d at 1323.

The Federal Circuit also considered how the special master examined the opinion of Ms. Moberly's expert, Dr. Kinsbourne, who had asserted the vaccine led to a breach in the blood-brain barrier. The Federal Circuit ruled that the special master was not arbitrary in rejecting Dr. Kinsbourne's testimony because Dr.

Kinsbourne "conceded there was no evidence in the record suggesting that the proposed mechanism was at work in Molly's case." Id. at 1324.

Moberly is nearly perfectly on all fours with the present case. Like Molly, Eilise was more-or-less healthy before receiving her vaccination.[39] Like Molly, Eilise developed her first seizure a short time after vaccination (36 hours following DTP for Molly and five days following MMR for Eilise). As in Molly's case, the vaccination is capable of causing seizures and brain damage. Finally, Dr. Shafrir has ruled out other causes because he discounts the improvement on the ketogenic diet as not contributing to information about the etiology of Eilise's disorder.

In addition to the ketogenic diet, another way that the present case is not exactly the same as Moberly is that in Moberly, Dr. Kinsbourne "conceded" that there was no evidence that his theory actually occurred in Molly. Here, the analysis cannot be based upon a simple concession. However, Dr. Shafrir was asked several questions about evidence supporting his diagnosis and he did not identify anything more than the temporal association and unspecified clinical signs. See Tr. 209-17.

The Moriartys assert that they cannot produce any supporting evidence because the doctors did not order any relevant testing at the time. Pet'rs' Remand Br. at 8. On an appeal, they almost certainly will argue that this decision's search for evidence supporting the autoimmune nature of Eilise's symptoms was tantamount to a demand for scientific certainty. Cf. Pet'rs' Mot. for Rev., at 2 (the special master erred in "impermissibly . . . requiring . . . direct evidence of how the MMR vaccine created an autoimmune response rather than simply a logical sequence of cause and effect").

The Moriartys, like other petitioners in the Vaccine Program, do not have to establish their case with scientific certainty. Hodge v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993). But, even the preponderance of the evidence standard has meaning as Moberly demonstrates. The evidence from Dr.

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[39] To be precise, Eilise had actually received special education services for developmental delay before vaccination. Exhibit 27 at 9, 12-17. However, as noted by the Federal Circuit, the therapies seemed to be helping her. Moriarty, 2016 WL 1358616, at *1.

Shafrir regarding the vaccinee's response to the vaccination is not meaningfully different from the evidence from Dr. Kinsbourne in Moberly.

4. Medical Articles Discussing Autoimmune Epilepsy

The final category of evidence concerning autoimmune epilepsy are a set of medical articles that discuss that condition. Although most of these articles were filed after the Federal Circuit's remand, one article was prominent in the Federal Circuit's opinion.

The main reason the Federal Circuit vacated the undersigned's August 15, 2014 decision was a failure to consider the Weibel article. On remand, the Moriartys argue "Eilise fits the description in the Weibel article cited by the [Federal] Circuit." Pet'rs' Remand Br. at 8. Later, they note more than half of the 48 subjects in the Weibel article exhibited seizures and nearly half developed a seizure disorder. Id. at 9. The Weibel authors reasoned that an autoimmune process might explain an observed connection between natural measles infection and a subsequent encephalopathy. Exhibit 41 (Weibel) at 383.

The Secretary distinguished the Weibel subjects from Eilise's case. The Secretary argued in the epilepsy cases reported by Weibel, the "cases involved were far more severe than Eilise's episode." Resp't's Remand Br. at 10. Of the 34 children who exhibited seizures, Weibel reported that three children died. Among the survivors, "all . . . had chronic encephalopathy with mental retardation" and most "continued to suffer from a seizure disorder."

The parties' post-remand briefing did not identify any testimony in which either Dr. Shafrir or Dr. MacDonald compared or contrasted Eilise's condition to what Weibel reported. The undersigned's review of the transcript has not located any such testimony. Thus, the undersigned has attempted to interpret the Weibel article based upon his "accumulated expertise." See Hodge, 9 F.3d at 961.

Both parties' arguments about Weibel raise questions. The Moriartys appear to assume that simply because Eilise suffered epilepsy like some of the subjects in Weibel suffered, Eilise's epilepsy must be autoimmune. The Federal Circuit has rejected similar reasoning. See Hibbard, 698 F.3d at 1365 ("even assuming the medical plausibility of Ms. Hibbard's theory of causation—that the vaccine triggered an immune response that damaged her autonomic nerves—her failure to show that she had autonomic neuropathy would be fatal to her case").

All epilepsies are not autoimmune. According to Dr. MacDonald, in at least half the cases with a seizure disorder, the cause is not known. Tr. 223. For a more extensive discussion about classification of epilepsies, including autoimmune epilepsies, see Kenney, 2015 WL 10012991, at *7-8.

On the other hand, the Secretary's attempt to differentiate Eilise from the Weibel subjects appears based primarily on outcome. The children's outcome depends, in significant part, on treatment. Because Weibel studied children who were vaccinated as early as 1970, the treatment they received is not known. Without having some information about when anti-seizure medications and the ketogenic diet became available, it is difficult to know if the children are comparable to Eilise. Without the ketogenic diet, Eilise may have continued to have seizures until she, too, fell into the category once known as "mentally retarded."

The purpose of the Weibel article was to determine whether the MMR vaccine can cause encephalopathies, as that term was defined in the article. Its purpose was not to set forth diagnostic criteria for autoimmune epilepsy. As such, attempts by attorneys to pick bits and pieces from the article and reach conclusions about Eilise, even on a more-likely-than-not basis, would seem beyond the grasp of people lacking a medical degree. Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 549 (Fed. Cir. 1994) ("the special masters are not 'diagnosing' vaccine-related injuries").

One of the problems with using Weibel for diagnostic purposes, the lack of explicit criteria for autoimmune epilepsy, is solved in the set of newly filed articles. Unlike Weibel, the other four articles (Zuliani, Suleiman, Graus, and Hacohen) attempt to set forth some diagnostic criteria.

The undersigned, again without the benefit of any expert testimony, has reviewed the four articles. The diagnostic criteria largely seem to overlap. Therefore, the undersigned chooses to discuss Graus in more detail.[40]

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[40] The choice of Graus is based upon the following factors: (1) it was published most recently, (2) the authors appear to intend to capture as many cases of autoimmune encephalopathy as possible, (3) it was published in a well-respected journal, and (4) the authors disclaim the use of antibody testing, which Eilise did not have. However, the Graus authors

(…continued)

In Graus, the authors were concerned that the existing diagnostic criteria for autoimmune encephalitis depended too heavily on antibody tests and a response to immunotherapy. Exhibit 57 at 391. The problems with antibody tests are that they are not widely available, getting the results take time once available, and the tests cannot detect all antibodies. The problem with using response to immunotherapy is that the response to treatment does not help the clinician decide whether to initiate the therapy. Graus and colleagues wanted doctors to initiate appropriate therapy as soon as possible because "early immunotherapy improves outcome." Id. Thus, the authors proposed an algorithm to decide whether autoimmune encephalitis is possible, probable, or definite.[41]

The first step is determining whether autoimmune encephalitis is even possible for the person in question. The criteria for reaching this determination are:

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advise that "these guidelines should be applied with caution in children, particularly in children younger than 5 years." Exhibit 57 at 392. Although the Suleiman guidelines could have been used, Suleiman and colleagues rely heavily on testing for antibodies. See exhibit 56 at 1038. Eilise was not tested for antibodies.

[41] The other articles contain similar algorithms. Exhibit 55 (Zuliani) at 643, exhibit 56 (Suleiman) at 1039.

1. Subacute onset (rapid progression of less than 3 months) of working memory deficits (short-term memory loss), altered mental status, or psychiatric symptoms

2. At least one of the following:
    a. New focal CNS findings
    b. Seizures not explained by previously known seizure disorder
    c. CSF pleocytosis (white blood cell count of more than five cells per mm)
    d. MRI features suggestive of encephalitis

3. Reasonable exclusion of alternative causes

Id. at 393 (bullets in item 2 replaced with letters). All three criteria must be met.

Here, for criterion 1, "altered mental status" means "decreased or altered level of consciousness, lethargy, or personality change." Attempting to determine whether Eilise fits the category of "altered mental state" illustrates the challenges for the undersigned to reach informed conclusions without the benefit of testimony from an expert. Although this task is difficult and the Moriartys could have done more to assist in the fact-finding, the undersigned ultimately finds that Eilise satisfies this criterion.

The criterion itself requires some interpretation. Although the authors define "altered mental state" as "decreased or altered level of consciousness, lethargy, or personality change," these subsidiary terms are not further defined. For example, how long must the symptom persist? If the person is tired for one day, does that satisfy the term "lethargy?" Is "lethargy" the same as simple tiredness? How extensive does a change in personality have to be? How do medications affect the analysis, if at all? For example, what if a pharmaceutical causes a personality change? The Graus article appears not to answer these questions and testimony from someone who uses these criteria in everyday practice would clarify the Graus standards.

After the Graus criteria are understood, the next question is how Eilise compares to those standards. Here, although the July 12, 2016 order instructed the

Moriartys to explain how Eilise fit the diagnostic criteria by citing "medical records by exhibit number and page number," the Moriartys assert in a conclusory way that "Eilise fulfilled this criteria. Her parents described the mental changes." Pet'rs' Supp'l Remand Br. at 4. Citations to exhibit numbers and page numbers are absent.

Consequently, the undersigned has taken on the task of looking for evidence that is relevant (one way or the other) to whether Eilise suffered a decreased level of consciousness, lethargy, or personality change within three months of the vaccination. The evidence is mixed, but there is enough evidence to find in the Moriartys' favor.

The first witnessed event relating to Eilise's seizure disorder occurred on January 7, 2001 in the presence of her brother, Harris. In the next days, Eilise had a fever and her mother brought her to Dr. Comunale on January 9, 2001. Dr. Comunale's notes say "fever x 1 ½ days; no emesis diarrhea; stuffy nose or [illegible]." Exhibit 10 at 2.

According to Ms. Moriarty's affidavit, after the first event, Eilise experienced fevers and lethargy. Exhibit 51, ¶ 14. In her oral testimony, Ms. Moriarty also said that when Eilise visited Dr. Comunale, Eilise was suffering from fever and malaise. Tr. 82; see also Tr. 27 (seeming tired). Mr. Moriarty, too, testified about lethargy after the first incident. Tr. 121, 136.

However, this testimony about tiredness, malaise, and lethargy is not reflected in the records from Dr. Comunale. If Eilise were feeling so tired, wouldn't Ms. Moriarty inform Dr. Comunale about this symptom? See Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1515, 1528 (Fed. Cir. 1993).

Any tiredness was not terribly limiting as Eilise attended preschool later that week. Tr. 68. On January 30, 2001, after Eilise had a seizure at preschool and was hospitalized at Fairfax, Eilise saw Dr. Vining at Johns Hopkins. The Moriartys told Dr. Vining about the events that occurred that month. They told Dr. Vining that after the first episode that Harris saw, Eilise returned to her baseline. Exhibit 4 at 18. The information that Dr. Vining recorded is not consistent with Dr. Shafrir's assertion that after January 7, 2001, Eilise deteriorated. Tr. 187.

January 23, 2001, was the date of Eilise's next witnessed seizure. Initially, she was taken to Reston. In the emergency room, her general presentation was

noted as "mild distress" and "alert and acting in age appropriate manner." Later, she was described as having a normal mental state. Exhibit 24 at 6. These reports do not seem consistent with having a decreased level of consciousness, lethargy, or personality change.

Before she was discharged from Reston, Eilise had another seizure. This seizure prompted her transfer to Fairfax. Here, after a passage of a few days, one doctor described her as "still encephalopathic but improving." Exhibit 7 at 178 (Dr. Watkin's handwritten note dated January 27, 2001). Dr. Shafrir relied upon this statement to support his belief that Eilise was encephalopathic. Tr. 169-70. Thus, this report provides some support that Eilise had some decreased level of consciousness, lethargy, or personality change. However, the duration of this altered mental state could not have lasted for many days because she was discharged on January 28, 2001, "after . . . returning to her regular level of activity." Exhibit 7 at 161.

By the end of March 2001, Eilise was having more frequent seizures. To try to control the seizures, the doctors were prescribing different medications and increasing the dosage of the prescribed medications. But, with each breakthrough seizure, Eilise lost some of her abilities. Tr. 36-37. She lost her interest in dancing with her peers. Exhibit 51 (Ms. Moriarty's affidavit) ¶¶ 20-22.

Eilise's behavior in March 2001 satisfies the definition of "altered mental state." Her personality changed because she had a decreased interest in dance.

Fulfilling these three criteria advances Eilise to the level of only "possible" autoimmune encephalitis. The next level requires a stepwise evaluation of other conditions, including limbic encephalitis, NMDAR encephalitis, and Bickerstaff's brainstem encephalitis. Exhibit 57 (Graus) at 394. Dr. Shafrir did not indicate that Eilise had those conditions. Furthermore, Eilise's MRI did not show demyelination. The next steps require analysis of antibody testing that Eilise did not have. The Moriartys failed to present any affirmative evidence that Eilise was antibody positive. This sequence of steps leads to a question of whether Eilise fulfilled the criteria for antibody negative autoimmune encephalitis.

These criteria are found in panel 7. There, the authors wrote:

Diagnosis can be made when all four of the following criteria have been met:

1. Rapid progression (less than 3 months) of working memory deficits (short-term memory loss), altered mental status, or psychiatric symptoms
2. Exclusion of well defined syndromes of autoimmune encephalitis
3. Absence of well characterized autoantibodies in serum and CSF, and at least two of the following criteria
    a. MRI abnormalities suggestive of autoimmune encephalitis
    b. CSF pleocytosis, CSF-specific oligoclonal bands or elevated CSF IgG index, or both
    c. Brain biopsy showing inflammatory infiltrates and excluding other disorders (eg, tumour)
4. Reasonable exclusion of alternative causes.

Id. at 399 (bullets in item 3 replaced with letters).

The problem with Eilise's case concerns criterion 3. She did not have a spinal tap that would have led to testing on her cerebrospinal fluid. She did not have a brain biopsy. Her MRI was not suggestive of autoimmune encephalitis. Thus, the undersigned's conclusion — again made without expert assistance — is that Eilise does not qualify as "probable autoimmune encephalitis." In this situation, Graus and colleagues recommended that "alternative diagnoses should be reconsidered." Id. at 400.

Among the disorders listed in the differential diagnosis in patients with possible autoimmune encephalitis is "metabolic encephalopathy." Although Graus and colleagues do not define "metabolic encephalopathy," the phrase seems at least reminiscent of a disorder that could be cured with a ketogenic diet.

Overall, with respect to the articles, the Moriartys' strongest point is that the Weibel authors suggested that the children with an encephalopathy --- including children with seizures --- suffered an autoimmune process. The Moriartys analogize Eilise's case to those Weibel children.

Regardless of the merit (or lack thereof) to the Weibel article's conclusions in the world of medical research, the Moriartys need to present persuasive evidence to prevail in the Vaccine Program. Sections 2, 3, and 4 constitute an attempt to review the evidence and, ultimately, finds that the evidence of Eilise's having any autoimmune disorder to be lacking. In deciding the motion for review, the Court was much more succinct: "there is very little evidence in the record supporting Petitioners' assertion of an autoimmune reaction." Moriarty, 120 Fed. Cl. at 107.

5. Statements from Treating Medical Professionals about the MMR Vaccine as the Cause of Eilise's Illness

As explained previously, Federal Circuit precedent indicates that the Moriartys must establish, on a more likely than not basis, that Eilise suffered not just an epileptic encephalopathy but one that was autoimmune in origin. See Hibbard, Broekelschen, and Moberly. Thus, the preceding sections has examined whether any evidence persuasively shows that Eilise's problem was autoimmune.

However, even though Dr. Shafrir has proposed a theory involving autoimmunity, the Moriartys have — contrary to those precedents — claimed that they are not required to present preponderant evidence that Eilise's epileptic encephalopathy was autoimmune. Pet'rs' Mot. for Rev., at 2 (the special master erred in "impermissibly . . . requiring . . . direct evidence of how the MMR vaccine created an autoimmune response rather than simply a logical sequence of cause and effect"). If so, then the evidence from treating doctors about the vaccine harming Eilise in any way (not just through an autoimmune mechanism) becomes relevant.[42]

On the broad issue of whether the MMR vaccine caused an adverse reaction in Eilise, the record is largely not supportive. From the undersigned's review of the complete record, the following records appear relevant.

Within approximately three months of the onset of Eilise's seizures, Ms. Moriarty expressed some concern that "immunizations" caused her injury. Exhibit 2 at 2 (April 2, 2001 record from the Chiropractic Healing Center in Vienna,

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[42] Section 2 above has considered whether treatment records and reports are consistent with an autoimmune epileptic encephalopathy.

Virginia). However, the undersigned has not located any document in which a doctor was affirmative about the MMR vaccine causing an adverse reaction in Eilise for several years. For example, soon after the seizures started, Dr. Elgin from Fairfax stated "There seemed to be no precipitating factors causing the seizures. Exhibit 21 at 55 (report dated Jan. 28, 2001). Likewise, Dr. Vining at Johns Hopkins stated: "By history, it is difficult to assess the etiology of her seizures." Exhibit 4 at 19 (report dated Jan. 30, 2001).[43] Dr. Rubenstein, who was following Eilise at Johns Hopkins University, stated in October 2003, that Eilise's condition had an "unknown etiology." Exhibit 4 at 6-7.[44]

The earliest opinions supporting the claim that the MMR vaccination harmed Eilise appear to have been written in the summer 2004. Summer 2004 is after the Moriartys had filed their petition seeking compensation and also is shortly after the Moriartys started disputing the educational services Fairfax County was providing to them. See exhibit 27 at 238. Around this time, both Rachna Varia, a psychologist, and Stephanie Cave, a pediatrician, saw Eilise.

The history of present illness that Dr. Cave obtained begins: "Reaction to MMR / 2001 – Sz." Exhibit 20 at 17. Because this information is recorded as part of the history, the information almost certainly came from Dr. Cave's patient. And, because Eilise was seven (nearly eight) years old when Dr. Cave saw her, the source of information about Eilise's health in 2001, when Eilise was four years old, almost certainly was Ms. Moriarty.

The basis for Ms. Moriarty's belief, in turn, is both important and unclear. Understanding how Ms. Moriarty came to believe that Eilise's seizures in 2001 constituted a reaction to the MMR vaccine is important because a special master

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[43] Dr. Vining's opinion is enhanced because, according to Dr. Shafrir, she is "one of the leading epileptologists in the United States." Exhibit 37 (Dr. Shafrir report) at 2.

[44] Ms. Moriarty testified that Dr. Rubenstein told her that a connection between the vaccination and Eilise's condition was a "possibility." Tr. 77. As Ms. Moriarty recognized, Dr. Rubenstein did not express this possibility in any of his written reports. More importantly, a treating doctor's statement about a possibility does not advance a petitioner's claim at all. Paterek v. Sec'y of Health & Human Servs., 527 F. App'x 875, 883 (Fed. Cir. 2013) (treating doctor had testified causation was "not impossible").

may not find that a vaccine caused an injury "based on the claims of a petitioner alone, unsubstantiated by medical records or medical opinion." 42 U.S.C. § 300aa−13(a)(1). The substantiation for Ms. Moriarty's 2004 report to Dr. Cave is not readily apparent because the undersigned's review of the record has not identified any medical provider who wrote that the MMR vaccine caused Eilise's seizures. With respect to statements from treating doctors who concluded that a vaccine caused Eilise's health problems, the Moriartys have an interest in identifying any helpful evidence. The Moriartys, however, have also not cited any treatment records from earlier than Dr. Varia's report. See Br. of Petitioners-Appellants at 12, 2015 WL 4068153, at *11; Pet'rs' Mot. for Rev., filed Sept. 15, 2014, at 5.[45]

In any event, after Dr. Cave obtained this history about Eilise and examined Eilise, Dr. Cave ordered a series of labs, which appear in the record. Dr. Cave's assessment of those results is contained in a series of handwritten notes. For many tests, the results were either "negative" or "ok." For minerals, Dr. Cave wrote "all but calcium low." Exhibit 20 at 5. For organic acids, Dr. Cave wrote "This is the pattern I see in the metal toxic children." Id. at 6. Dr. Cave recommended supplements. For urine, Dr. Cave wrote "pre challenge — 10 metals — in reference range. I will be anxious to see her urine after challenge with DMSA."[46] Id. at 9. It appears that Dr. Cave did not explicitly confirm in a note she authored that Eilise suffered a reaction to MMR.

It is possible that Dr. Cave's report of Eilise's organic acid pattern as consistent with the pattern of "metal toxic children" could be construed as a link to a vaccine that introduced metal into Eilise's body. Such an interpretation would be unfortunate, however, and not in accord with medical science. The Office of Special Masters ("OSM") has evaluated Dr. Cave's work for more than a decade. The special masters have, as far as independent research has revealed, uniformly and consistently rejected Dr. Cave's work. Examples include: Hardy v. Sec'y of Health & Human Servs., No. 08-108V, 2015 WL 7732603, at *34 (Fed. Cl. Spec.

[45] Actually, the Moriartys have not even cited Dr. Cave's records.

[46] For information about DMSA, see Hazlehurst v. Sec'y of Health & Human Servs., No. 03-654V, 2009 WL 332306, at *64-72 (Fed. Cl. Spec. Mstr. Feb. 12, 2004), mot. for rev. denied, 88 Fed. Cl. 473 (2009), aff'd, 604 F.3d 1343 (Fed. Cir. 2010).

Mstr. Nov. 3, 2015); Miller v. Sec'y of Health & Human Servs., No. 02-235V, 2015 WL 5456093, at *8-12, 41-43 (Fed. Cl. Spec. Mstr. Aug. 8, 2015); Blake v. Sec'y of Health & Human Servs., No. 03-313V, 2014 WL 2769979, at *15 (Fed. Cl. Spec. Mstr. May 20, 2014); Nilson v. Sec'y of Health & Human Servs., No. 98-797V, 2005 WL 6122524 (Fed. Cl. Spec. Mstr. Aug. 31, 2005), mot. for rev. denied, 69 Fed. Cl. 678 (2006). Not only have the special masters found that Dr. Cave's opinions were not persuasive, the special masters found that Dr. Cave's opinions were "muddled [and] often illogical," Hardy, 2015 WL 7732603, at *34, and offered in fields "she lacks expertise in," including "developmental pediatrics, pediatric neurology, and pediatric immunology," Blake, 2014 WL 2769979, at *15.

For these reasons, special masters have refrained from compensating Dr. Cave. Miller, 2016 WL 3746160, at *9-10 (Fed. Cl. Spec. Mstr. June 3, 2016) (finding no reasonable basis to engage Dr. Cave as an expert); Hardy, 2015 WL 2015 WL 7732603, at *34 (placing petitioners on notice that retaining Dr. Cave is unlikely to be compensated). In the undersigned's experience, special masters warn that they will not compensate experts for their work only when the expert is extremely deficient. The fact that Dr. Cave falls within this group of discredited doctors greatly reduces the value of her opinion.

It is also notable that the Moriartys did not cite to Dr. Cave's records. The Moriartys' attorney did not address any questions about Eilise's treatment with Dr. Cave to either Mr. or Ms. Moriarty.[47] Dr. Shafrir, too, did not discuss Dr. Cave. See exhibits 35, 37. All these factors suggest that Dr. Cave's opinion is not a reliable basis for finding that the MMR vaccine caused an adverse reaction in Eilise.

As previously mentioned, Eilise's visit with Dr. Cave occurred around the same time as her appointments with Dr. Varia, the psychologist whom the Moriartys retained to assess Eilise's needs for special educational services from Fairfax County. The bulk of the eight-page single-spaced report explains Eilise's performance on various tests that Dr. Varia had administered to Eilise. For purposes of this decision, the more important portion of Dr. Varia's report is found in the "Relevant Background Information." In this context, Dr. Varia states "Eilise

[47] Ms. Moriarty testified briefly about Dr. Cave as part of cross-examination. Tr. 75-77.

has a medically acknowledged MMR reaction, Lennox Gasto, which led to complex partial seizures and brain damage. Mrs. Moriarty reports that the left side of Eilise's brain suffered the most damage." Exhibit 18 at 74.

Lennox-Gastaut syndrome "combines multiple seizure patterns associated typically with intellectual problems that may persist despite the seizures getting better, and then a very typical EEG pattern." Tr. 268 (Dr. MacDonald). Although on admission to the hospital on March 26, 2001, Dr. Elgin was worried about the possibility of Lennox-Gastaut, the March 27, 2001 EEG did not support Lennox-Gastaut. Exhibit 7 at 69-70 (admission notes), 27 (EEG). On April 18, 2001, Dr. Elgin listed the principal diagnosis as "other convulsions." Id. at 114. This sequence suggests that Eilise's treating neurologists did not diagnose Eilise with Lennox-Gastaut syndrome. Dr. Shafrir was explicit on this point: "I don't think that at any point she had the EEG of Lennox-Gastaut." Tr. 301.

These factors suggest that the history given to Dr. Varia about "a medically acknowledged MMR reaction, Lennox Gasto" was erroneous, at least as far as the Lennox-Gastaut portion. The portion of the report referring to "a medically acknowledged MMR reaction" remains unsettled. Like the history of present illness that Dr. Cave obtained, the context of Dr. Varia's statement suggests that the source of information was Ms. Moriarty. The Moriartys have not identified the doctor who "acknowledged" the MMR reaction. An independent review of the medical records suggests that the doctor could be Dr. Cave, but Dr. Cave's opinion on this topic is, for the reasons explained above, practically worthless.

Following Dr. Varia's report, the next set of records from a health care provider commenting on any cause for Eilise's epilepsy comes from therapists in February, March, and April 2005. This group of four records includes: (1) a physical therapy evaluation at Georgetown, (2) an occupational therapy evaluation at Georgetown, (3) a speech and language evaluation at Georgetown, and (4) a speech therapy report from George Washington. Exhibit 18 at 85-89, exhibit 18 at 42-47, exhibit 26 at 40-42, exhibit 18 at 62-63. The various statements from these therapists almost certainly represents a memorialization of a history provided by Ms. Moriarty. Physical therapists, occupational therapists, and speech therapists do not usually have the expertise or training to diagnose adverse reactions that occurred approximately four years earlier.

In October 2005, Eilise returned to Johns Hopkins, where Dr. Rubenstein saw her again. Dr. Rubenstein's history of present illness does not mention the

MMR vaccine but does state that Ms. Moriarty "engaged a physician in Louisiana who is a specialist in metabolic analysis in children with developmental and neurological disorders." Exhibit 8 at 18. Dr. Rubenstein reported that "Eilise has been successfully treated by the ketogenic diet for her severe atonic seizures." For diagnoses, Dr. Rubenstein reported "1. Static encephalopathy of unknown etiology. 2. Intractable atonic seizures, secondary to #1, off the ketogenic diet and seizure-free now for 9 months." Id. at 19. Dr. Rubenstein's characterization of the encephalopathy as having an "unknown etiology" is not consistent with saying that the MMR vaccine caused the encephalopathy.

A few months after seeing Dr. Rubenstein, Eilise had her first appointment with Dr. Brandys at Kennedy Krieger. The "history of present illness" is more or less accurate, although it omits any mention of the vaccinations in January 2001. In the context of a "review of systems," Dr. Brandys stated that Ms. Moriarty "reports that she was diagnosed with increased mercury level; however, I have no medical records to review in this regard." Exhibit 8 at 14 (report signed February 11, 2006).[48] Dr. Brandys did not say anything about the cause of Eilise's problems, although she noted, in the history of present illness, that Eilise responded to the ketogenic diet "with complete cessation of seizures." Id. at 13.

At some point in the summer 2006, Eilise saw Dr. Megson. See exhibit 19 at 32 (reporting, on July 15, 2006, results that Dr. Megson had ordered). In a handwritten passage located on the bottom of a form Dr. Megson used to report lab results, Dr. Megson stated "I think the 4 year old MMR overwhelmed her immune system." Exhibit 23 at 15.

Dr. Megson's reputation at the Office of Special Masters is similar to Dr. Cave's reputation. She has provided opinions that have been so unreliable that special masters have warned petitioners' attorneys not to retain her. Long v. Sec'y of Health & Human Servs., No. 08-792V, 2015 WL 1011740, at *19 (Fed. Cl. Spec. Mstr. Feb. 9, 2015); see also Doe 21 v. Sec'y of Health & Human Servs., No. 02-411V, 2009 WL 3288295, at *19-20 (Fed. Cl. Spec. Mstr. Jan. 16, 2009),

[48] Actually, a lab that Dr. Cave had ordered showed that Eilise's mercury was within normal levels. Exhibit 48 at 23.

mot. for rev. granted, 88 Fed. Cl. 178 (2009), reinstated sub. nom., Paterek v. Sec'y of Health & Human Servs., 527 F. App'x 875 (Fed. Cir. 2013).

Likewise, the Moriartys paid as little attention to Dr. Megson's opinion as they did to Dr. Cave's opinion. The Moriartys did not cite to Dr. Megson's report and did not bring forth any testimony about Dr. Megson's treatment of Eilise. Dr. Shafrir, too, did not discuss Dr. Megson.

The most recent record from a doctor treating Eilise that discussed the cause of Eilise's problem came from Dr. Brandys at Kennedy Krieger. The medical summary and interval history again omits the January 2001 vaccination. Dr. Brandys does record that Dr. Megson was consulted and recommended chelation therapy. Dr. Brandys commented:

> The etiology of Eilise's seizures, encephalopathy, and decline [in] cognitive and motor function is still not completely clear; however, the family and her providers believe that she was exposed to some heavy metal toxicity and may have some immune system dysfunction which her mom describes as a "reaction to a vaccination". I do not have her medical records to provide a more detailed comment on the nature of her developmental dysfunction.

Exhibit 8 at 8.

Dr. Brandys's second report appears to complete the list of reports from treating health care providers that commented about the possible cause of Eilise's problem. Some of these health care providers were therapists who almost certainly were reciting information Ms. Moriarty gave to them. Among physicians, two doctors from respected institutions (Johns Hopkins University and Kennedy Krieger Institute) described the etiology as "unknown." The only doctors who appear to have reached an independent conclusion that the MMR vaccination caused an adverse reaction in Eilise were Dr. Cave and Dr. Megson.

As previously explained, Dr. Cave and Dr. Megson happen to be among the few doctors whom special masters have discredited. Their reputations make accepting their opinions difficult. However, an expert's reputation and track record at OSM is not the only basis for accepting or rejecting an expert's opinion

in a particular case. See LaLonde, 110 Fed. Cl. at 208 (discussing Dr. Kinsbourne). The undersigned has independently reviewed the medical records, which primarily consist of results of laboratory tests, from both Dr. Cave and Dr. Megson. The undersigned cannot ascertain the basis for any conclusion that the MMR vaccine harmed Eilise. In this regard, testimony from Dr. Shafrir could have helped illuminate the reasoning from Dr. Cave and/or Dr. Megson. But, in the absence of any helpful explanation from Dr. Shafrir, the undersigned cannot give any appreciable weight to opinions from Dr. Cave or Dr. Megson.

As part of the Federal Circuit's remand, the undersigned has re-reviewed all of Eilise's medical records, looking for information from treating doctors to substantiate the Moriartys' belief that the MMR vaccine harmed their daughter. The undersigned has not located any persuasive evidence from a treating doctor.

V. Conclusion

The August 15, 2014 decision found that the Moriartys had failed to establish Althen prong one and Althen prong two. The Federal Circuit vacated the judgment based on this decision, emphasizing an error with respect to Althen prong one but leaving Althen prong two largely unreviewed.

In accord with the Federal Circuit's instruction, this decision finds a different outcome for Althen prong one. However, the Moriartys have not shored up the deficiencies in their proof regarding Althen prong two. Thus, they cannot be awarded compensation.

The Clerk's Office is instructed to issue judgment in accord with this decision. Pursuant to Vaccine Rule 28.1(a), the Clerk's Office is also instructed to transmit this decision to the presiding judge.

IT IS SO ORDERED.

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