In the United States Court of Federal Claims

No. 14-65V
(Filed: April 18, 2019)[1]
Opinion originally issued under seal on April 2, 2019

HEIDI SHARPE, as legal representative of her minor child, L.M., Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	)	Vaccine; Encephalopathy; Table Significant Aggravation; Off-Table Significant Aggravation; Qualifications and Aids to Interpretation.

Curtis R. Webb, Twins Falls, ID for petitioner.

Amy P. Kokot, Civil Division, United States Department of Justice, Washington, D.C., with whom were *Joseph H. Hunt*, Assistant Attorney General, *C. Salvatore D'Alessio*, Acting Director, *Catherine E. Reeves*, Deputy Director, and *Heather L. Pearlman*, Assistant Director, for respondent.

O P I N I O N

FIRESTONE, *Senior Judge*

Heidi Sharpe ("petitioner"), as the legal representative of her daughter, L.M.,

[1] Pursuant to Rule 18(b) of Appendix B of the Rules of the United States Court of Federal Claims ("RCFC, App. B"), this Opinion was initially filed under seal on April 2, 2019. The parties had fourteen days from the date of filing of this Opinion to propose redactions of any of the information herein. Neither party submitted any redactions.

seeks review of the Special Master's Decision Denying Entitlement under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 ("Vaccine Act" or "Act"), as amended. *Sharpe v. Sec'y of Health & Human Servs.*, No. 14-65V, 2018 WL 7625360 (Fed. Cl. Spec. Mstr. Nov. 5, 2018) ("Decision" or "Dec.") (ECF No. 102).

I. BACKGROUND

A. Factual Background

The essential facts of this case are set forth in the Special Master's Decision, *see generally* Dec. at 2-7, and may be summarized as follows. L.M. was born on July 26, 2010. Dec. at 2. Over the next six months, she received routine childhood vaccinations without incident, including Pediarix (diphtheria-tetanus-acellular pertussis ("DTaP"), hepatitis B, and inactivated polio), haemophilus influenzae type B ("Hib"), pneumococcal conjugate, and rotavirus. *Id*. On January 17, 2011, L.M. had a well-child visit. *Id*. Petitioner stated that L.M. had developed symptoms of an upper respiratory infection ("URI") and a rash; she was diagnosed with a viral infection that causes rashes, but she was otherwise healthy. *Id*. at 2, n.4. L.M.'s vaccinations were postponed due to her illness. *Id.* at 2. The next day, petitioner brought L.M. to the emergency room reporting "inconsolable crying" for one hour; her examination was normal. *Id*.

On February 2, 2011, petitioner brought L.M. to her doctor's office describing congestion and thick nasal drainage for six weeks. *Id.* at 3 (citing Petitioner's Exhibit ("Pet. Ex.") 2 at 8). L.M. was diagnosed with congestion, and an antibiotic was prescribed. Dec. at 3.

On February 10, 2011, L.M. received her third DTaP, Hib, and pneumococcal

conjugate vaccinations. Dec. at 3. The next afternoon, petitioner phoned L.M.'s pediatrician, reporting that L.M. "had 'developed a fever and [was] whimpery [and] wak[ing] up "screaming."'"[2] *Id.* (quoting Pet. Ex. 2 at 19). Petitioner stated that L.M. had not reacted to her previous immunizations she received in the fall. *Id.* L.M.'s doctor "proposed 'that this [was] most likely not related to the injections,' and attributed L.M.'s symptoms to a possible viral illness[.]" *Id.*

On February 15, 2011, petitioner brought L.M. to the emergency room because she "had 'suddenly become "stiff all over" [and] unresponsive,'" which had lasted approximately thirty seconds. Dec. at 3. During the episode, L.M. was afebrile. *Id*. Petitioner conveyed that one month earlier, L.M. had "experienced an 'unexplained episode of sudden flaccidity [and] unresponsiveness' for approximately thirty seconds, followed by several minutes of crying and irritability." *Id*.; *see also id.* at 8 n.10 (stating that petitioner recounted "'a few other episodes of [L.M.] "spacing out" where she had a strange look in her eye and was not responsive for several seconds'"). L.M.'s temperature was 97.5 degrees Fahrenheit, and she was alert. *Id.* at 3. Yet she was observed to have "'floppy' motor control and skills" and poor head control. *Id.*

Later that day, L.M. had another seizure, and she was transferred to St. Vincent Hospital. *Id.* at 4. During her stay, she had an evaluation with Tarif Bakdash, M.D., a

[2]Petitioner contacted L.M.'s doctor's office and the emergency room earlier in the day as well on February 11, 2011, and she filed phone records to document these calls. *See* Pet. Ex. 73 at 17; Pet. Ex. 74 at 1-2. She averred that on February 12 and 13, 2011, L.M. had a high fever and displayed "floppiness and an uncharacteristic disinterestedness." Dec. at 3. Petitioner claimed that she phoned the emergency room twice to report these concerns, and she was "rebuffed," although no records confirm these calls. *Id.*

pediatric neurologist. *Id.* Petitioner described L.M. as "'being hypotonic or floppy' since birth." *Id.* Dr. Bakdash summarized L.M.'s seizure-like activity, which included three spells over the past twenty-four hours. *Id*. His impression was that L.M. suffered from a generalized seizure pattern and infantile spasms. *Id*.

The following day's electroencephalogram ("EEG") revealed hypsarrhythmia, a "primary clinical characteristic of infantile spasms." *Id.* On February 17, 2011, L.M. was discharged with a diagnosis of infantile spasms, also known as West Syndrome. *Id.*. at 5. Although L.M. had returned to her pre-hospitalization baseline (with some generalized hypotonia), she returned to the emergency room on March 21, 2011, due to ongoing seizures and URI symptoms. *Id*. At that time, L.M. was having five or six seizures per day. *Id.* Upon discharge, she had no new diagnoses. *Id*. (citing Pet. Ex. 3 at 57).

Throughout the remainder of 2011, L.M. had several appointments with Dr. Bakdash and with her pediatrician. *Id*. at 5. Another EEG, performed on April 18, 2011, again showed hypsarrhythmia, as well as new-onset seizure activity in the left temporal region. *Id*. As of November 8, 2011, Dr. Bakdash's differential diagnoses for L.M. included infantile spasms, complex partial seizures, and global developmental delay. *Id.* at 6 (citing Pet. Ex. 7 at 8)

Other specialists also evaluated L.M. *Id*. On October 27, 2011, Laura Nicholson, M.D., a developmental and behavioral pediatrician, "diagnosed L.M. with static encephalopathy with epilepsy." *Id.* She concluded that L.M.'s condition "appeared metabolic, 'with a sudden onset with the stress of the six month shots, recurrent

regression with illness . . . [i]t looks like a mitochondrial disorder . . . but the initial labs do not show acidosis.'" *Id.* (quoting Pet. Ex. 10 at 357-58).

Samuel Yang, M.D., a geneticist, examined L.M. on December 8, 2011. *Id.* at 6. He observed that although L.M.'s EEG was consistent with infantile spasms, "her clinical picture and lack of response to steroids were 'more typical for complex partial seizures.'" *Id*. Dr. Yang proposed that L.M. could have a cerebral folate deficiency, and he recommended treatments aimed at addressing the deficiency. *Id.*

L.M. had improved by March 14, 2012, when she returned to Dr. Bakdash. *Id.* Since starting treatment for the folate deficiency, L.M.'s generalized seizures had ceased, and an EEG showed no hypsarrhythmic changes. *Id*. Although L.M. still had infantile spasms, petitioner believed they were less frequent. *Id*. At that time, L.M. was receiving occupational, physical, and speech therapies. *Id*. On May 1, 2012, Dr. Yang indicated that L.M.'s seizure frequency had decreased, and her spasms occurred only once or twice per week. *Id.* Her diagnoses included cerebral folate deficiency, infantile spasms, global developmental delay, and esotropia. *Id.*

On January 12, 2016, genetic testing revealed that L.M. was "'heterozygous for the alteration in the *DYNC1H1* [dynein cytoplasmic 1 heavy chain 1] gene.'" *Id*. at 7; *see also id.* (quoting respondent's geneticist: "L.M. is 'heterozygous for the alteration c.3278T>C (p.F1093S) in *DYNC1H1* in exon 13'"). These records conclude that "'[c]ollectively, the evidence supports the likelihood that the alteration in the *DYNC1H1* gene . . . is the cause of [L.M.'s] clinical symptoms.'" *Id.* (quoting Pet. Ex. 42 at 38); *see also id.* (quoting Pet. Ex. 42 at 40 ("Based on the available evidence, the clinical overlap

of this gene with [L.M.'s] reported phenotype is positive. [L.M.'s] overlapping features include infantile spasms, intellectual disability, ongoing refractory epilepsy, and diffuse hypotonia.")). Moreover, the report refers to another female patient with the same *de novo* mutation who experienced infantile spasms, intellectual disability, autism spectrum disorder, and reduced muscle tone. *Id.* at 7, 24. L.M.'s geneticist confirmed that her "clinical picture is consistent with the central nervous system involvement seen with this [genetic] condition, which can include developmental delays and seizures." Pet. Ex. 42 at 32.

On February 12, 2016, L.M.'s geneticist documented epilepsy, global developmental delay without speech, hypotonia, and mental retardation. Dec. at 7; Pet. Ex. 42 at 31-32. To date, L.M. continues to experience seizures and developmental delays. Dec. at 6.

B. Procedural Background

On January 27, 2014, petitioner filed for compensation under the Act. Dec. at 1-2. After twice amending the petition, petitioner's ultimate allegations were that the DTaP and other vaccinations administered to L.M. on February 10, 2011, caused L.M. to suffer: (1) an on-Table injury with regard to the significant aggravation of her underlying condition; and (2) an off-Table injury with regard to the significant aggravation of her underlying condition. L.M.'s "underlying condition" was characterized as a "brain malformation/white matter deficiency/other genetic mutation" that "constituted an encephalopathy." *Id.* The petitioner relies on L.M.'s *de novo* mutation of the *DYNC1H1* gene to support her claim that L.M. had a pre-existing encephalopathy.

In support of L.M.'s petition, petitioner filed three opinions from pediatric neuropathologist Robert Shuman, M.D., and one from geneticist Richard Boles, M.D. *Id*. at 10-21. The Respondent offered two medical expert reports from pediatric neurologist and epileptologist John Zempel, M.D., Ph.D., and one from geneticist Maria Descartes, M.D. *Id.* at 21-30.[3]

An entitlement hearing was held in March 2018. *Id*. at 31. Drs. Shuman and Boles, as well as L.M.'s parents testified for petitioner,[4] and Drs. Zempel and Descartes testified for respondent.

The Special Master issued his Decision on November 5, 2018, denying compensation. Following a comprehensive review of the record, the Special Master determined that petitioner failed to establish that L.M.'s vaccinations significantly aggravated her underlying condition to meet the standards for an on- or off-Table claim. First, the Special Master concluded that L.M. did not suffer from an encephalopathy under the Qualifications and Aids to Interpretation. The Special Master also found regardless of

[3] In addition, on February 26, 2016, petitioner filed a Motion for a Determination of Law Governing Petitioner's Table Significant Aggravation Claim. Dec. at 44. Respondent filed a response on April 25, 2016, and petitioner replied on May 13, 2016. *Id.* at 47 n.45. The issue concerning the proof needed for petitioner's on-Table significant aggravation claim will be discussed at length in this opinion.

[4] L.M's parents offered factual testimony regarding L.M.'s medical history and development prior to her vaccinations on February 10, 2011, as well as their recollections about L.M.'s symptoms over the ensuing days. *See* Dec. at 8-10. During her testimony, petitioner disputed the accuracy of the records that mentioned seizures prior to the vaccinations at issue. *See id.* at 8 & n.10. She also "denied informing treaters that L.M. had been floppy or hypotonic since her birth." *Id.* at 8. Petitioner further testified that between February 11 and 15, 2011, L.M. "remained in a distressed condition," but she did not "opt to bring L.M. in for a visit, maintaining that a nurse had made her feel that she was overreacting and that [the pediatrician's] office was otherwise booked up." *Id.* at 9.

whether petitioner had met her burden that the respondent had established that a "factor unrelated" to the vaccinations was the cause of L.M.'s current condition. *See* Dec. at 50-51, n. 47; 56. Petitioner timely moved for review of the Special Master's Decision on December 5, 2018. (ECF No. 104). The respondent filed a response (ECF No. 108) and on January 18, 2019 the court asked the parties to file supplemental responses (ECF No. 111). Argument was heard on March 21, 2019.

II. DISCUSSION

A. Legal Standards

1. Standard of Review of Special Master's Decision

The Court of Federal Claims may set aside a Special Master's findings of fact or conclusions of law only if "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. § 300aa-12(e)(2)(B); RCFC, App. B, Vaccine Rule 27(b). Under established precedent, this court does "not reweigh the factual evidence, assess whether the [S]pecial [M]aster correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses – these are all matters within the purview of the fact finder." *Porter v. Sec'y of Health and Human Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011) (citing *Broekelschen v. Sec'y of Health and Human Servs*, 618 F.3d 1339, 1349 (Fed. Cir. 2010)). As long as "the [S]pecial [M]aster has considered the relevant evidence," "drawn plausible inferences," and stated, "a rational basis for the decision," reversible error is extremely difficult to establish. *Hines v. Sec'y of Health and Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991).

2. The Standards for Proving On-Table and Off-Table Claims

In this case, petitioner alleged that L.M.'s vaccinations, administered on February 10, 2011, resulted in a significant aggravation of a preexisting encephalopathy as the basis for her on-Table and off-Table claims. It is not disputed that the diphtheria-tetanus-acellular pertussis ("DTaP") is the only vaccine that could serve as the "the basis for a Table claim alleging significant aggravation of a preexisting encephalopathy." Dec. at 44 n.44. According to petitioner the DTaP vaccination caused L.M. to suffer: (1) an on-Table injury with regard to the significant aggravation of her underlying condition; and (2) an off-Table injury with regard to the significant aggravation of her underlying condition.

The Act provides a presumption of vaccine injury "if the petitioners have shown that the injury is 'on-Table.'" *Turner v. Sec'y of Health and Human Servs.*, 268 F.3d 1334, 1337 (2001). Once the petitioner has shown that the injury is on-Table and afforded the presumption, the government may "rebut the presumption of an on-Table injury by showing the injury complained of resulted from some factor unrelated to the vaccine." *Id.*

In order to be afforded the presumption of causation for an on-Table claim with regard to a significant aggravation of an underlying condition, the petitioner had to establish by a preponderance of the evidence that the requisite vaccine "significantly aggravated . . . any illness, disability, injury, or condition set forth in the Vaccine Injury Table," and that "the first symptom or manifestation . . . of the significant aggravation of

any such illness, disability, injury, or condition . . . occurred within the time period[5] after vaccine administration set forth in the Vaccine Injury Table." 42 U.S.C. § 300aa-11(c)(1)(C)(i). The Act defines "significant aggravation" as "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." 42 U.S.C. § 300aa-33(4).

In *Whitecotton v. Sec'y of Health and Human Servs.*, 81 F.3d 1099, 1107 (Fed. Cir. 1996), the Federal Circuit set out a four-part test for analyzing claims alleging significant aggravation of a Table injury. Under *Whitecotton*, the Special Master must: (1) assess the individual's condition prior to vaccination; (2) assess the individual's current condition; (3) determine if the individual's current condition constitutes a "significant aggravation" of her condition prior to vaccination within the meaning of the statute; and (4) determine whether the first symptom or manifestation of the significant aggravation occurred within the time period specified by the Table. *Whitecotton*, 81 F.3d at 1107. In *Whitecotton,* the Federal Circuit further stated that "the permissible scope of the special master's inquiry is virtually unlimited. Congress desired the special masters to have very wide discretion with respect to the evidence they would consider, and the weight assigned that evidence. . . . Thus, the special master is free to consider evidence from outside the table time period in determining whether an individual suffered the first symptom or manifestation of a significant aggravation of an injury within the table time

[5] The Vaccine Injury Table provides that the applicable time period for an encephalopathy to occur in order to meet the Table's definition is within 72 hours of the administration of the vaccine. 42 U.S.C. §300aa-14(a).

period." *Id*. at 1108. If the petitioner meets these tests with a preponderance of the evidence, compensation will be awarded unless the respondent shows by a preponderance of the evidence that the injury was "due to factors unrelated" to the vaccine. *See* 42 U.S.C. § 300aa-13(a)(1)(B).[6]

In deciding whether a petitioner has suffered either an on-Table injury or a significant aggravation of an on-Table injury, Special Masters apply the Qualifications and Aids to Interpretation ("QAI") set forth in regulations. 42 U.S.C. § 300aa-14(b). These QAI are read in conjunction with the Table and define its key terms. *See* 42 C.F.R. § 100.3(b) (effective July 22, 2011, to July 22, 2015).[7] Pursuant to the QAI, an individual has suffered an encephalopathy only if she "manifests, within the applicable period, an injury meeting the description [herein] of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination." 42 C.F.R. § 100.3(b)(2). The QAI set forth detailed criteria for both "acute" and "chronic" encephalopathy. *See id.* § 100.3(b)(2)(i)-(ii).[8] The QAI defines

[6] A "factor unrelated" may include "infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible" for causing the petitioner's injury or death. 42 U.S.C. § 300aa-13(a)(2)(B).

[7] The Vaccine Injury Table was amended after this petition was filed. The amended Table only governs petitions filed on or after March 21, 2017, the effective date of the final rule. 42 C.F.R. § 100.3(e)(1); 82 Fed. Reg. 11321 (Feb. 22, 2017). Therefore, citations are to the Table that was in effect when this petition was filed.

[8] *See also id.* § 100.3(b)(2)(iii) (stating that "[a]n encephalopathy shall not be considered to be a condition set forth in the Table if . . . it is shown by a preponderance of the evidence that the encephalopathy was caused by an infection, a toxin, a metabolic disturbance, a structural lesion, a genetic disorder or trauma (without regard to whether the cause of the infection, toxin, trauma, metabolic disturbance, structural lesion or genetic disorder is known).").

"encephalopathy" in relevant part as follows:

> [A] vaccine recipient shall be considered to have suffered an encephalopathy only if [she] manifests, within the applicable period, an injury meeting the description below of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination.
> (i) An acute encephalopathy is one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).
> (A) For children less than 18 months of age who present without an associated seizure event, an acute encephalopathy is indicated by a significantly decreased level of consciousness lasting for at least 24 hours. Those children less than 18 months of age who present following a seizure shall be viewed as having an acute encephalopathy if their significantly decreased level of consciousness persists beyond 24 hours and cannot be attributed to a postictal state [seizure] or medication.

Id. The application of the QAI for proving on-Table significant aggravation claims is at issue in this petition.

If a petitioner is unable to establish an on-Table claim, a petitioner may seek compensation for pre-existing injuries that are "significantly aggravated" by a vaccination under the Act as an off-Table claim or causation-in-fact claim. 42 U.S.C. § 300aa-11(c)(1)(C)(ii); *id.* § 300aa-33(4). The Federal Circuit has explained that a petitioner bears a heavy burden to meet the preponderance standard in causation-in-fact cases. *See Althen v. Sec'y of Health and Human Servs.*, 418 F.3d 1274, 1280 (Fed. Cir. 2005); *see also Hodges v. Sec'y of Health and Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993). The elements of proof needed to establish an off-Table claim were set forth by this court in *Loving v. Sec'y of Health and Human Servs.*, 86 Fed. Cl. 135, 144 (2009) and endorsed by the Federal Circuit in *W.C. v. Sec'y of Health and Human Servs.*, 704 F.3d 1352, 1357 (Fed. Cir. 2013).

Under *Loving*, a petitioner who alleges an off-Table significant aggravation claim must by the preponderance of the evidence establish the below-listed six elements:

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) evidence that the person's current condition constitutes a "significant aggravation" of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving, 86 Fed. Cl. at 144 (citing *Whitecotton*, 81 F.3d at 1107; *Althen*, 418 F.3d at 1278); *see also id.* ("[T]he appropriate framework for determining whether a petitioner has made a *prima facie* showing that she has a compensable significant-aggravation off-Table claim is a combination of the first three prongs of the *Whitecotton* test with the three-part test articulated in *Althen*.").

In addition to the foregoing, for an off-Table claim, the petitioner must prove by a preponderance of the evidence "that the vaccine . . . was the actual cause of the injury." *Munn v. Sec'y of Health and Human Serv.*, 970 F.2d 863, 865 (Fed. Cir. 1992). The Special Master must assess whether the petitioner has established that the vaccine – rather than the natural course of the pre-existing condition – is responsible for the post-vaccination outcome. *See Locane v. Sec'y of Health and Human Servs.*, 685 F.3d 1375, 1381 (Fed. Cir. 2012) (upholding the determination that the petitioner's "condition was not inconsistent with the disease generally" and unaffected by vaccination); *see also Faoro v. Sec'y of Health and Human Servs.*, No. 10-704V, 2016 WL 675491, at *27 (Fed. Cl. Spec. Mstr. Jan. 29, 2016). The medical theory must be "persuasive" – that is,

specific to the petitioner's case and supported by a "reputable" (*i.e.*, reliable) scientific or medical explanation. *Moberly v. Sec'y of Human and Health Servs.*, 592 F.3d 1315, 1322 (Fed. Cir. 2010).

Under Federal Circuit precedent, proving causation by the preponderance of evidence does not mean proof to a scientific certainty. *See Bunting v. Sec'y of Health and Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). The Circuit has explained that the "preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body," and a petitioner may use circumstantial evidence to meet her burden. *Althen*, 418 F.3d at 1280. It is not, however, enough to demonstrate a "plausible" or "possible" causal link between a vaccination and an injury to meet this standard. *LaLonde v. Sec'y of Health and Human Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014); *see also W.C.*, 704 F.3d at 1356. Rather, "the statutory standard of preponderance of the evidence requires a petitioner to demonstrate that the vaccine more likely than not caused the condition alleged." *LaLonde*, 746 F.3d at 1339. Thus, a Special Master may conclude that there is simply too great an analytical gap between the data and the opinion proffered, if the petitioner has failed to produce sufficiently reliable evidence. *Cedillo v. Sec'y of Health and Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). Finally, a Special Master may not award compensation "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." 42 U.S.C. § 300aa-13(a)(1).

The respondent is "'permitted to offer evidence to demonstrate the inadequacy of

the petitioner's evidence on a requisite element of the petitioner's case-in-chief.'" *Stone v. Sec'y of Health and Human Servs.*, 676 F.3d 1373, 1379-80 (Fed. Cir. 2012) (quoting *de Bazan v. Sec'y of Health and Human Servs*, 539 F.3d 1347, 1353 (Fed. Cir. 2008)). The Special Master may weigh that evidence in determining whether a petitioner has met her burden. *See id.*; *see also Doe v. Sec'y of Health and Human Servs.*, 601 F.3d 1349, 1358 (Fed. Cir. 2010).

As with on-Table cases, if a petitioner proves a *prima facie* case of causation, the burden switches. The respondent, government, then bears the burden of showing by a preponderance of the evidence that some factor other than the vaccine was the actual cause of the injury. *Walther v. Sec'y of Health and Human Servs.*, 485 F.3d 1146, 1151 (Fed. Cir. 2007).

B. The Special Master's Decision Was Not Arbitrary, Capricious, an Abuse of Discretion, or Otherwise Not in Accordance with Law.

In this case, L.M. was found to possess a *de novo* mutation of the *DYNC1H1* gene, which the petitioner contends is the basis for L.M.'s pre-existing encephalopathic disorder. *See* Dec. at 2, 7, 22-23, 30. The impact of that diagnosis on her on-Table and off-Table claims is at the heart of the Special Master's decision denying petitioner's on-Table and off-Table claims. We begin with summarizing the Special Master's factual findings and then review his denial of petitioner's on-Table and off-Table claims.

1. The Special Master's Review of Expert Testimony

The petitioner relied on the expert testimony of Drs. Robert Shuman and Richard

Boles.[9] They opined that L.M.'s immunizations significantly aggravated her pre-existing genetic condition stating that her condition would have been milder had she not been vaccinated. Specifically, they opined that L.M.'s post vaccination seizures were evidence of a new symptom that she had not previously experienced and proved an aggravation. *See, e.g.*, Dec. at 16, 21, 51.

Dr. Shuman testified that L.M.'s imaging studies revealed "structural deficiencies," and that she had a type of white matter deficiency known as Perinatal TeloLeukoEncephalopathy ("PNTLE"), which "he characterized as 'part of the preexistent encephalopathy of [L.M.]'s genetic disease.'" *Id.* at 11-12, 51 (citation omitted). In his view, L.M.'s vaccinations aggravated these deficiencies and prompted her seizures. *Id.* at 13. Specifically, Dr. Shuman reasoned that a person like L.M. would be vulnerable to "decompensation" if she was hit with the immunologic stress of vaccination. *Id.* at 16 (citing Tr. at 131). In concluding that L.M. suffered from structural deficiencies he relied on MRIs obtained on February 16, 2011, April 2011, and May 2012 to conclude that L.M.'s brain had PNTLE. *Id.* at 11-12. In support of the causal relationship between vaccination and L.M.'s symptoms, Dr. Shuman relied on the

[9] Dr. Shuman is a pediatric neuropathologist with expertise in child neurology. He received his M.D. from Stanford, completed his residency in pediatrics at the University of Colorado, a residency in pathology at the University of Washington, and a residency in child neurology at the University of Kentucky. He is board certified in pathology, neuropathology, and child neurology. Dec. at 11.

Dr. Boles received his M.D. from the University of California Los Angeles where he completed a pediatrics residency, followed by a genetics fellowship at Yale University. He was a professor of clinical pediatrics at the University of Southern California from 1993 until 2014. Dec. at 17.

"National Childhood Encephalopathy Study" performed in the United Kingdom in the late 1970s. *Id.* at 14 (citing Richard Alderslade et al., *The National Childhood Encephalopathy Study: A Report of 1000 Serious Cases of Serious Neurological Disorders in Infants and Young Children from the NCES Research Team,* Reports from the Comm. on Safety of Med. & Joint Comm. on Vaccination & Immunisation (1981)). However, on cross-examination, Dr. Shuman acknowledged that his conclusion that L.M.'s seizure disorder/development problems by vaccination were worsened by the vaccination beyond what would otherwise have been expected given her genetic mutation lacked a sufficient basis. *Id.* at 17 (citing Tr. at 151).

Dr. Boles opined that the mutation's location on the *DYNC1H1* "chromosomal protein chain was critical in determining the symptoms an individual would experience when the mutation is expressed." *Id*. at 17. He hypothesized that because L.M.'s mutation was in the gene's stem or tail, as opposed to the motor or stalk domain, her outcome should have been less severe. *Id.* at 17-18. Dr. Boles claimed that L.M.'s vaccinations "worsened the expected, comparatively milder course otherwise attributable to her mutation[.]" *Id.* at 19; *see also id.* at 51. Dr. Boles reasoned, that the vaccine constituted a sufficient "'environmental insult'" to exacerbate the effects of L.M.'s underlying mutation which made the progress of the encephalopathic disorder more severe than it would have been otherwise. *Id.* at 20 (quoting Tr. at 188, 220).

The Special Master also heard testimony from Dr. Maria Descartes, one of the

respondent's two experts,[10] who explained that a *DYNC1H1* mutation "impact[s] the function of a gene intended to code the production of dynein, a protein important to cell function[.]" Dec. at 22. She described L.M.'s mutation as rare and severe, as *de novo* mutations "are more commonly associated with negative outcomes." *Id.* at 23. In particular, "[p]atients with *de novo DYNC1H1* mutations have been identified with severe intellectual handicaps," as well as seizures and hypotonia. Resp. Ex. R at 6 (ECF No. 67-1 at 6); *see also* Dec. at 23-25 (summarizing literature on *DYNC1H1* mutations). Dr. Descartes testified as to literature on L.M.'s mutation which references another female patient who had infantile spasms, like L.M, and had intellectual disabilities, autism spectrum disorder, and reduced muscle tone. Dec. at 24. Dr. Descartes noted that the individual in the literature has a phenotypic presentation "highly similar" to L.M.'s in that she had "infantile spasms coupled with a subsequent epileptic encephalopathy[.]" *Id.* at 24-25. This patient, as reported in the medical literature, Dr. Descartes emphasized, shows "the commonalities between the [*DYNC1H1*] mutation and the kinds of symptoms L.M. experienced." *Id.* at 25; *see also id.* at 30, 53.

The Special Master also heard additional testimony from Dr. John Zempel,[11] the

[10] Dr. Descartes received her M.D. from the University of Puerto Rico. She completed a residency at San Juan City Hospital in Puerto Rico as well as fellowship in genetics at Baylor College of Medicine in Houston, Texas. She is board certified in genetics as well as pediatrics. Dec. at 22.

[11] Dr. Zempel received an M.D. and Ph.D. from Washington University in St. Louis. He completed residencies in pediatrics, adult neurology, and child neurology as well as fellowships in pediatric epilepsy and clinic neurophysiology. He is board certified in neurology, child neurology and psychiatry. Dec. at 26.

other expert for the respondent, who explained that L.M. likely was suffering from seizures prior to her vaccination, whether or not the seizures were recognized as such, and that the "course of her illness from before vaccination to the present" was consistent with that of "treatment-nonresponsive" individuals suffering from infantile spasms. *Id.* at 29, 55. The Special Master found Dr. Zempel's testimony regarding prior seizures persuasive, reiterating in his opinion that "parents often do not recognize initial seizure activity as part of a greater disorder before a more alarming seizure incident." *Id.* at 55; *see also id.* at 16.

After considering the testimony of all experts, the Special Master determined that petitioner's theories regarding both her on-Table and off-Table claims lacked reliable scientific support. Dec. at 51-54. He explained that Dr. Shuman's opinion was "the weaker of the two," particularly because his first two reports were filed prior to the discovery of L.M.'s *DYNC1H1* mutation, and "thus proposed a theory that did not take into account a significant fact." *Id.* at 51. The Special Master explained that Dr. Shuman "did not abandon his initial theory" at the hearing which the Special Master found made his opinion questionable. *See id.* The Special Master also determined that Dr. Shuman's opinion that L.M. had a pathogenic brain malformation was uncorroborated by her records. *Id.* The Special Master further determined that Dr. Shuman's assertion that L.M. had a white matter deficiency was not well-supported. *Id.* The Special Master stated that Dr. Shuman "relied upon a diagnosis that not only L.M. never received but which elevated a diagnostic concept (PNTLE) into something that it does not appear medical science recognizes with any degree of trustworthy sufficiency." *Id.*; *see also id.*

at 48.[12] Finally, the Special Master determined that Dr. Shuman's opinion regarding pertussis toxin-containing vaccines and his contention that they could promote seizures was not well supported or persuasive. The Special Master explained that Dr. Shuman relied on obsolete literature "and/or involved conflation of the DPT vaccine with the DTaP version L.M. actually received." *Id.* at 51.

The Special Master found Dr. Boles's opinion testimony to be similarly unpersuasive. *See* Dec. at 52-54. According to the Special Master, Dr. Boles failed to "establish with reliable proof [the] contention that location [of the gene mutation] was *as* outcome-determinative as he maintained[.]" *Id.* at 52 (emphasis in original). In this regard, the Special Master explained that he found the opinion of the respondent's expert, Dr. Descartes, that the *DYNC1H1* mutation *itself* matters far more than its location, was more persuasive. *Id.* at 52; *see id*. at 23. Dr. Decartes challenged Dr. Boles's contention that mutations on the stem or tail domain "were *invariably* associated only with more benign outcomes[,]" and she discussed several articles in support of her opinion. *See id.* at 23-25, 52-53. Dr. Decartes opined that an individual with a *DYNC1H1* mutation on the motor or stalk domain can have a mild outcome, and, as here, an individual with a mutation on the stem or tail domain can have one that is more severe. *See id.* at 52. In this connection, the Special Master found particularly "compelling" the evidence that the medical literature contained evidence of another patient with L.M.'s identical mutation

[12]Dr. Zempel noted that PNTLE is "not a commonly-employed diagnostic term," and it is "subsumed within the category of periventricular leukomalacia," a common and severe complication of extreme prematurity. *Id.* at 27. L.M. was not born prematurely. *Id.* n.31.

who had similar symptoms without reference to the location of the gene mutation. *Id*. The Special Master found such evidence demonstrates that "the location of a genetic mutation is not alone predictive of mutation outcome." *Id.* (describing the individual with the same *DYNC1H1* mutation in the stem/tail domain who suffered from infantile spasms and an epileptic encephalopathy).

The Special Master also determined that neither Dr. Shuman nor Dr. Boles articulated how any of L.M.'s vaccinations, including the DTaP, could interact with her genetic disorder to worsen her outcome significantly. *Id.*. at 51, 53-54. For example, he found that Dr. Shuman 's opinion "lacked a basis for the conclusion that L.M.'s seizure disorder/developmental problems were worsened by vaccination beyond what would otherwise have been expected given her alleged encephalopathic brain malformation/ white matter deficiency." *Id.* at 17. There, the Special Master cited to Dr. Shuman's opinion testimony wherein he admitted on cross-examination that he had "no evidence" that L.M's seizure threshold had been reduced and that the vaccination worsened her genetic condition. Tr. 151:15-22. In addition, the Special Master noted that Dr. Boles offered no reliable support or literature "addressing the propensity of any vaccine to exacerbate a disease otherwise attributable to a genetic mutation, and this component of his overall opinion had a conclusory character to it, relying more on his *ipse dixit* than independent evidence." *Id.* at 20; s*ee also id.,* n.25 ("Dr. Boles admitted he could not pinpoint *which* specific vaccine received by L.M. was causal of her illness, but proposed awareness that the MMR and DTaP had been implicated in other contexts.").

2. The Special Master's Entitlement Decision Regarding Petitioner's On-Table Claim

After hearing the evidence, the Special Master turned first to the petitioner's on-Table claim. The Special Master began by examining whether petitioner had suffered a pre-vaccination encephalopathy sufficient to qualify for a post-vaccination aggravation claim. The petitioner argued in her Memorandum In Support of Determination of Law Governing Petitioner's Table Significant Aggravation Claim (ECF No. 41), that petitioner should only have to establish a pre-existing encephalopathy consistent with "the common, ordinary, and accepted meaning" of encephalopathy and not the definitions of the condition set forth in the QAI. Pet. Mem. of Law (ECF No. 41). The respondent in their response to the petitioner's motion did not challenge the petitioner's assertion that L.M. had a preexisting encephalopathy. Resp. Mem. of Law (ECF No. 44). Rather, respondent argued that the Special Master could not award compensation based on an on-Table claim because "there is nothing beyond petitioner's claim to support a finding that L.M. suffered critical symptoms within seventy-two hours of her DTaP vaccination, let alone those consistent with an acute encephalopathy." Resp. Mem. of Law at 9. In petitioner's reply, she did not dispute the respondent's contention that L.M. had not met the criteria for an acute encephalopathy as defined by the QAI within 72 hours of her vaccination. Rather, petitioner argued that it would be enough for her to show that within 72 hours, L.M. began to show some "change for the worse" of her pre-vaccination encephalopathy even if that worsening was not sufficient to meet the QAI definition of acute encephalopathy. Pet. Reply to Mot. at 2 (ECF No. 47). Specifically, the petitioner

argued that so long as she can establish that she experienced symptoms of "change for the worse" within 72 hours of the February 10, 2011 DTaP vaccination, "those symptoms *need not satisfy* the definition of encephalopathy in the Qualifications and Aids to Interpretation[.]" *Id.* at 4.

The Special Master determined that petitioner had not established a pre-vaccination encephalopathy to support an on-Table claim because she could not meet the definition of encephalopathy in the QAI prior to receiving her vaccinations. Relying on the decision in *DeRoche v. Sec'y of Health and Human Servs.*, No. 97-643V, 2002 WL 603087, at *25 (Fed. Cl. Spec. Mstr. Mar. 28, 2002),[13] the Special Master determined that to establish an on-Table significant aggravation claim the petitioner had to prove "at a minimum that L.M. experienced a pre-vaccination 'acute' encephalopathy as set forth in the QAIs." Dec. at 48. Based on his review of the evidence the Special Master concluded that L.M.'s pre-vaccination symptoms never "rose to the level of an 'acute encephalopathy'" and therefore "Petitioner's Table claim cannot succeed." Dec. at 49.

[13] In *DeRoche*, the then-Chief Special Master applied the QAI definition of encephalopathy to the child's underlying condition in denying compensation in the petitioner's presumptive significant aggravation claim. In *DeRoche,* the then-Chief Special Master stated, "[T]o prove a Table significant aggravation claim brought pursuant to [Section] 11(c)(1)(C)(i), petitioner must first demonstrate *an underlying Table injury as that injury is defined by the applicable [QAI]*". *DeRoche v. Sec'y of Health & Human Servs.,* No. 97-643, 2002 WL 603087, *25 (Fed. Cl. Spec. Mstr. Mar. 28, 2002). In applying the QAI definition, the Chief Special Master "read out" the phrase "within the applicable period" (of vaccination) because for a significant aggravation claim, an encephalopathy is necessarily pre-existing and thus cannot arise post-vaccination. *Id.* at *27, *29. Similarly, he did not apply the "chronic encephalopathy" component because given the compressed timetable for childhood vaccines, almost always, a child would receive an immunization before six months had elapsed, rendering it difficult to establish a Table encephalopathy. *Id.* He did, however, require the petitioner to show that there had been an encephalopathy consistent with the QAI post-vaccination to support an on-Table significant aggravation claim. *Id* at *31-32.

On appeal, petitioner argues that the Special Master's on-Table entitlement decision must be set aside because the Special Master applied the wrong legal definition of "pre-vaccination encephalopathy." *See* Mot. for Review at 9-17. Petitioner contends she did not have to show that L.M. suffered an "encephalopathy" as defined in the QAI regulations before L.M. received her vaccinations in order to establish an on-Table significant aggravation claim. *Id*. at 15-16.[14] She asserts that the Special Master erred in following the approach set forth in *DeRoche*, and that the Special Master instead should have "relied on the 'common, ordinary and accepted meaning' of encephalopathy for the definition of a vaccine recipient's pre-vaccination encephalopathy." *Id.* at 15; *see also* Dec. at 47-48.

The respondent does not directly challenge petitioner's contention that *DeRoche* is not the appropriate standard to apply for on-Table significant aggravation claims. Rather, the respondent maintains, as it did before the Special Master, that it is not necessary to

[14] As noted above, the QAI defines "encephalopathy" in part as follows (*see* 42 C.F.R. § 100.3(b)(2)):

> [A] vaccine recipient shall be considered to have suffered an encephalopathy only if [she] manifests, within the applicable period, an injury meeting the description below of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination.
>
> (i) An acute encephalopathy is one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).
>
> (A) For children less than 18 months of age who present without an associated seizure event, an acute encephalopathy is indicated by a significantly decreased level of consciousness lasting for at least 24 hours. Those children less than 18 months of age who present following a seizure shall be viewed as having an acute encephalopathy if their significantly decreased level of consciousness persists beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication.

resolve whether L.M. met the QAI definition of encephalopathy pre-vaccination because petitioner undisputedly failed to meet the QAI definition of acute encephalopathy within 72 hours of her DTaP vaccination as mandated by the statute. 42 U.S.C. § 300aa-11(c)(1)(C)(i). The respondent argues that "[r]egardless of the definition the Special Master employed for 'pre-vaccination encephalopathy' the outcome does not change." Resp. Supl. at 3.

The petitioner argues that if the Special Master's pre-vaccination definition of encephalopathy is corrected that she should prevail because the statute does not require proof of an encephalopathy meeting the QAI definition within 72 hours to establish an on-Table significant aggravation claim. The petitioner argues that under the language of the Vaccine Injury Act, she only had to prove that L.M's condition "changed for the worse," citing 42 U.S.C. § 300aa-33(4):

> For the purposes of this subtitle . . . . .
> (4) The term 'significant aggravation' means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.

To prove an on-Table *onset* case based on an encephalopathy, the petitioner agrees that she would have had to prove that the first symptom or manifestation of an encephalopathy as defined by the QAI occurred within 72 hours. *See* 42 C.F.R. § 100.3(b)(2). But to prove an on-Table *significant aggravation* claim the petitioner argues, she only needed to show a "change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." 42 U.S.C. § 300aa-33(4). The petitioner argues that the QAI

definitions of encephalopathy are not relevant to on-Table significant aggravation claims. Petitioner argues that she met her burden because the first symptom or manifestation of L.M.'s significant aggravation occurred within 72 hours of her February 10, 2011 DTaP vaccination. In addition, petitioner argues that a comparison of L.M.'s condition before her February 10, 2011 DTaP vaccination to her current condition shows that L.M. suffered a significant aggravation of her preexisting condition following her February 10, 2011 DTaP vaccination.

Petitioner argues her claim is supported by the Special Master's acknowledgment that L.M's condition worsened within 72 hours after she received the DTaP vaccination:

> The record does support the conclusion that L.M.'s condition was worse *immediately* post-vaccination (if compared only to her immediate pre-vaccination condition). In addition, Petitioner has pointed to evidence from the medical record that L.M. displayed some motor control issues and diminished responsiveness on February 15, 2011, after the seizure that resulted in her being taken to the hospital . . .

Dec. at 50 (emphasis in the original).

The petitioner also relies on the affidavit of L.M.'s father in which he describes a healthy baby at six months and compares that description to the Special Master's description of L.M.'s current condition:

> At present, L.M. continues to experience seizures and developmental delays. Petitioner alleges that, at 7 years and 5 months of age, L.M. can crawl, as well as walk with a walker when aided (someone needs to direct her and catch her if she stumbles). Tr. at 60-61. She takes the anticonvulsant Tegretol and a low dose of CBD oil (medical marijuana) to control her seizures. Tr. at 64. In her prehearing submission, Petitioner asserts that L.M. experiences "occasional breakthrough seizures" even during periods of relatively good health, has a poorly coordinated grasp, suffers from cortical visual impairments, and is nonverbal, though she can use a few signs to express ideas such as 'hungry,' 'thirsty," "I want,"

"yes," and "no." Pet'r's Pre-Hr'g Brief at 12, dated Dec. 12, 2017, ECF No. 73 ("Pet. Brief").

Dec. at 6-7.

Whether a petitioner must meet the QAI definition prior to her vaccination or after the vaccination to make an on-Table significant aggravation claim is the key issue to be decided. The respondent argues that it is not necessary to determine whether an encephalopathy meeting the QAI definition prior to the vaccination is necessary because to establish an on-Table significant aggravation claim the petitioner must meet the QAI definition of encephalopathy post-vaccination to meet the on-Table significant aggravation standard.

The court agrees with the respondent that the purpose of on-Table claims is to provide petitioners with a presumption of causation based on a defined set of symptoms set by regulation in the QAI. If the defined set of QAI symptoms are not met, the Vaccine Act allows for petitioners to seek redress under the procedures for off-Table claims. The respondent correctly argues that the significant aggravation standard set in the statute does not mean the QAI definitions of the Table injuries are irrelevant for the purposes of determining if a petitioner suffered a significant aggravation of an on-Table injury. In fact, the statutory scheme creating on-Table claims states that in order to recover, the petitioner must experience within the applicable timeframe "the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths" as provided for in the Table and as defined by the QAI. 42 U.S.C. § 300aa-14(a). Thus, to prove a significant aggravation on-Table

claim, the petitioner must be able to show that the vaccine caused a significant aggravation consistent with the QAI definition within the time-frames provided on the Table.[15]

Here, the petitioner has not met her burden. The evidence in the record established that L.M. never experienced an encephalopathy meeting the QAI definition after she received her vaccination (within the relevant 72-hour period). The petitioner only identified that L.M. had a fever with whimpering and screaming. Pet. Ex. 2 at 19. Indeed, even outside of the 72-hour period provided by the Table, her condition did not meet the QAI definition. When L.M. was taken to the emergency room by her mother, the attending doctor stated she "was alert and playful, and although a 'bit listless,' she displayed few other alarming clinical symptoms." Dec. at 3 (citation omitted). Additionally, neither of petitioner's experts opined that L.M. suffered an acute encephalopathy consistent with QAI definition during this period. Dr. Zempel, the respondent's expert, on the other hand, stated that a severe acute encephalopathy was not present at the time of L.M.'s presentation or subsequently through the initial hospital stay. Dec. at 26-28. This opinion was not refuted by petitioner's experts.

It is for these reasons that the court finds that petitioner's objections to the Special

[15] The court notes that if it adopted the petitioner's argument, the purpose of the on-Table scheme would be undermined. Specifically, if a petitioner was not required to show the manifestation of either an onset or a significant aggravation of a preexisting condition that was consistent with the QAI definition for that on-Table condition, petitioners would be able take advantage of the presumption of causation afforded by the on-Table scheme without meeting the rigorous definition of the condition that was thought necessary for there to be a presumption of causation.

Master's conclusion that petitioner failed to establish an on-Table significant aggravation claim cannot be sustained. Regardless of whether the *DeRoche* standard is correct, petitioner did not present evidence to show the first symptoms of an acute encephalopathy within 72 hours as required by the Vaccine Act for a significant aggravation claim. For this reason, L.M. failed to establish that her post-vaccination course constituted a "significant aggravation" of her prior condition. *See* 42 C.F.R. § 100.3(a)(II)(B); *id.* § 100.3(b)(2)(i)-(ii); 42 U.S.C. § 300aa-33(4). Petitioner's on-Table significant aggravation claim fails, and the Special Master's rejection of the on-Table significant aggravation claim is affirmed.

3. The Special Master's Denial of Petitioner's Causation-In-Fact Aggravation Claim

As discussed above, to prevail on an off-Table significant aggravation claim, petitioner had to meet the 6 elements set in *Loving* by the preponderance of the evidence:

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) evidence that the person's current condition constitutes a "significant aggravation" of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving, 86 Fed. Cl. at 144 (citing *Whitecotton*, 81 F.3d at 1107; *Althen*, 418 F.3d at 1278).

In rejecting petitioner's off-Table significant aggravation claim, the Special Master focused on petitioner's failure to meet elements 3, 4, and 5 of the *Loving* test.

Petitioner challenges each of those conclusions and each are examined in turn below.

The Special Master, after reviewing the evidence, found that although the record supported a finding that L.M.'s condition worsened immediately following her vaccination, the evidence established that her "outcome would most likely be as it was regardless of vaccination." Dec. at 50. The petitioner takes issue with that statement arguing that the decision must be reversed because the Special Master applied the wrong legal standard. Specifically, petitioner argues that the Special Master erred because he "unambiguously required [the petitioner] to predict [L.M.'s] current condition" had L.M. not been vaccinated. Mot. for Review at 21.

The court finds that this is not a fair reading of the decision. The Special Master correctly cited precedent for the proposition that to determine whether there was a significant aggravation of a preexisting condition, the Special Master had to evaluate what is known about L.M.'s preexisting condition. Therefore, the Special Master had to evaluate what can be attributed to her genetic mutation and what impact the mutation would have on her life without the vaccinations. Assessing an off-Table significant aggravation claim therefore necessarily involves asking whether the individual's "clinical course and outcome [would have been] any different than it would have been if [she] had not been vaccinated[.]" *See, e.g.*, *Oliver v. Sec'y of Health and Human Servs.*, No. 10-394V, 2017 WL 747846, at *23 (Fed. Cl. Spec. Mstr. Feb. 1, 2017); *Faoro*, 2016 WL 675491, at *27 (citing *Locane*, 685 F.3d at 1375 (upholding the Special Master's finding that the "petitioner's condition was not inconsistent with the disease generally and not affected by the vaccinations")).

A review of the decision demonstrates that the Special Master did not require petitioner to prove the full trajectory of L.M.'s condition with her mutation to prove causation. Petitioner relied on experts to say that L.M.'s trajectory should have been mild. Here, a review of the record demonstrates that the Special Master, based on the credible evidence presented about the *DYNC1H1* mutation, reasonably determined that L.M. was not guaranteed a mild outcome. Rather, her outcome, as demonstrated by the medical literature, was consistent with children who experienced infantile spasms and specifically the condition of another little girl with the same genetic mutation. Based on the foregoing, the Special Master determined that the assumption of petitioner's experts to the effect that L.M.'s mutation would not have been as severe without the vaccination was not established. Dec. at 49-50. The Special Master's discussion of L.M.'s condition was therefore consistent with the petitioner's obligation to prove that the vaccine in fact had worsened that condition. As discussed above, the respondent is permitted to demonstrate the inadequacy of the petitioner's evidence on a requisite element to prove an injury claim and the Special Master may determine based on his consideration of all the evidence presented that the petitioner did not meet her burden. *Stone*, 676 F.3d at 1379-80.

Petitioner also needed to show by a preponderance of the evidence a theory causally connecting the DTaP vaccine to a significant worsening of her condition. *Loving*, 86 Fed. Cl. at 144 (citing *Althen*, 418 F.3d at 1278). The Special Master considered Dr. Boles' opinion testimony regarding how the vaccine could impact L.M.'s mutation and found that "Dr. Boles did not persuasively explain *how* the vaccines

interacted with the mutation." Dec. at 52. The Special Master found Dr. Bole's reliance on "personal supposition, or the general proposition that vaccination constitutes an environmental factor that can interact with genetic expression, basing such contentions on his own generalized observations from the treatment of unspecified twins," was not a reliable theory of causation. *Id.* The Special Master also found that Dr. Shuman's statements regarding the seizure-inducing potential of the DPT vaccine were not persuasive because L.M. did not receive the DPT vaccine but the different DTaP vaccine. Dec. at 54. The petitioner therefore did not have any specific evidence to explain how the DTaP vaccine that L.M. received could have caused a worsening of her condition.

The Special Master also properly considered if the logical sequence of events could support a finding that the DTaP vaccination caused the alleged significant aggravation of L.M.'s genetic condition. The Special Master agreed that L.M. experienced a post-vaccination fever and a reaction but rejected petitioner's claim that the seizures L.M. started experiencing post-vaccination were new and the result the vaccination. The Special Master reasonably concluded that the record demonstrated that there was a strong "likelihood that L.M. had *already experienced* seizures before her February 15th ER visit[,]" and that this evidence was consistent with Dr. Zempels' testimony as confirmed by the medical literature, that parents often do not recognize initial seizure activity before a more alarming incident. Dec. at 55.

In this connection, it is worth noting, that in rejecting the petitioner's off-Table claim the Special Master explained that even if L.M.'s expected prognosis should instead be considered as a "factor unrelated" for which the respondent has the burden, that he

"would find that respondent *did* establish a 'factor unrelated' in the form of the relationship between the DYNC mutation and L.M's illness." *Id*. at 50-51 n.47. In reaching this conclusion, the Special Master relied on cases involving children with Dravet syndrome (a rare seizure disorder involving a mutation in the SCN1A gene). *See id*. at 29 n.35, 41-42. In the cases involving Dravet syndrome, as in this case, the petitioners acknowledged that the children's SCN1A mutations were responsible for many of their symptoms but argued that their vaccinations had worsened their outcomes. *Id.* at 41-42.[16] While acknowledging that the evidence in this case was not as conclusive as the evidence involving the SCN1A mutations and Dravet syndrome, he concluded that in this case, as in those, the evidence established that the genetic mutation and not the vaccination that was responsible for the child's condition post-vaccination. Thus, the Special Master stated that even if petitioner had proven her *prima facie* case, he would nevertheless find that respondent established "a 'factor unrelated,' in the form of the relationship between the [*DYNC1H1*] mutation and L.M.'s illness." Dec. at 50-51, n.47.

Although this court does not have to reach whether the respondent met its burden for proving a factor unrelated, given the Special Master's conclusions regarding the petitioner's failure to establish a causal connection between L.M.'s DTaP vaccination and her condition post-vaccination to establish a significant aggravation case, it is clear from

[16] To date, compensation has been denied in more than one dozen such cases. *See Oliver*, 2017 WL 747846, at *1 & n.3 (listing the decisions), *aff'd*, 133 Fed. Cl. 341 (2017), *aff'd*, 900 F.3d 1357 (Fed. Cir. 2018).

the record that the Special Master considered the entire record and reached the rational conclusion that petitioner's had failed to establish that L.M.'s condition had worsened because of her DTaP vaccination. For these reasons the Special Master's decision rejecting petitioner's off-Table significant aggravation claim must be affirmed.

CONCLUSION

Because petitioner has failed to demonstrate that the Special Master erred in applying the law, abused his discretion or that his findings were arbitrary or capricious the Special Master's decision is **AFFIRMED**.

IT IS SO ORDERED.

s/Nancy B. Firestone
NANCY B. FIRESTONE
Senior Judge