In the United States Court of Federal Claims

No. 12-312V
Filed: August 8, 2017
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K.L.,	*	
Petitioner,	*	**Vaccine Act; HPV Vaccine; Special Master; Althen v. Secretary of Health and Human Services; Due Process; Expert Testimony; Vaccine Rule 3; Vaccine Rule 8.**
v.	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	
* * * * * * * * * * * * * * * * * * * *		

Paul S. Dannenberg, Huntington, Vermont for petitioner.

Robert P. Coleman, III, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C. for Respondent. With him were **Chad A. Readler**, Acting Assistant Attorney General, **Catherine E. Reeves**, Deputy Director, **Alexis B. Babcock**, Assistant Director, Torts Branch, Civil Division.

O P I N I O N

HORN, J.

On May 11, 2012 petitioner K.L.[2] filed a timely petition for compensation with the National Vaccine Injury Compensation Program, under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 (2012) (Vaccine Act). On March 17, 2017,

[1] This opinion was issued under seal on August 8, 2017. The parties did not propose redactions to the August 8, 2017 opinion, thus, the court issues the decision without redactions for public distribution.

[2] Pursuant to an August 10, 2016 Order filed by Special Master Brian H. Corcoran, petitioner's name was redacted at her request in order to protect her privacy.

Special Master Brian H. Corcoran[3] of the United States Court of Federal Claims denied petitioner's claim for an award of compensation, finding that the weight of evidence was insufficient to support petitioner's causation theory. See K.L. v. Sec'y of Health & Human Servs., No. 12-0312V, 2017 WL 1713110, at *17 (Fed. Cl. Spec. Mstr. March 17, 2017). Subsequently, on April 16, 2017, petitioner moved this court to review the Special Master's decision to deny her claim, pursuant to Rule 23 of the Vaccine Rules of the United States Court of Federal Claims (RCFC) Appendix B (2017). This case comes to the court upon that motion.

FINDINGS OF FACT

Petitioner K.L. was born on March 25, 1993. Petitioner alleges that she was healthy prior to receiving a third dose of the human papillomavirus (HPV) vaccine Gardasil on February 9, 2010. The record before the court indicates that K.L. was healthy during her childhood, with the exceptions of recurring otitis media,[4] anxiety disorder, reading difficulties, and one instance of vasovagal attack with syncope.[5] Regarding K.L.'s family history, according to notes in K.L.'s medical records taken on March 22, 2010 by K.L.'s physician, Dr. Melissa Volansky, and reconfirmed in notes taken on June 2, 2010 by Dr. Annapurna Poduri, another of K.L.'s treating physicians, K.L. has some family history of seizures, including three paternal cousins, one of whom had a formal epilepsy diagnosis. Dr. Volansky's March 22, 2010 notes further indicate that K.L.'s father once had a seizure after sleep deprivation.

K.L. received doses of Gardasil on May 18, 2009, August 18, 2009, and February 9, 2010. K.L. does not allege any injury or adverse effects from either of the first two doses. On February 11, 2010, two days after she received the third dose of Gardasil, K.L. was hospitalized after suffering a seizure. According to petitioner's hospital record, before the seizure, K.L's mother witnessed K.L.'s right hand twitching, and then, within minutes, K.L. slumped against a cabinet and hit her head on a door handle. Her mother then helped her to the floor where K.L. "had foaming at the mouth, was biting her tongue, and was somewhat blue around the mouth" for approximately four minutes, after which she was conscious, but disoriented. K.L. was taken via ambulance to the Emergency Room (ER) of Copley Hospital in Morrisville, Vermont. K.L. complained of headaches at the ER, but according to ER records, testing indicated she had no fever, respiratory distress, or other underlying or concurrent symptoms. K.L.'s head and neck computed tomography (CT)

[3] The case originally was assigned to Special Master Christian J. Moran and transferred to Special Master Corcoran on April 2, 2014.

[4] Otitis media is defined as "inflammation of the middle ear." Dorland's Illustrated Medical Dictionary 1351 (32nd ed. 2012).

[5] Vasovagal syncope is defined as "a transient vascular and neurogenic reaction marked by pallor, nausea, sweating, bradycardia, and rapid fall in arterial blood pressure which, when below a critical level, results in loss of consciousness and characteristic electroencephalographic changes." Dorland's Illustrated Medical Dictionary 1818.

scan, complete blood count (CBC), and electrocardiogram (EKG) tests also were normal. K.L.'s hospital records show her mother told ER physicians that before the seizure, K.L. had been experiencing ear pain and had taken Benadryl and Sudafed for a recent cold**.**

On the same day, K.L. was transferred to the Fletcher Allen Health Care facility at the Vermont Children's Hospital (FAHC), where she was admitted to the Pediatric Intensive Care Unit (PICU), sedated and intubated. At FAHC, K.L. had a lumbar puncture to test her cerebrospinal fluid (CSF) for indications of a central nervous system infection, which was negative. K.L. also had a magnetic resonance imaging test (MRI), which was normal, and an electroencephalogram (EEG),[6] which indicated an impaired arousal mechanism, but no epileptiform features.[7]

On February 13, 2010, K.L. had her intubation tube removed and regained consciousness, and was then transferred out of the PICU and discharged from Vermont Children's Hospital. Upon discharge, K.L. was given a diagnosis of "Single Seizure – right body onset, mild [T]odd's paralysis of right face." Notes in her patient record indicate that "[a]t transfer the cause of her seizure was thought to be multifactorial with potential contributors including a mild URI [upper respiratory infection], OTC [over the counter] pharmacotherapy with benadryl and sudafed, and recent HPV vaccine administration."

On February 15, 2010, K.L. had a follow-up appointment with Dr. Volansky who noted K.L. complained of headaches, vomiting, nausea, and dizziness. Dr. Volansky also noted that K.L.'s recent seizure was caused by an "unclear etiology, may have been new onset epilepsy, may have been effect of recent Gardasil and/or decongestants." She confirmed K.L.'s prior imaging test results showed no sign of infection or brain trauma.

On February 27, 2010, K.L. exhibited pre-seizure symptoms of twitching, arm jerking and leg buckling, and she was admitted to FAHC, where she experienced a seizure that was treated with 1000 mg of Keppra[8] and lorazepam.[9] Notes from this visit

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[6] An electroencephalogram is defined as "a recording of the potentials on the skull generated by currents emanating spontaneously from nerve cells in the brain . . . . Fluctuations in potential are seen in the form of waves, which correlate well with different neurologic conditions and so are used as diagnostic criteria." Dorland's Illustrated Medical Dictionary 600.

[7] Epileptiform is defined as "resembling epilepsy or its manifestations." Dorland's Illustrated Medical Dictionary 633.

[8] Keppra is defined as a "trademark for a preparation of levetiracetam," which is "an anticonvulsant administered orally as an adjunct in the treatment of partial and myoclonic seizures and idiopathic generalized epilepsy." Dorland's Illustrated Medical Dictionary 979, 1031.

[9] Lorazepam is defined as "a benzodiazepine with anxiolytic and sedative effects, administered orally in the treatment of anxiety disorders and short-term relief of anxiety symptoms." Dorland's Illustrated Medical Dictionary 1074.

indicate this was her first seizure since the February 11, 2010 hospitalization, and that she had a stomach illness a few days before. On February 28, 2010, K.L. was discharged and instructed to take 500 mg doses of Keppra and to consult a pediatric neurologist.

On March 22, 2010, Dr. Louisa Kalsner, a pediatric neurologist in Burlington, Vermont, evaluated K.L.'s condition. In her report, Dr. Kalsner noted that K.L. had experienced no seizures since February 27, 2010, was having some difficulty using her right hand and recalling words, and complained she had been having headaches since her third dose of Gardasil. Dr. Kalsner prescribed K.L. Ativan[10] and recommended that she increase her Keppra dosage to 750 mg twice daily.

On June 1, 2010, K.L. had an appointment with Dr. Poduri, a neurologist and epileptologist[11] at the Boston Children's Hospital, who reviewed K.L.'s medical records and symptoms, and who noted that K.L. had complained of a stomach illness and had received a Gardasil vaccination two days prior to her first seizure. At this visit, K.L. informed Dr. Poduri that she had experienced a dead feeling in her right arm after throwing a baseball or while after writing before her third Gardasil vaccination. Dr. Poduri also noted that based on anecdotes K.L. related during their appointment, K.L. may have had episodes of hand-twitching similar to her February 11, 2010 seizure "in the past," as well as other seizure symptoms, and Dr. Poduri wrote "there is certainly the possibility that she has had some sensory only seizures as well." Based on her examination, K.L.'s family history, and the association between epilepsy and a certain brain abnormality and reading difficulties at K.L.'s age, Dr. Poduri determined that K.L. had a juvenile onset form of idiopathic partial onset epilepsy.[12] She noted this was "the most likely diagnosis given her otherwise normal developmental history and her normal examination." Dr. Poduri's notes do not indicate a diagnostic connection between the seizures and Gardasil. She also recommended that K.L. have a more detailed MRI for additional evaluation.

On June 22, 2010, K.L. had a follow-up appointment with Dr. Kalsner, who noted that K.L. was responding well to the Keppra and had experienced no seizures since February. Dr. Kalsner noted that "[t]here was some concern about having Gardasil vaccination, third dose, 2 days prior to having her first seizure onset and maybe that indicates seizures should improve; however, would continue antiseizure medication for a total duration of 2 years and then gradually try to taper it off." Her notes gave no indication as to whether she agreed or disagreed with a Gardasil-related theory. She recommended

[10] Ativan is defined as "a trademark for preparations of lorazepam," defined in the preceding footnote. Dorland's Illustrated Medical Dictionary 173.

[11] Epileptologist is defined as "a specialist in the study, diagnosis, and treatment of epilepsy." Dorland's Illustrated Medical Dictionary 634.

[12] Idiopathic epilepsy is defined as "epilepsy of unknown origin, possibly associated with some inherited predisposition for seizures." Dorland's Illustrated Medical Dictionary 633.

a follow-up visit at the neurology clinic in six months. Dr. Kalsner was aware of K.L.'s prior evaluation by an epileptologist, but had not received a record of Dr. Poduri's evaluation.

On June 30, 2010, Dr. Poduri performed and reviewed the results of the more detailed MRI she had recommended and found no brain abnormalities. Thereafter, she diagnosed K.L. with "partial-onset epilepsy that appears to be truly idiopathic."

In the following months, records from K.L.'s visits with her physicians on July 27, 2011, August 11, 2011, and January 19, 2012 indicate that although K.L. did not have any additional seizures, she suffered from frequent headaches and vomiting, which was controlled by migraine medication, and from functional dyspepsia[13] and gastroparesis,[14] which improved after she eliminated dairy from her diet. On January 9, 2012, K.L. had a comprehensive educational evaluation because of difficulties she was having in college, and was diagnosed with a language-based disorder of written expression. She was advised to obtain a tutor and reduce her course load, and also began to see a psychiatrist and take antidepressants to reduce her anxiety.

On May 4, 2012, Dr. Kalsner recommended that K.L. reduce her Keppra medication to 500 mg twice a day, because she thought it "might help with her symptoms of anxiety and difficulty with sleep." The record indicates that K.L. informed Dr. Katherine A. Wayman, a physician who evaluated K.L. at FAHC on January 29, 2013, that she had reduced her Keppra dosage to 500 mg "around September." K.L. reported to Dr. Wayman that "about [one] week ago" she had started having partial seizures every few minutes, in the form of twitching in various places on her body. To control them, Dr. Wayman prescribed her Ativan for five days and advised K.L. to return to the higher dose of Keppra, 750 mg twice a day, which controlled her seizures.

On May 11, 2012, petitioner filed her timely petition for compensation under the Vaccine Act in the United States Court of Federal Claims, Office of Special Masters, and her case was assigned to Special Master Christian J. Moran. Because the petition was filed without all the statutorily required supporting medical records, see 42 U.S.C. § 300aa-11(c), petitioner twice requested, and Special Master Moran granted, extensions of time for petitioner to file all the necessary medical records. On October 26, 2012, petitioner filed some of the missing records and a statement of completion. On November 26, 2012, respondent submitted a status report regarding the lack of completeness of petitioner's medical records filed to date, and noted a number of remaining deficiencies.

[13] Functional dyspepsia is defined as "dyspepsia with no physical cause, usually resulting from nervousness or anxiety; it can have serious manifestations, resembling the symptoms of peptic ulcer, although no ulcer is detectable." Dorland's Illustrated Medical Dictionary 579.

[14] Gastroparesis is defined as "paralysis of the stomach, usually from damage to its nerve supply, so that food empties out much more slowly, if at all. Symptoms include early satiety, nausea, and vomiting." Dorland's Illustrated Medical Dictionary 765.

The parties had a status conference on December 11, 2012. On the same date, Special Master Moran issued an Order for petitioner to file the remaining required medical records and an amended petition "clearly stating the alleged injury or injuries caused by her . . . vaccinations." On January 25, 2013, petitioner filed notice of her intent to continue her petition because the statutory 240-day time period for the Special Master's issuance of a decision had lapsed. See Vaccine Rule 10(b). Pursuant to the December 11, 2012 Order and an April 12, 2013 Order, petitioner filed an amended petition and additional medical records.

On June 10, 2013, respondent filed a Report pursuant to Vaccine Rule 4(c), the due date for which had been suspended up to this point pending petitioner's filing of complete medical records. Respondent argued that compensation was not appropriate under the terms of the Vaccine Act, since petitioner had not met her burden of proof. Respondent argued that, because petitioner was alleging non-Table injuries from the Gardasil vaccination, she was required to demonstrate, by a preponderance of the evidence, that her injuries were caused-in-fact by the vaccine. Respondent further argued that no compensation should be awarded because (1) petitioner had failed to offer a reputable scientific or medical theory that Gardasil could or did cause epilepsy or migraines, (2) that a merely "possible" causal link between the vaccination and injury is insufficient to meet petitioner's burden under the Vaccine Act, and (3) that temporal proximity alone is insufficient to prove causation.

On December 23, 2013, Special Master Moran issued a draft Order regarding the parties' proposed expert witnesses, instructing the parties that "the expectation is that the expert's written report will constitute the expert's direct testimony," in lieu of offering direct testimony at trial, and allowing the parties until January 10, 2014 to file any response. Neither party filed an objection. The draft Order was discussed further at a status conference held on January 15, 2014, at which Special Master Moran "reminded the parties" that after the expert reports were filed, "further direct testimony from their experts should not be expected at hearing." At the January 15, 2014 conference, once again, neither party objected. Also on January 15, 2014, Special Master Moran issued a final version of the draft Order and an "Order Regarding Expert Reports," which described "the minimum information necessary from the expert," along with an Order directing that the parties' "expert's report will constitute that expert's direct testimony." Finally, given the multiple extensions already given to petitioner and her counsel, Special Master Moran's January 15, 2014 Order instructed petitioner to file her expert report by March 21, 2014. It was not until January 24, 2014 that petitioner's counsel moved for reconsideration, arguing that petitioner had a right to have her expert give direct testimony at trial. In a January 29, 2014 Order denying the Motion for Reconsideration, Special Master Moran explained that the January 15, 2014 Order was intended to expedite the proceedings, and that the "practice of submitting direct testimony in writing as part of a non-jury case has been used in a variety of contexts," as it gives the parties "flexibility in presenting the expert's opinions and basis for those opinions" through a "more developed and more thoroughly presented report."

As noted above, on April 2, 2014, petitioner's case was reassigned to Special Master Brian H. Corcoran. Petitioner finally filed her expert report on June 20, 2014,

followed by a supplemental expert report on December 31, 2014. Petitioner produced Dr. Beatrice C. Engstrand as her medical expert. Dr. Engstrand is board-certified in neurology and has completed three residencies, one in medicine and two in neurology. Regarding Dr. Engstrand's credentials, Special Master Corcoran noted in his decision, "[a]s she acknowledged at hearing, however, Dr. Engstrand lacks specialized expertise in the condition of epilepsy (whether in her education, or through research or study), other than from what she has learned from those patients she has seen with it." K.L. v. Sec'y of Health & Human Servs., 2017 WL 1713110, at *4. In her expert report submitted to the Special Master on June 20, 2014, Dr. Engstrand offered her opinion that "[s]eizure is confirmed as an adverse event following HPV Gardasil vaccine" and that "[K.L.'s] persistent neurological sequelae, poor concentration, migraines, learning disorder and seizure disorder were caused by a postvaccinal reaction to her HPV/Gardasil vaccine of February 9, 2010." Dr. Engstrand's report indicated that "[t]he most likely mechanism(s) of injury and it's [sic] biological basis in this case, is that the release of the cytokine[15] interleukin-1 beta in the course of the immune response to a [sic] infectious agent such as a vaccine, could in turn trigger a cluster of afebrile convulsions or seizures." Dr. Engstrand's report placed significant weight on the temporal proximity of the Gardasil vaccination and K.L.'s first seizure. Dr. Engstrand offered three scientific articles to support her opinion, the first of which reported on two patients who had experienced seizures (one of whom had a prior epilepsy diagnosis) out of approximately 700,000 Gardasil vaccinations,[16] the second of which did not mention Gardasil,[17] and the last of which described autoimmune reactions to HPV without reference to epilepsy or seizures.[18]

Respondent produced Dr. Shlomo Shinnar as an expert witness, who is board certified in neurology with special competence in child neurology, and who has additional qualifications in clinical neurophysiology and epilepsy. Dr. Shinnar produced his expert report, along with twenty pieces of supporting medical literature on August 25, 2014. Dr. Shinnar's report maintained that there neither was any evidence persuasively linking HPV

[15] A cytokine is defined as "a generic term for nonantibody proteins released by one cell population (e.g., primed T lymphocytes) on contact with specific antigen, which act as intercellular mediators, as in the generation of an immune response." Dorland's Illustrated Medical Dictionary 466.

[16] Tara Harris, et al., Adverse Events Following Immunization in Ontario's Female School-Based HPV Program, 32 Vaccine 1061 (2014), filed as petitioner's Exhibit 25.

[17] David C. Wraith, et al., Vaccination and Autoimmune Disease, 362 The Lancet 1659 (2003), filed as petitioner's Exhibit 26.

[18] Paolo Pellegrino, et al., On the Relationship Between Human Papilloma Virus Vaccine and Autoimmune Diseases, 13 Autoimmunity Revs., 736 (2014), filed as petitioner's Exhibit 27.

with epilepsy, nor any indication that K.L. had experienced an autoimmune reaction from Gardasil.

Consistent with Dr. Poduri, referred to by Dr. Shinnar as a "renowned epilepsy expert," but in contrast with K.L.'s other treating physicians, who Dr. Shinnar referred to as "general neurologists," after a review of K.L.'s medical history, Dr. Shinnar concluded that the most likely explanation for K.L.'s seizures was idiopathic epilepsy. Dr. Shinnar specifically contrasted K.L.'s condition with autoimmune epilepsy, which he identified as a rare condition that is characterized by intractable seizures and a markedly abnormal EEG with epileptiform activity, none of which were symptoms K.L. demonstrated. Furthermore, Dr. Shinnar explained that K.L.'s normal MRI and lumbar puncture, lack of fever, and lack of epileptiform features in her EEG after the first seizure all showed no evidence of autoinflammation. Regarding Dr. Engstrand's theory identifying the cytokine interleukin-1 beta as the mechanism for injury, Dr. Shinnar stressed that scientific evidence strongly supports that interleukin-1 beta is the chief cytokine that mediates fever, and, thus, it has been associated with febrile seizures,[19] but not afebrile seizures like the one K.L. experienced. Among the articles Dr. Shinnar included in his expert report was Lisen Arnheim-Dahlstrom et al., Autoimmune, Neurological and Venous Thromboembolic Adverse Events After Immunization of Adolescent Girls with Quadrivalent Human Papillomavirus Vaccine in Denmark and Sweden: Cohort Study, 347 BMJ (2013), filed as respondent's Exhibit S[20] (the Arnheim-Dahlstrom study), which was a population-based study that compared seizure rates of girls who did and did not receive the Gardasil vaccine. This study found that the seizure rate was higher for girls who did not receive the vaccine, which Dr. Shinnar explained meant that it is unlikely the vaccine causes seizures, and that the data was reliable because it analyzed actual observed cases, not self-reported events. Dr. Shinnar also pointed out that K.L.'s January 2013 seizure was explainable by her doctor's failed attempt to reduce her dosage of the Keppra medication, as opposed to showing that the medication was ineffective against her condition.

On December 30, 2014, petitioner filed Dr. Engstrand's first supplemental expert report, in which Dr. Engstrand asserted that K.L. had evidenced no seizure symptoms before petitioner's February 11, 2010 seizure and offered answers to questions, as ordered by Special Master Corcoran in an October 9, 2014 Order. Dr. Engstrand's report also cited to an article from a Spanish medical journal, M.A. Rodriguez-Galan, et al., Adverse Reactions to the Human Papillomavirus Vaccine in the Valencian Community (2007-2011), 81 Anales Pediatria 303 (2014), filed as petitioner's Exhibit 29 (the Valencian study), which analyzed self-reported adverse events following vaccination; out of 194 events analyzed in the article, six were seizures, and four of these were related to syncope. Dr. Engstrand's second supplemental report was filed on May 18, 2015. In it,

[19] A febrile seizure is one associated with high fever; an afebrile seizure occurs without a fever. Dorland's Illustrated Medical Dictionary 411.

[20] Petitioner filed exhibits using numerical designations, and respondent filed exhibits using alphabetical designations.

she sought to rebut Dr. Shinnar's expert report by asserting that autoimmune-related epilepsy was more common than Dr. Shinnar had suggested, and that a patient could have it even without an abnormal EEG or prior or concurrent fever. Dr. Engstrand then asserted that K.L.'s observed symptoms could be associated with autoimmune epilepsy, and denied the importance of the absence of autoimmune inflammation indicated in K.L.'s tests. Dr. Engstrand attached literature that described risks associated with Gardasil generally,[21] and articles about epilepsy that did not mention Gardasil.[21]

On July 22, 2016 and August 19, 2016, respectively, the parties filed their prehearing submissions. Petitioner argued that she would be able to meet her burden of proof under the test laid out by the United States Court of Appeals for the Federal Circuit in Althen v. Secretary of Health and Human Services, 418 F.3d 1274 (Fed. Cir. 2005), to prove a causal connection between the vaccine and her alleged injuries by a preponderance of the evidence. Petitioner emphasized that she was not required to prove a scientifically certain theory of causation, but only "a plausible medical theory causally connecting the vaccination and the injury" by a preponderance of the evidence.

Respondent argued petitioner had failed to meet her burden of proof under the Althen standard to establish that Gardasil had more likely than not caused K.L.'s alleged injuries because (1) her causation theory was not supported by reliable scientific evidence, (2) there was not a sufficient logical relationship between the vaccine and alleged injury, and (3) petitioner did not establish that her condition began within a medically appropriate timeframe. Respondent also emphasized that the Special Master has authority to weigh the credibility of expert testimony and supporting evidence offered, including their scientific validity.

An entitlement hearing was held before Special Master Corcoran on September 27, 2016. Although both Special Masters had indicated earlier that the expert reports would operate as the experts' direct testimony, and that the experts would only appear at the hearing for cross examination, at the hearing, Special Master Corcoran did allow both

[21] Charlotte Haug, The Risks and Benefits of HPV Vaccination, 302 JAMA 795 (2009), filed as petitioner's Exhibit 34; Lucija Topmlijenovic, et al., Too Fast or Not Too Fast: the FDA's Approval of Merck's HPV Vaccine Gardasil, J.L. Med. & Ethics 673 (2012), filed as petitioner's Exhibit 36; and Gardasil Prescribing Information, Merck & Co., Inc. (2015), filed as petitioner's Exhibit 37.

[21] Ignacio Valencia, Epilepsy in Systemic Autoimmune Disorders, 21 Seminars in Pediatric Neurology 226 (2014), filed as petitioner's Exhibit 32; Jehan Suleiman, et al. Autoimmune Epilepsy in Children: Case Series and Proposed Guidelines for Identification, 54 Epilepsia 1036 (2013), filed as petitioner's Exhibit 33; and Barbara A. Slade, et al. Post Licensure Safety Surveillance for Quadrivalent Human Papillomavirus Recombinant Vaccine, 302 JAMA 750 (2009), filed as petitioner's Exhibit 35.

parties' experts to give brief direct testimony. At the opening of the hearing, Special Master Corcoran stated,

> What I am going to allow each side to do is to very briefly, in less than five minutes, if not quicker, allow the expert to provide the essence of what their testimony is going to be or what their report says, and then we will go into cross examination and then we'll have redirect, and then, at that time, counsel will have the opportunity to follow up with their expert. That's the process that I'm going to follow today.

It is noteworthy that in her direct testimony, petitioner's expert witness, Dr. Engstrand, abandoned the theory she had proposed in her first submitted report, which specified the interleukin-1 beta cytokine as the mechanism of K.L.'s injury, and instead suggested that K.L.'s brain had been irritated and become hyper-excitable from "an immune-mediated response, like an interleukin or any other cytokine, not knowing which one in particular," triggered by the vaccine. In response to questioning at the hearing by Special Master Corcoran, Dr. Engstrand said she had modified her theory because she realized that K.L.'s cytokines had never been tested, so there was no way to be certain that interleukin-1 beta had been the specific trigger. When Special Master Corcoran asked Dr. Engstrand to elaborate on her modified theory of causation, Dr. Engstrand admitted that she was relying heavily on the fact of the seizure, and not on direct evidence of cytokines, inflammation or indicia in K.L.'s MRI. Dr. Engstrand contended that even though K.L.'s tests were normal, her lumbar puncture did not include testing for cytokines, and stated, "But I don't fault them because that's not routinely done." She also testified that the temporal association between the February 9, 2010 vaccination and K.L.'s seizure two days later was medically appropriate.

During cross examination, counsel for the respondent asked Dr. Engstrand questions about the evidence in the record regarding K.L.'s learning, literacy, and social difficulties which predated her HPV vaccination, which Dr. Engstrand maintained had worsened after K.L. received the vaccine. On re-direct examination, petitioner's counsel asked questions about petitioner's Exhibit 17, K.L.'s comprehensive learning evaluation, and Dr. Engstrand responded that K.L. had experienced a decline in her cognitive abilities post-seizure. On re-cross, however, Dr. Engstrand admitted that K.L. may have had a cognitive problem well before her seizure, as indicated in notes about learning difficulties early in K.L.'s education in the comprehensive learning evaluation.

In response to questioning regarding the fact that K.L.'s seizure was afebrile, Dr. Engstrand was unable to point to anything in the literature she had cited in her expert reports that showed a connection between the HPV vaccination and afebrile seizures. Dr. Engstrand referenced data reported in the Valencian study to support her theory that there was a logical relationship between K.L.'s vaccination and seizures. Dr. Engstrand remarked that the fact that the Valencian study made no mention of whether the seizures were febrile meant that they must have been afebrile, because "if they were febrile seizures, [the authors] would have to comment on it and they didn't comment on it." Regarding K.L.'s consultation with Dr. Poduri, Dr. Engstrand noted Dr. Poduri had included in her records that K.L. "notably had her Gardasil vaccination two days prior to

the first seizure," but on re-cross examination admitted that even with this knowledge, Dr. Poduri had diagnosed K.L.'s epilepsy as idiopathic.

In his testimony, Dr. Shinnar stated that interleukin-1 beta was irrelevant in this case because patients cannot have interleukin-1 beta-mediated reactions without fever, and K.L. did not have a fever with her seizure. Dr. Shinnar indicated that K.L. had idiopathic epilepsy, likely caused by her genetic predisposition and not by Gardasil, based on his review of her medical records, including her normal test results, family history of epilepsy, response to treatment, and other co-morbidities. Dr. Shinnar also noted that K.L.'s learning deficits predated and were not exacerbated by her vaccine, based on notes about K.L.'s cognitive abilities over time in the comprehensive learning evaluation and supported in his report by relevant medical literature. Dr. Shinnar noted that the literature Dr. Engstrand relied on that cited seizures associated with syncope was irrelevant to K.L.'s case because such seizures are "very different than an epileptic seizure." Dr. Shinnar also noted that, while K.L.'s normal EEG was not inconsistent with an epileptic seizure, it was inconsistent with autoimmune epilepsy and made Dr. Engstrand's theory "extremely unlikely." He also pointed out that cytokine testing is not even available in a lumbar puncture, as Dr. Engstrand had suggested.

On cross examination, Dr. Shinnar stated that "[t]emporal relationship is one of the factors used" in a causation analysis, "but does not stand by itself," especially when analyzing a common type of seizure experienced by adolescents. Dr. Shinnar also explained that "there is no evidence in this case that the prolonged seizure is a cause of her epilepsy; it is the onset of her epilepsy." When questioned about the large "population-based study" he cited in his expert report (the Arnheim-Dahlstrom study), Dr. Shinnar noted that the study's finding that the seizure rate was higher in patients who never received the Gardasil vaccine indicated that it was unlikely the vaccine caused an increased risk of seizures. By comparison, Dr. Shinnar testified that the Valencian study was not reliable evidence for petitioner's theory because its journal of publication was "an obscure journal" and the study relied on self-reported adverse events, compared to studies like Arnheim-Dahlstrom, which analyzed actual diagnosed and observed vaccination cases, and was published in a "highly regarded peer-reviewed journal." Dr. Shinnar also pointed to the publication by the Institute of Medicine[22] he had cited in his expert report, which, pursuant to a contract, was charged by the Health Resources and Services Administration (HRSA)[23] with reviewing the available data on adverse events or complications resulting from vaccines, including neurological events like seizures.[24] See

[22] The Institute of Medicine is now affiliated with the Health and Medicine Division of the National Academies of Sciences, Engineering and Medicine. See http://www.nationalacademies.org/hmd/.

[23] The HRSA is an agency of the United States Department of Health and Human Services that administers the Vaccine Injury Compensation Program (VICP) under the Vaccine Act. See www.hrsa.gov.

[24] The Report Brief explains,

Institute of Medicine, National Academies of Science, Adverse Effects of Vaccines: Evidence and Causality (2012). This report did not list epilepsy among the possible complications of Gardasil, and noted that there was insufficient data connecting it with other neurologic complications. See id.

The parties filed post-hearing briefs on November 14, 2016. Respondent's post-hearing brief reiterated its arguments from its Vaccine Rule 4(c) report that petitioner's claim should fail because she did not meet her burden of proof under Althen to demonstrate by a preponderance of the evidence that the vaccine was more likely than not the cause of her alleged injuries. Respondent further argued, as Dr. Shinnar had explained at the hearing, that petitioner's expert's theory of K.L.'s condition was unsupported by scientific evidence or by K.L.'s clinical symptoms, whereas K.L.'s symptoms were consistent with other known causes of epileptic seizures, as her treating physician's diagnosis had indicated. Petitioner's post-hearing memorandum relied on Dr. Engstrand's expert report and testimony regarding the cause of K.L.'s medical condition, and argued that Dr. Poduri's diagnosis should not be considered in evaluating K.L.'s right to compensation because "a diagnosis of an idiopathic disease or injury cannot be used to deny a petitioner compensation [under the Vaccine Act] because it is of an unknown cause."

The Special Master subsequently granted petitioner's request to file an additional post-hearing affidavit from Dr. Engstrand with additional exhibits. On September 6, 2016, petitioner's expert filed the affidavit, attaching three more scientific studies and the introduction to a book discussing adverse effects of many types of vaccines, Committee to Review Adverse Effects of Vaccines: Institute of Medicine 27, Adverse Effects of Vaccines: Evidence and Causality, (Kathleen Stratton et al., eds., 2011), filed as petitioner's Exhibit 44. Dr. Engstrand stated in her affidavit that one of the scientific studies supported the possibility of afebrile seizures following an HPV vaccine, Nigel W. Crawford et al., Syncope and Seizures Following Human Papillomavirus Vaccination: A Retrospective Case Series, 194 Med. J. Austl. 16 (2011), filed as petitioner's Exhibit 41 (the Crawford study), which was a retrospective study of passive surveillance reporting

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> Under the National Childhood Vaccine Injury Act of 1986, Congress established the National Vaccine Injury Compensation Program (VICP) to provide compensation to people injured by vaccines . . . . The Health Resources and Services Administration (HRSA), the agency within the Department of Health and Human Services that administers VICP, can use evidence that demonstrates a causal link between an adverse event and a vaccine to streamline the claims process. As such, HRSA asked the Institute of Medicine (IOM) to review a list of adverse events associated with vaccines covered by VICP and to evaluate the scientific evidence about the event-vaccine relationship.

Adverse Events of Vaccines: Evidence and Causality, Report Brief, Chapter 9, Human Papillomavirus Vaccine, 505-524, Institutes of Medicine, National Academies Press, 2012.

adverse vaccine events. The affidavit also referenced a report that studied the involvement of cytokines in epilepsy, Gang Li et al., Cytokines and Epilepsy, 20 Seizure 249 (2011), filed as petitioner's Exhibit 42 (the Li study). The third study, Sarah von Spiczak et al., A Retrospective Population-Based Study on Seizures Related to Childhood Vaccination, 52 Epilepsia 1506 (2011), filed as petitioner's Exhibit 43 (the Spiczak study), referenced afebrile seizures experienced by children under six years old, none of whom had been vaccinated with Gardasil.

After reviewing the administrative record, on March 17, 2017, Special Master Corcoran denied petitioner's claim seeking compensation for her alleged injuries, which petitioner argued were the result of her Gardasil vaccination, finding that petitioner had failed to carry her burden of proof to show by a preponderance of the evidence that the vaccine had caused her injuries under the three-pronged Althen test. See K.L. v. Sec'y of Health & Human Servs., 2017 WL 1713110, at *14. Specifically, Special Master Corcoran found:

> Beyond the close temporal relationship between K.L.'s receipt of the third dose of Gardasil and onset of her first diagnosed seizure, the medical record does not support the conclusion that her epilepsy was vaccine-caused. More fundamentally, she has not established a reliable scientific theory that the HPV vaccine could cause epilepsy of the kind experienced by Petitioner.

Id. Special Master Corcoran was not persuaded by petitioner's expert witness or the literature submitted by petitioner, finding also that petitioner's theory of causation "exceed[ed] the expertise of Dr. Engstrand to espouse," because the crux of her theory required expertise in immunology and Dr. Engstrand had not demonstrated any competence or skill as an immunologist. See id.

With regard to the first prong of the Althen test, whereby petitioner must show a reliable medical theory causally connecting the vaccination and injury, the Special Master found overall that petitioner's causation theory was not supported by reliable and reasonable scientific evidence. See id. The Special Master determined that "[w]hile the individual articles offered proved reasonable and reliable individually, taken as a whole they do not assist Petitioner's case," because "much of the literature offered either involved autoimmune forms of epilepsy (which are irrelevant under the facts of the case), different vaccines, or involved the relationship between the HPV vaccine and febrile seizures, which K.L. unquestionably never experienced." Id. The Special Master further wrote:

> The epidemiologic evidence, such as the Valencian Article, Crawford [study], and Spiczak [study], offered to suggest that afebrile seizures are also possible not only involved VAERS [Vaccine Adverse Event Reporting System]-like passive surveillance (which is inherently less trustworthy than a retrospective study observing actual diagnosed instances of illness or conditions like epilepsy following vaccination) but was commonly distinguishable when examined closely.

See id. Special Master Corcoran noted that while petitioner need not prove scientific causation to a certainty, the court is permitted to scrutinize the evidence a claimant offers in support of her theory, including its scientific validity. The Special Master found that the authority cited by petitioner's expert in support of her theory "was insufficiently related to vaccines, or did not even facially support the concept." See id.

The Special Master highlighted how Dr. Shinnar had refuted Dr. Engstrand's original theory of causation in her first expert report of interleukin-1 beta as the primary cytokine involved in causing K.L.'s symptoms when "[i]n response, Dr. Shinnar noted that this cytokine was associated with fever – but K.L. unquestionably had experienced an afebrile seizure, making it impossible for that particular cytokine to have been involved in the alleged process by which the HPV vaccine caused K.L.'s seizure." Id. at *15. The Special Master noted that Dr. Engstrand subsequently had modified her theory of causation at the hearing and in a post-hearing affidavit. See id. The Special Master also analyzed the literature Dr. Engstrand attached to her reports and affidavit and found the studies "largely unpersuasive." See id. For example, the Valencian study "[made] no mention of whether the few reported instances of seizure were afebrile." Id. At the hearing, during cross examination by petitioner's counsel, Dr. Engstrand made the following assertion:

> Q: So, you're assuming that they did not have fevers; it doesn't say they did not have fevers. You're not quoting the article.
>
> A: If they were febrile seizures, they would have to comment on it and they didn't comment on it. They would have said seizures with fever and there's no mention of a fever with the seizures.

The Special Master noted in his decision that this assumption was "a somewhat unreasonable inference." Id.

Regarding the Li study, the Special Master found that the study showed an association between the effect seizures have on cytokine upregulation and not "the other way around," i.e., upregulation of cytokines causing seizures per Dr. Engstrand's theory. See id. The Special Master went on to closely analyze and explain how other studies provided by petitioner following the hearing were similarly unhelpful to her case. See id. The Special Master found that the evidence respondent cited in support of its theory of the causes of K.L.'s medical condition by respondent was supported by more reliable and more persuasive evidence, including studies that tended to show that Gardasil was not a likely cause of injuries of the kind K.L. experienced, because those studies had analyzed observed cases rather than self-reported reactions. See id.

Because the Special Master found that petitioner had failed to carry her burden of proof under the first Althen prong, he noted that it was "unnecessary to discuss Petitioner's showings under the other two Althen prongs," but, nevertheless, considered and addressed each. See id. at *16. Regarding the second Althen prong, whereby petitioner must show by a preponderance of the evidence that there is a logical sequence of cause and effect between the vaccine and her alleged injury, the Special Master found

that petitioner "had not successfully demonstrated with preponderant evidence that the HPV vaccine did cause her initial seizure as alleged." See id. The Special Master considered the testimony of respondent's expert more convincing, and found:

> K.L.'s medical records indicated no signs of an autoimmune process occurring contemporaneous with her initial hospitalization, or the kind of biologic markers that would reflect the cytokine upregulation that Dr. Engstrand opined was happening herein. Rather, her test results throughout treatment were normal, including an MRI and multiple EEGs. Dr. Shinnar also effectively distinguished K.L.'s presentation with that of a patient with autoimmune epilepsy . . . . In addition, particularly trustworthy treaters with significant epilepsy expertise, like Dr. Poduri, were aware of the vaccine's administration but concluded, based on their review of the developing medical record, that more likely than not K.L.'s epilepsy was idiopathic.

Id.

As to the third Althen prong, whereby petitioner must show that there is a proximate temporal relationship between vaccination and the injury, the Special Master noted that temporal proximity would not alone support a claim for compensation under the Vaccine Act. See id. Moreover, the Special Master determined petitioner's expert had "offered little authority to support Petitioner's conclusion that [the timeframe between her vaccination and the alleged injury was] medically appropriate." See id. The Special Master "acknowledge[d] that a two-day period between vaccination and seizure has been deemed medically acceptable in other [Vaccine Injury] Program cases involving epilepsy." See id. Regarding the third Althen prong, the Special Master emphasized that "even were [he] to find that the balance of evidence on this matter barely favored K.L., that determination would not alter" his decision denying entitlement, because he had already found that petitioner's causation theory was "too deficient" and "unsupported by the actual medical history," and, thus, failed to meet the first Althen prong. See id. at *17. Moreover, the Special Master noted that defining a "medically appropriate" timeframe necessarily refers to a theory of causation. See id. Therefore, given that petitioner's claim alleged a non-Table injury, and finding that the weight of evidence did not support her claim, Special Master Corcoran denied compensation. See id.

On April 16, 2017, petitioner filed a Motion for Review of the Special Master's decision, and the case was assigned to the undersigned. In her motion, petitioner alleges that the Special Master violated due process, that he impermissibly increased petitioner's burden of proof, and that the Special Master's ruling was arbitrary and capricious.

On May 17, 2017, the Secretary of Health and Human Services' filed a Memorandum in Response to Petitioner's Motion for Review asserts that the Vaccine Rules expressly confer discretionary authority on the Special Master to decide the best manner in which to proceed, including to allow direct testimony by the experts or to take into evidence the experts' written reports as the direct testimony. Regarding petitioner's argument that the Special Master increased petitioner's burden of proof, respondent

argues that the Special Master correctly applied the Althen test to petitioner's case. Respondent also argues that, as the factfinder, the Special Master's weighing and evaluation of evidence is entitled to substantial deference by this court. According to respondent, because Special Master Corcoran carefully considered the relevant evidence, his decision was not arbitrary or capricious and this court should affirm his decision.

DISCUSSION

Although petitioner's Motion for Review is confusingly structured and the filings are repetitive and poorly articulated, petitioner appears to assert three main grounds to argue why the Special Master's decision should be reversed. First, petitioner alleges that the procedures followed by the Special Master during the September 27, 2016 entitlement hearing violated due process. Specifically, petitioner alleges that the Order by the Special Master previously assigned to this case, that the parties' expert reports would constitute their direct testimony, violated petitioner's "fundamental right to a full and fair hearing," as guaranteed by Vaccine Rules 3(b)(2) and 8. Second, petitioner alleges that the Special Master erred by applying the incorrect legal standard to analyze whether petitioner met her burden of proof for compensation under the Vaccine Act. Third, petitioner alleges that the Special Master's decision was arbitrary and capricious because it did not address alleged flaws in the testimony of respondent's expert, while, simultaneously, unfairly criticizing petitioner's expert, it improperly discounted the medical literature presented by petitioner, and it misinterpreted or failed to review "numerous exhibits" included in the record. The government, however, argues that the Special Master did not violate due process because the Special Master has the discretion to have the experts' written reports serve as direct testimony, that the Special Master properly considered the credibility of the expert witnesses and evidence presented, and that the Special Master's decision was not arbitrary or capricious because it was based on a thorough review of the evidence in the record, including the expert testimony presented.

When reviewing a Special Master's decision, the assigned Judge of the United States Court of Federal Claims shall:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
>
> (B) set aside any findings of fact or conclusions of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
>
> (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2). The legislative history of the Vaccine Act states: "The conferees have provided for a limited standard for appeal from the [special] master's decision and do not intend that this procedure be used frequently, but rather in those

cases in which a truly arbitrary decision has been made." H.R. Rep. No. 101-386, at 517 (1989) (Conf. Rep.), reprinted in 1989 U.S.C.C.A.N. 3018, 3120.

In order to recover under the Vaccine Act, petitioners must prove that the vaccine caused the purported injury. See W.C. v. Sec'y of Health & Human Servs., 704 F.3d 1352, 1355-56 (Fed. Cir. 2013) ("The Vaccine Act created the National Vaccine Injury Compensation Program, which allows certain petitioners to be compensated upon showing, among other things, that a person 'sustained, or had significantly aggravated' a vaccine-related 'illness, disability, injury, or condition.'" (quoting 42 U.S.C. § 300aa–11(c)(1)(C))); Lombardi v. Sec'y of Health & Human Servs., 656 F.3d 1343, 1350 (Fed. Cir. 2011) ("A petitioner seeking compensation under the Vaccine Act must prove by a preponderance of the evidence that the injury or death at issue was caused by a vaccine."); see also Shapiro v. Sec'y of Health & Human Servs., 105 Fed. Cl. 353, 358 (2012), aff'd, 503 F. App'x 952 (Fed. Cir. 2013); Jarvis v. Sec'y of Health & Human Servs., 99 Fed. Cl. 47, 54 (2011).

Regarding the standard of review, articulated in Markovich v. Secretary of Health and Human Services, the United States Court of Appeals for the Federal Circuit wrote, "[u]nder the Vaccine Act, the Court of Federal Claims reviews the Chief Special Master's decision to determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.' 42 U.S.C. § 300aa-12(e)(2)(B)." Markovich v. Sec'y of Health & Human Servs., 477 F.3d 1353, 1355-56 (Fed. Cir.), cert. denied, 552 U.S. 816 (2007); see also Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d 1363, 1366 (Fed. Cir.) (The United States Court of Appeals for the Federal Circuit stated that "we 'perform[ ] the same task as the Court of Federal Claims and determine[ ] anew whether the special master's findings were arbitrary or capricious.'" (quoting Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000))) (brackets in original), reh'g and reh'g en banc denied (Fed. Cir. 2013); W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1355; Hibbard v. Sec'y of Health & Human Servs., 698 F.3d 1355, 1363 (Fed. Cir. 2012); Avera v. Sec'y of Health & Human Servs., 515 F.3d 1343, 1347 (Fed. Cir.) ("Under the Vaccine Act, we review a decision of the special master under the same standard as the Court of Federal Claims and determine if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" (quoting 42 U.S.C. § 300aa-12(e)(2)(B))), reh'g and reh'g en banc denied (Fed. Cir. 2008); de Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1350 (Fed. Cir.), reh'g and reh'g en banc denied (Fed. Cir. 2008); Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1277; Dodd v. Sec'y of Health & Human Servs., 114 Fed. Cl. 43, 47 (2013); Taylor v. Sec'y of Health & Human Servs., 108 Fed. Cl. 807, 817 (2013). The arbitrary and capricious standard is "well understood to be the most deferential possible." Munn v. Sec'y of Health & Human Servs., 970 F.2d 863, 870 (Fed. Cir. 1992).

Therefore, this court may set aside a Special Master's decision only if the court determines that the "findings of fact or conclusion of law of the special master . . . [are] arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . ." 42 U.S.C. § 300aa-12(e)(2)(B); see also Lombardi v. Sec'y of Health & Human Servs., 656 F.3d at 1350 ("We uphold the special master's findings of fact unless they are arbitrary or capricious.") (internal citations omitted); Moberly ex rel. Moberly v. Sec'y of Health &

Human Servs., 592 F.3d 1315, 1321 (Fed. Cir. 2010); Markovich v. Sec'y of Health & Human Servs., 477 F.3d at 1356-57; Lampe v. Sec'y of Health & Human Servs., 219 F.3d at 1360. The United States Court of Appeals for the Federal Circuit has indicated that:

> These standards vary in application as well as degree of deference. Each standard applies to a different aspect of the judgment. Fact findings are reviewed by us, as by the Claims Court judge, under the arbitrary and capricious standard; legal questions under the "not in accordance with law" standard . . . ; and discretionary rulings under the abuse of discretion standard. The latter will rarely come into play except where the special master excludes evidence.

Munn v. Sec'y of Dep't of Health & Human Servs., 970 F.2d at 871 n.10; see also Carson ex rel. Carson v. Sec'y of Health & Human Servs., 727 F.3d 1365, 1369 (Fed. Cir. 2013); Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d at 1366; W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1355; Griglock v. Sec'y of Health & Human Servs., 687 F.3d 1371, 1374 (Fed. Cir. 2012); Porter v. Sec'y of Health & Human Servs., 663 F.3d 1242, 1249 (Fed. Cir. 2011) (citing Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339, 1345 (Fed. Cir. 2010)) (explaining that the reviewing court "do[es] not reweigh the factual evidence, assess whether the special master 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"); Dodd v. Sec'y of Health & Human Servs., 114 Fed. Cl. at 56. "With regard to both fact-findings and fact-based conclusions, the key decision maker in the first instance is the special master. The Claims Court owes these findings and conclusions by the special master great deference – no change may be made absent first a determination that the special master was 'arbitrary and capricious.'" Munn v. Sec'y of Health & Human Servs., 970 F.2d at 870; see also 42 U.S.C. § 300aa-12(e)(2)(B).

Generally, "if the special master 'has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate.'" Hibbard v. Sec'y of Health & Human Servs., 698 F.3d at 1363 (quoting Hines on Behalf of Sevier v. Sec'y of Dep't of Health & Human Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991)); see also Porter v. Sec'y of Health & Human Servs., 663 F.3d at 1253-54; Lampe v. Sec'y of Health & Human Servs., 219 F.3d at 1360; Avila ex rel. Avila v. Sec'y of Health & Human Servs., 90 Fed. Cl. 590, 594 (2009); Dixon v. Sec'y of Health & Human Servs., 61 Fed. Cl. 1, 8 (2004) ("The court's inquiry in this regard must therefore focus on whether the special master examined the 'relevant data' and articulated a 'satisfactory explanation for its action including a "rational connection between the facts found and the choice made." (quoting Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) (quoting Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168 (1962)))).

As noted by the United States Court of Appeals for the Federal Circuit:

> Congress assigned to a group of specialists, the special masters within the Court of Federal Claims, the unenviable job of sorting through these painful

> cases and, based upon their accumulated expertise in the field, judging the merits of the individual claims. The statute makes clear that, on review, the Court of Federal Claims is not to second guess the special masters [sic] fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process. Our cases make clear that, on our review . . . we remain equally deferential. That level of deference is especially apt in a case in which the medical evidence of causation is in dispute.

Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d at 1366 (quoting Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993)) (modification in original); Hibbard v. Sec'y of Health & Human Servs., 698 F.3d at 1363; Locane v. Sec'y of Health & Human Servs., 685 F.3d 1375, 1380 (Fed. Cir. 2012). The Court of Appeals for the Federal Circuit has further explained that the reviewing courts "'do not sit to reweigh the evidence. [If] the special master's conclusion [is] based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary and capricious.'" See Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d at 1367 (quoting Lampe v. Sec'y of Health & Human Servs., 219 F.3d at 1363) (modification in original); see also Hibbard v. Sec'y of Health & Human Servs., 698 F.3d at 1363 (citing Cedillo v. Sec'y of Health & Human Servs., 617 F.3d 1328, 1338 (Fed. Cir. 2010)).

The Special Master has discretion to determine the relative weight of evidence presented, including contemporaneous medical records and oral testimony. See Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (finding that the Special Master had thoroughly considered evidence in record, had discretion not to hold an additional evidentiary hearing); Hibbard v. Sec'y of Health & Human Servs., 698 F.3d at 1368 (finding it was not arbitrary or capricious for the Special Master to weigh diagnoses of different treating physicians against one another, including when their opinions conflict). "'Clearly it is not then the role of this court to reweigh the factual evidence, or to assess whether the special master correctly evaluated the evidence. And of course we do not examine the probative value of the evidence or the credibility of the witnesses. These are all matters within the purview of the fact finder.'" Dodd v. Sec'y of Health & Human Servs., 114 Fed. Cl. at 56 (quoting Munn v. Sec'y of Dept. of Health & Human Servs., 970 F.2d at 870 n.10); see also Rich v. Sec'y of Health & Human Servs., 129 Fed. Cl. 642, 655 (2016); Paluck v. Sec'y of Health & Human Servs., 104 Fed. Cl. 457, 467 (2012) ("A special master's findings regarding the probative value of the evidence and the credibility of witnesses will not be disturbed so long as they are 'supported by substantial evidence.'" (quoting Doe v. Sec'y of Health & Human Servs., 601 F.3d 1349, 1355 (Fed. Cir.), cert. denied, 562 U.S. 1029 (2010))).

Additionally, as instructed by the United States Court of Appeals for the Federal Circuit, "[u]nder the Vaccine Act, Special Masters are accorded great deference in determining the credibility and reliability of expert witnesses. Indeed, we have held that a Special Master's 'credibility determinations are virtually unreviewable.'" Cedillo v. Sec'y of Health & Human Servs., 617 F.3d at 1347 (quoting Hanlon v. Sec'y of Health & Human Servs., 191 F.3d 1344, 1349 (Fed. Cir. 2010) (quotation omitted)); see also Porter v. Sec'y

of Health & Human Servs., 663 F.3d at 1253-54 ("'Reversible error will be extremely difficult to demonstrate' where the Special Master 'has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision.'") (quoting Hines on behalf of Sevier v. Sec'y of Health & Human Servs., 940 F.2d at 1528); Lombardi v. Sec'y of Health & Human Servs., 656 F.3d at 1353; Anderson v. Sec'y of Health & Human Servs., 131 Fed. Cl. 735, 752 (2017); Holt v. Sec'y of Health & Human Servs., 132 Fed. Cl. 194, 199 (2017). Additionally, a Special Master is "not required to discuss every piece of evidence or testimony in [his or] her decision." Snyder ex rel. Snyder v. Sec'y of Health & Human Servs., 88 Fed. Cl. 706, 728 (2009); see also Paluck ex rel. Paluck v. Sec'y of Health & Human Servs., 104 Fed. Cl. at 467 ("[W]hile the special master need not address every snippet of evidence adduced in the case, see id. [Doe v. Sec'y of Health & Human Servs., 601 F.3d at 1355], he cannot dismiss so much contrary evidence that it appears that he 'simply failed to consider genuinely the evidentiary record before him.'" (quoting Campbell v. Sec'y of Health & Human Servs., 97 Fed. Cl. 650, 668 (2011))).

Regarding the causation analysis, as indicated by the United States Court of Appeals for the Federal Circuit in Althen v. Secretary of Health and Human Services:

> The [Vaccine] Act provides for the establishment of causation in one of two ways: through a statutorily-prescribed presumption of causation upon a showing that the injury falls under the Vaccine Injury Table ("Table injury"), see 42 U.S.C. § 300aa-14(a); or where the complained-of injury is not listed in the Vaccine Injury Table ("off-Table injury"), by proving causation in fact, see 42 U.S.C. §§ 300aa-13(a)(1), -11(c)(1)(C)(ii)(I).

Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278; W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1356; Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1346; Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1356 (Fed. Cir.), reh'g and reh'g en banc denied (Fed. Cir. 2006), cert. denied, 551 U.S. 1102 (2007); Dodd v. Sec'y of Health & Human Servs., 114 Fed. Cl. at 50; Paluck v. Sec'y of Health & Human Servs., 104 Fed. Cl. 467-68; Fesanco v. Sec'y of Health & Human Servs., 99 Fed. Cl. 28, 31 (2011). The United States Supreme Court has explained that:

> Claimants who show that a listed injury first manifested itself at the appropriate time are prima facie entitled to compensation. No showing of causation is necessary; the Secretary bears the burden of disproving causation. A claimant may also recover for unlisted side effects, and for listed side effects that occur at times other than those specified in the Table, but for those the claimant must prove causation.

Bruesewitz v. Wyeth LLC, 131 S. Ct. 1068, 1073-74 (2011) (footnotes omitted); Kennedy v. Sec'y of Health & Human Servs., 99 Fed. Cl. 535, 539 (2011), aff'd, 485 F. App'x. 435 (Fed. Cir. 2012).

As both parties recognize, the injuries petitioner alleges she suffered as a result of the Gardasil vaccination are not included on the Vaccine Injury Table. See 42 U.S.C.

§ 300aa-14. Petitioner, therefore, must proceed under an off-Table theory of recovery. Under the off-Table theory of recovery, a petitioner is entitled to compensation if he or she can demonstrate, by a preponderance of the evidence, see 42 U.S.C. § 300aa-13(a)(1)(A), that the recipient of the vaccine sustained, or had significantly aggravated, an illness, disability, injury, or condition not set forth in the Vaccine Injury Table, but which was caused by a vaccine that is listed on the Vaccine Injury Table. See 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I); see also LaLonde v. Sec'y of Health & Human Servs., 746 F.3d 1334, 1339 (Fed. Cir. 2014); W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1356 ("Nonetheless, the petitioner must do more than demonstrate a 'plausible' or 'possible' causal link between the vaccination and the injury; he must prove his case by a preponderance of the evidence." (quoting Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d at 1322)); Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278; Hines on Behalf of Sevier v. Sec'y of Dep't of Health & Human Servs., 940 F.2d at 1525. While scientific certainty is not required, the Special Master "is entitled to require some indicia of reliability to support the assertion of the expert witness." Moberly ex rel. Moberly ex rel. v. Sec'y of Health & Human Servs., 592 F.3d at 1324; see also Hazlehurst v. Sec'y of Health & Human Servs., 88 Fed. Cl. 473, 439 (2009), aff'd, 604 F.3d 1343 (Fed. Cir. 2010) (quoting Andreu ex rel. Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009)).

Additionally, petitioner must prove causation-in-fact. See Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1147-48 (Fed. Cir. 1992). The United States Court of Appeals for the Federal Circuit has held that causation-in-fact in the Vaccine Act context is the same as the "legal cause" in the general torts context. See Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999). Therefore, drawing from the Restatement (Second) of Torts, the vaccine is a cause-in-fact when it is "a substantial factor in bringing about the harm." de Bazan v. Sec'y of Health & Human Servs., 539 F.3d at 1351 (quoting the Restatement (Second) of Torts § 431(a)); see also Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d at 1367 ("To prove causation, a petitioner must show that the vaccine was 'not only a but-for cause of the injury but also a substantial factor in bringing about the injury.'" (quoting Shyface v. Sec'y of Health & Human Servs., 165 F.3d at 1352–53)). A "'substantial factor' standard requires a greater showing than 'but for' causation." de Bazan v. Sec'y of Health & Human Servs., 539 F.3d at 1351 (quoting Shyface v. Sec'y of Health & Human Servs., 165 F.3d at 1352). "However, the petitioner need not show that the vaccine was the sole or predominant cause of her injury, just that it was a substantial factor." Id. (citing Walther v. Sec'y of Health & Human Servs., 485 F.3d 1146, 1150 (Fed. Cir. 2007)). A Judge of the United States Court of Federal Claims has explained the relationship between "but-for" causation and "substantial factor" causation in our court's decision in Deribeaux ex rel. Deribeaux v. Secretary of Health and Human Services:

> The de Bazan court defined but-for causation as requiring that "the harm be attributable to the vaccine to some nonnegligible degree," and noted that, although substantial is somewhere beyond the low threshold of but-for causation, it does not mean that a certain factor must be found to have definitively caused the injury. Id. [de Bazan v. Sec'y of Health & Human Servs., 539 F.3d at 1351] Accordingly, a factor deemed to be *substantial* is

> one that falls somewhere between causing the injury to a non-negligible degree and being the "sole or predominant cause." Id.
>
> This definition of substantial—somewhere between non-negligible and predominant—is applicable to respondent's burden to prove a sole substantial factor unrelated to the vaccine. Accordingly, a respondent's burden is to prove that a certain factor is the only *substantial* factor—one somewhere between non-negligible and predominant—that caused the injury.

Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 105 Fed. Cl. 583, 595 (2012), aff'd, 717 F.3d 1363 (Fed. Cir.), reh'g and reh'g en banc denied (Fed. Cir. 2013) (emphasis in original).

A petitioner must prove his or her case by a preponderance of the evidence. See 42 U.S.C. § 300aa-13(a)(1)(A). According to the United States Court of Appeals for the Federal Circuit, the preponderance of evidence standard is "one of proof by a simple preponderance, of 'more probable than not causation.'" Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1279-80 (citing concurrence in Hellebrand v. Sec'y of Dep't of Health & Human Servs., 999 F.2d 1565, 1572-73 (Fed. Cir. 1993)); see also W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1356 ("In this off-table case, the petitioner must show that it is 'more probable than not' that the vaccine caused the injury." (quoting Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1279-80)). A petitioner who meets this burden is then entitled to recovery under the Vaccine Act, unless the respondent proves by preponderant evidence that the injury was caused by factors unrelated to the vaccine. See Stone v. Sec'y of Health & Human Servs., 676 F.3d 1373, 1379-80 (Fed. Cir. 2012); see also Rus v. Sec'y of Health & Human Servs., 129 Fed. Cl. 672, 680 (2016) (citing 42 U.S.C. § 300aa-13(a)(1)(B); Shalala v. Whitecotton, 514 U.S. 268, 270-71 (1995)); Walther v. Sec'y of Health & Human Servs., 485 F.3d at 1551. "But, regardless of whether the burden of proof ever shifts to the respondent, the special master may consider the evidence presented by the respondent in determining whether the petitioner has established a *prima facie* case." Rus v. Sec'y of Health & Human Servs., 129 Fed. Cl. at 680 (citing Stone v. Sec'y of Health & Human Servs., 676 F.3d at 1379; de Bazan v. Sec'y of Health & Human Servs., 539 F.3d at 1353).

For petitioner to establish a *prima facie* case, decisions of the Federal Circuit permit the use of circumstantial evidence, which the court described as "envisioned by the preponderance standard" and by the vaccine system created by Congress, in which "close calls regarding causation are resolved in favor of injured claimants" without the need for medical certainty. See Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1280; see also Cloer v. Sec'y of Health & Human Servs., 654 F.3d 1322, 1332 n.4 (Fed. Cir. 2011), cert. denied, 566 U.S. 956 (2012); Andreu ex rel. Andreu v. Sec'y of Health & Human Servs., 569 F.3d at 1379 ("In Althen, however, we expressly rejected the Stevens test, concluding that requiring 'objective confirmation' in the medical literature prevents 'the use of circumstantial evidence . . . and negates the system created by Congress' through the Vaccine Act.") (modification in original); LaLonde v. Sec'y of Health & Human Servs., 110 Fed. Cl. 184, 198 (2013) ("Causation-in-fact can be established with

circumstantial evidence, i.e., medical records or medical opinion."), aff'd, 746 F.3d 1334 (Fed. Cir. 2014). The Althen court further noted that "the purpose of the Vaccine Act's 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." Id. (citing Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 549 (Fed. Cir. 1994)); see also W.C. v. Sec'y of Health & Human Servs., 704 F.3d at 1356. When proving eligibility for compensation for an off-Table injury under the Vaccine Act, however, petitioner may not rely on her testimony alone. According to the Vaccine Act, "[t]he special master or court may not make such a finding 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 Federal Circuit in Althen defined a three-prong test which a petitioner must meet to establish causation in an off-Table injury case:

> To meet the preponderance standard, [petitioner] must "show a medical theory causally connecting the vaccination and the injury." Grant v. Sec'y of Health & Humans Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992) (citations omitted). A persuasive medical theory is demonstrated by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]" the logical sequence being supported by "reputable medical or scientific explanation[,]" i.e., "evidence in the form of scientific studies or expert medical testimony[.]" Grant, 956 F.2d at 1148. [Petitioner] may recover if she shows "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Shyface, 165 F.3d at 1352-53. Although probative, neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation. See Grant, 956 F.2d at 1149. Concisely stated, [petitioner's] burden is to show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278 (brackets in original); see also Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d at 1367; Porter v. Sec'y of Health & Human Servs., 663 F.3d at 1249; Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d at 1322; Pafford v. Sec'y of Health & Human Servs., 451 F.3d at 1355; Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1324 (Fed. Cir. 2006); C.K. v. Sec'y of Health & Human Servs., 113 Fed. Cl. 757, 766 (2013).

With regard to the first Althen prong, "a medical theory causally connecting the vaccination and the injury," Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278, the Federal Circuit in Althen analyzed the preponderance of evidence requirement as allowing medical opinion as proof, even without scientific studies in medical literature that

provide "objective confirmation" of medical plausibility. Id. at 1278, 1279-80; see also Shapiro v. Sec'y of Health & Human Servs., 105 Fed. Cl. at 358. In rejecting a requirement that a claimant under the Vaccine Act prove confirmation of medical plausibility from the medical community and medical literature, the Althen court turned to the analysis undertaken in Knudsen ex rel. Knudsen v. Secretary of Health and Human Services, 35 F.3d at 549. See Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1279-80. In Knudsen ex rel. Knudsen v. Secretary of Health and Human Services, the United States Court of Appeals for the Federal Circuit wrote, "to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program. The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims." Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs., 35 F.3d at 549. The Federal Circuit stated further:

> [t]he Court of Federal Claims is therefore not to be seen as a vehicle for ascertaining precisely how and why DTP and other vaccines sometimes destroy the health and lives of certain children while safely immunizing most others. This research is for scientists, engineers, and doctors working in hospitals, laboratories, medical institutes, pharmaceutical companies, and government agencies. The special masters are not "diagnosing" vaccine-related injuries. The sole issues for the special master are, based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [petitioner's] injury or that the [petitioner's] injury is a table injury, and whether it has not been shown by a preponderance of the evidence that a factor unrelated to the vaccine caused the child's injury. See 42 U.S.C. § 300aa-13(a)(1), (b)(1).

Id. (brackets added). The Federal Circuit has also indicated that:

> Although a finding of causation "must be supported by a sound and reliable medical or scientific explanation," causation "can be found in vaccine cases…without detailed medical and scientific exposition on the biological mechanisms." Knudsen v. Sec'y of the Dep't of Health & Human Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994). It is not necessary for a petitioner to point to conclusive evidence in the medical literature linking a vaccine to the petitioner's injury, as long as the petitioner can show by a preponderance of the evidence that there is a causal relationship between the vaccine and the injury, whatever the details of the mechanism may be.

Simanski v. Sec'y of Health & Human Servs., 671 F.3d 1368, 1384 (Fed. Cir. 2012) (omission in original).

The second prong of the Althen test requires the petitioner to demonstrate "a logical sequence of cause and effect, showing that the vaccination was the reason for the injury" by a preponderance of the evidence. Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278; see also Pafford v. Sec'y of Health & Human Servs., 451 F.3d at 1355. In order to prevail, the petitioner must show "that the vaccine was not only a but-for cause

of the injury but also a substantial factor in bringing about the injury." Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278 (quoting Shyface v. Sec'y of Health & Human Servs., 165 F.3d at 1352). In Capizzano v. Secretary of Health and Human Services, 440 F.3d at 1326, the Federal Circuit stated, "'[a] logical sequence of cause and effect' means what it sounds like – the claimant's theory of cause and effect must be logical. Congress required that, to recover under the Vaccine Act, a claimant must prove by a preponderance of the evidence that the vaccine caused his or her injury." Capizzano v. Sec'y of Health & Human Servs., 440 F.3d at 1326 (quoting 42 U.S.C. §§ 300aa-11(c)(1) – 13(a)(1) (2006)); see also Cozart v. Sec'y of Health & Human Servs., 126 Fed. Cl. 488, 498 (2016) (quoting Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278).

The third prong of the Althen test requires the petitioner to demonstrate, by a preponderance of evidence, "a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278. The United States Court of Appeals for the Federal Circuit emphasized the importance of a temporal relationship in Pafford v. Secretary of Health and Human Services, when it noted that, "without some evidence of temporal linkage, the vaccination might receive blame for events that occur weeks, months, or years outside of the time in which scientific or epidemiological evidence would expect an onset of harm." Pafford v. Sec'y of Health & Human Servs., 451 F.3d at 1358. Requiring evidence of strong temporal linkage is consistent with the third requirement articulated in Althen because "[e]vidence demonstrating petitioner's injury occurred within a medically acceptable time frame bolsters a link between the injury alleged and the vaccination at issue under the 'but-for' prong of the causation analysis." Id. (citing Capizzano v. Sec'y of Health & Human Servs., 440 F.3d at 1326). The Capizzano court further explained,

> [i]f, for example, symptoms normally first occur ten days after inoculation but petitioner's symptoms first occur several weeks after inoculation, then it is doubtful the vaccination is to blame. In contrast, if symptoms normally first occur ten days after inoculation and petitioner's symptoms do, in fact, occur within this period, then the likelihood increases that the vaccination is at least a factor. Strong temporal evidence is even more important in cases involving contemporaneous events other than the vaccination, because the presence of multiple potential causative agents makes it difficult to attribute "but-for" causation to the vaccination. After all, credible medical expertise may postulate that any of the other contemporaneous events may have been the sole cause of the injury.

Id. at 1358. A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." de Bazan v. Sec'y of Health & Human Servs., 539 F.3d at 1352. Determining what constitutes a medically appropriate timeframe, thus, is linked to the petitioner's theory of how the vaccine can cause petitioner's injury. See id.; see also K.T. v. Sec'y of Health & Human Servs., 132 Fed. Cl. 175, 186 (2017); Shapiro v. Sec'y of Health & Human Servs., 101 Fed. Cl. at 542.

According to the court in Capizzano v. Secretary of Health and Human Services, evidence used to satisfy one of the Althen prongs may overlap with and be used to satisfy another prong. Capizzano v. Sec'y of Health & Human Servs., 440 F.3d at 1326 ("We see no reason why evidence used to satisfy one of the Althen III prongs cannot overlap to satisfy another prong."). If a petitioner satisfies the Althen burden and meets all three prongs of the test, the petitioner prevails, "unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine." Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs., 35 F.3d at 547 (brackets in original; citation omitted).

In cases in which a petitioner relies upon expert testimony to prove causation, the expert testimony must rest upon an objective and reliable scientific basis and must prove causation to a degree of legal certainty, but not to a medical or scientific certainty. See Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d at 1322 ("A petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be "legally probable, not medically or scientifically certain.'"); see also Cedillo v. Sec'y of Health & Human Servs., 617 F.3d at 1339; Terran ex rel. Terran v. Sec'y of Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999), cert. denied, 531 U.S. 812 (2000). While a petitioner may rely solely on expert testimony, "[a]n expert opinion is no better than the soundness of the reasons supporting it." Perreira v. Sec'y of Health & Human Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994). Therefore, a Special Master does not need to credit "expert opinion testimony that is connected to the existing data or methodology 'only by the *ipse dixit*[25] of the expert,' or where 'there is simply too great an analytical gap between the data and the opinion proffered.'" Jarvis v. Sec'y of Health & Human Servs., 99 Fed. Cl. at 61 (quoting Cedillo v. Sec'y of Health & Human Servs., 617 F.3d at 1339). The Special Master may conduct an inquiry into the scientific reliability of expert testimony as may be reasonable and necessary, and may consider the experts' credentials when determining the relative weight to afford opinion testimony. See Terran v. Sec'y of Health & Human Servs., 195 F.3d at 1316; see also Copenhaver v. Sec'y of Health & Human Servs., 129 Fed. Cl. 176, 183 (2014); Tompkins v. Sec'y of Health & Human Servs., 117 Fed. Cl. 713, 719 (2014); Holmes v. Sec'y of Health & Human Servs., 115 Fed. Cl. 469, 490 (2014); Locane v. Sec'y of Health & Human Servs., 99 Fed. Cl. 715, 727 (2011), aff'd, 685 F.3d 1375, 1380 (Fed. Cir. 2012).

I. The Manner in Which the Special Master Conducted the September 27, 2016 Hearing Did Not Violate Vaccine Rule 3(b)(2) or Vaccine Rule 8.

Petitioner argues in her Motion for Review that this court should reverse the Special Master's Decision Denying Entitlement because the Special Master violated

[25] *Ipse dixit* is Latin for "he himself said it." Black's Law Dictionary 956 (10th ed. 2014). The term is defined as "[s]omething asserted but not proved. . . . The phrase is commonly used in court decisions analyzing the admissibility of expert testimony. A court may reject expert-opinion evidence that is connected to existing data only by the expert's 'ipse dixit.'" Id.

Vaccine Rules 3(b)(2) and 8, which she alleges resulted in a "fundamental abuse of petitioner's right to a full and fair opportunity to present her case." Petitioner initially argues that Special Master Corcoran, to whom the case had been reassigned, erred when, regarding the September 27, 2016 entitlement hearing, he indicated he intended to follow the January 15, 2014 Order issued by Special Master Moran that the parties' expert witness reports would be entered into the record, without the need for oral, direct expert testimony. Although Special Master Corcoran, in fact, allowed limited, direct, expert testimony at the September 27, 2016 hearing, petitioner alleges that the limitations were inappropriate and that the restrictions imposed on the direct testimony by the experts were "not uniformly enforced" by Special Master Corcoran. Petitioner asserts that respondent's expert, Dr. Shinnar, was allowed to give more direct testimony than petitioner's expert, Dr. Engstrand. Petitioner claims that because Dr. Engstrand was not allowed to give full direct testimony at the hearing, it "set up the petitioner to fail by preventing [Dr. Engstrand] from fully explaining her opinions," i.e., "her medical theory, the logical sequence of cause and effect, or the appropriate time period for reactions to the vaccination to comply with the Althen prongs." Petitioner argues that the Special Master's actions violated Vaccine Rule 3(b)(2) because, pursuant to this rule, "[p]etitioner's position is that she has a right to present her expert witness testimony at the hearing including direct testimony," and that Dr. Engstrand had insufficient time to "fully elucidate her opinions." According to petitioner, it was "unreasonable" for the Special Master to expect petitioner's expert to fully explain her theory in written format. [26]

Petitioner also argues in her Motion for Review that the Special Master violated Vaccine Rule 8, on the grounds that, after the Special Master had elected to hold a hearing, petitioner had the right to fully examine her witness and petitioner was allegedly denied this right by the procedures employed by the Special Master. During oral argument, held on May 31, 2017, this court asked petitioner's counsel to identify legal authority in support of this alleged absolute right, and counsel was unable to do so. Petitioner's counsel stated: "[The Special Master] can take written testimony if there is no hearing. If there is a hearing, the rules don't address that," and cited Vaccine Rule 8. The only case law petitioner cites in his brief is Richardson v. Secretary of Health and Human Services, 89 Fed. Cl. 657 (2009), which, although not helpful to petitioner, is a case in which a Judge of this court found that a Special Master at a hearing had "failed to

[26] Petitioner also alleges that "this new rule developed by the special masters, further puts additional financial burdens on petitioner" because "[t]he rule requires petitioner's experts to devote much more time into preparing and drafting their reports then [sic] would take them to orally explain their opinions at hearing, consequently increasing their retainer requirements." In this argument, petitioner and petitioner's counsel seem to suggest that a petitioner should prepare a less complete expert report and save a more complete theory of causation to be presented by the expert on direct examination at the hearing. The court roundly rejects this theory of how to prepare a case. To proceed in this manner would automatically place respondent at a disadvantage, with the inability to review petitioner's theory of causation in order to be prepared for a response and for the hearing.

satisfy . . . fundamental due process requirements." [27] Richardson v. Sec'y of Health & Human Servs., 89 Fed. Cl. at 660.[28]

In its Memorandum in Response to Petitioner's Motion for Review, the government argues that the Special Master is authorized by 42 U.S.C. § 300aa-12(d)(2)(D) and by Vaccine Rules 8(d) and (e) to direct that written expert reports can serve as direct testimony, and that the procedures the Special Master followed provided both parties with a full and fair opportunity to present their cases in furtherance of the goals in Vaccine Rule 3(b)(2). The government additionally asserts that petitioner's Motion for Review is deficient because it fails to specify how her case has been prejudiced by the procedures the Special Master followed.

First, Vaccine Rule 3(b) sets forth the Special Master's "Duties" regarding the manner in which to conduct the proceedings, emphasizing that proceedings should be "expeditious, flexible, and less adversarial, while at the same time affording each party a full and fair opportunity to present its case and creat[e] a record sufficient to allow review of the special master's decision." Vaccine Rule 3(b)(2); see also Campbell ex rel. Campbell v. Sec'y of Health & Human Servs., 69 Fed. Cl. 775, 778 (2006) (finding that the concept of "fundamental fairness" incorporated into Vaccine Rule 3(b) "surely entails

[27] At oral argument, counsel for petitioner also attempted to assert the Fourth Amendment of the United States Constitution as a source of petitioner's alleged denied right to due process of law, but was unable to articulate the basis for this position and was unable to cite any case law in support of his baseless Fourth Amendment due process argument.

[28] In Richardson, a Judge of this court "conclude[d] that the procedures used by the Special Master . . . failed to satisfy these fundamental due process requirements," referring to Vaccine Rules 3(b)(2) and 8(b)(1). Richardson v. Sec'y of Health & Human Servs., 89 Fed. Cl. at 660 The Richardson court so found because the Special Master had "precluded any coherent direct examination" and effectively "functioned as a third adversary to the proceedings, rather than as a judicial officer" when he repeatedly, and disproportionately (e.g., 113 interruptions by the Special Master, compared to petitioner's counsel's 25 questions during direct testimony), interrupted the proceedings such that "the [petitioner's] witness essentially had to endure two cross-examinations instead of one," which the court found "eviscerate[d] the fairness of the proceedings." Id. at 659. In Richardson, the Special Master also rejected the testimony of all fact witnesses, making his decision solely on the written record and "applied every conceivable inference against Petitioners." Id. at 659-60. The Richardson court wrote, "[Vaccine Rule 8(c)(1)] permit[s] a Special Master to propound questions to a witness . . . but not in a way that eviscerates the fairness of the proceedings." Id. at 660. By contrast, here, Special Master Corcoran gave both expert witnesses significant and relatively equal opportunity to summarize their reports, albeit with shortened expert direct testimony, and allowed each counsel to cross-examine and re-direct both witnesses. The only time Special Master Corcoran interrupted a witness was at the beginning of Dr. Shinnar's testimony when he instructed respondent's expert, not petitioner's, not to give more direct testimony than a brief summary of his report.

notice and an effective opportunity to be heard at a meaningful time and in a meaningful manner."); Plavin v. Sec'y of Health & Human Servs., 40 Fed. Cl. 609, 622 (1998) ("The Vaccine Act contemplates evidentiary flexibility and informality in proceedings. . . . In addition, '[i]n conducting a proceeding on a petition a special master . . . may require the testimony of any person . . . as may be reasonable and necessary.'" (quoting 42 U.S.C. § 300aa-12(d)(3)(B)(iii))).

Contrary to petitioner's argument, the procedures followed by the Special Masters in the present case complied with the discretionary responsibilities outlined in Vaccine Rule 3(b)(2). Special Master Moran issued his draft Order on December 23, 2013, which gave advance notice that "the expectation is that the expert's written report will constitute the expert's direct testimony." The draft Order further explained:

> The purpose of this requirement is two-fold. First, because everyone understands that the expert report constitutes the direct testimony, the report will be complete. A complete report is likely to present the considered views of the expert. Thus, the expert's opinion will not be based upon an oral presentation, during which the expert may not express her (or his) opinions as clearly as the expert could have presented them in written format. Second, the amount of time spent at hearing will decrease because the expert will not need to repeat the content of the report.

This language suggests that Special Master Moran was attempting to fulfill his duty to "endeavor[] to make the proceedings expeditious, flexible, and less adversarial." Vaccine Rule 3(b)(2). Special Master Moran subsequently followed up his draft Order with a final Order, issued on January 15, 2014, to the same effect. The Special Master, thus, gave notice to the parties of how the case would proceed well in advance of the filing by both parties of their expert reports.[29] Further, prior to issuing the final Order, Special Master Moran offered both parties over two weeks to file objections. Petitioner failed, during these two weeks, to object to the draft or final Orders, but instead waited until January 24, 2014 to ask that the January 15, 2014 final Order be reconsidered, a request Special Master Moran denied in an Order issued on January 29, 2014.

At the September 27, 2016 entitlement hearing, however, Special Master Corcoran ultimately allowed each expert a roughly equal opportunity to briefly, orally summarize his or her expert report in truncated, direct testimony, in addition permitted each counsel to cross-examine the other party's expert, and to re-direct their own experts. Further, Special Master Corcoran questioned both witnesses himself to be sure he understood their theories of causation. Petitioner, nonetheless, alleges that

> petitioner's expert neurologist Dr. Beatrice Engstrand, could not discuss the detailed meaning of the medical articles she filed because she was not

[29] Petitioner's brief acknowledges that when the case was transferred to the present Special Master, petitioner was informed that Special Master Moran's Order curtailing direct testimony at the hearing would be followed.

> afforded the opportunity to testify directly at the hearing, neither could she fully explain her medical theory, the logical sequence of cause and effect, or the appropriate time period for reactions to the vaccination to comply with the Althen prongs.

Contrary to petitioner's allegations, in Dr. Engstrand's first expert report, two subsequent, supplemental expert reports, and her post-hearing affidavit, as well as during her brief direct testimony,[30] in her much more extensive cross examinations, and in her re-direct testimony, Dr. Engstrand was given more than sufficient opportunities to address her reasons and explanation for her theory of causation.

To the extent petitioner argues that more time for direct testimony would have given Dr. Engstrand "the opportunity to more fully expound upon her cytokine induced seizure medical theory," petitioner's argument is not supported by the facts of this case. During the course of the hearing before Special Master Corcoran, he permitted Dr. Engstrand multiple opportunities to discuss her theory. Moreover, he asked Dr. Engstrand several times to elaborate on the details of her modified cytokine theory and particularly why she had changed her theory of causation from the theory included in her first expert report. Further, not only did Special Master Corcoran permit Dr. Engstrand, prior to the hearing, to file two supplemental reports in addition to her initial, filed expert report, but, even after the hearing, Special Master Corcoran permitted Dr. Engstrand to file a supplementary post-hearing affidavit to "more fully expound upon" her theory, which she had, by her own admission, modified by the time of the hearing. The record before this court indicates that the Special Master gave petitioner multiple opportunities to fully present Dr. Engstrand's view of causation. Furthermore, Special Master Corcoran offered a detailed discussion in his final opinion which addressed the evidence upon which Dr. Engstrand relied to offer her expert opinion. See K.L. v. Sec'y of Health & Human Servs., 2017 WL 1713110, at *4-6.

Finally, contrary to petitioner's allegations, the record before this court contains no evidence that the procedures followed "were not uniformly enforced" on both parties. The Special Master does not appear to have given Dr. Shinnar a significantly greater opportunity at the hearing to summarize his report in the brief direct testimony than he gave to Dr. Engstrand. In the hearing transcript, Dr. Shinnar's direct testimony takes up four pages, each of twenty-five lines, plus ten lines, and Dr. Engstrand's covers three pages, each of twenty-five lines, plus eight lines. The method of conducting the proceedings in K.L.'s case complied with the responsibilities of a Special Master included as specified in Vaccine Rule 3(b)(2), to "endeavor[] to make the proceedings expeditious, flexible, and less adversarial," including by avoiding repetition, "while at the same time affording each party a full and fair opportunity to present its case." The Special Master was not arbitrary and capricious, and did not prevent K.L. from fully explaining her theory of causation.

[30] At the September 27, 2016 hearing, petitioner's counsel directly examined his expert, Dr. Engstrand, albeit briefly, about her opinions regarding all three of the Althen prongs.

Next, petitioner argues that, under Vaccine Rule 8, "she has a right to present her expert witness testimony at the hearing including direct testimony." Vaccine Rule 8 provides the Special Master with broad discretionary authority to "determine the format for taking evidence and hearing argument based on the specific circumstances of each case and after consultation with the parties." Vaccine Rule 8(a). In doing so, the Special Master "will not be bound by common law or statutory rules of evidence, but must consider all relevant and reliable evidence governed by principles of fundamental fairness to both parties." Vaccine Rule 8(b)(1). According to Rule 8, the Special Master "may conduct an evidentiary hearing to provide for the questioning of witnesses either by the special master or by counsel, or for the submission of sworn testimony in written form." Vaccine Rule 8(c)(1) (emphasis added).[31] The plain language of the Vaccine Act and the Vaccine Rules allows broad discretion to the Special Master, including the choice of whether or not to schedule a hearing, and, if so, which witnesses, including the experts, should testify on direct and/or only on cross examination, in addition to submitting expert reports and affidavits. Indeed, the Federal Circuit, explicitly, has approved of a Special Master's decision to forego any expert testimony and decide a case solely on the written record. See Burns v. Sec'y of Health & Human Servs., 3 F.3d at 416-17 (finding it was proper for the Special Master not to hear oral expert medical testimony, after holding an evidentiary hearing and reviewing the expert reports); see also D'Tiole v. Sec'y of Health & Human Servs., 132 Fed Cl. 421, 434-35 at *11 (2017) (finding that the Special Master did not violate Vaccine Rule 3(b) when he or she decided not to hold an evidentiary hearing on an otherwise fully developed record); Murphy v. Sec'y of Health & Human Servs., 23 Cl. Ct. 726, 730 (1991) (finding that, if the Special Master finds that the written record is fully developed, the Special Master may decide the case without an evidentiary hearing, notwithstanding the desires of one or both of the parties).

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[31] The relevant underlying statute states:

> (B) In conducting a proceeding on a petition the special master –
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> > (i) may require such evidence as may be reasonable and necessary,
> >
> > (ii) may require the submission of such information as may be reasonable and necessary,
> >
> > (iii) may require the testimony of any person and the production of any documents as may be reasonable and necessary,
> >
> > (iv) shall afford all interested persons an opportunity to submit relevant written information . . . , and
> >
> > (v) may conduct such hearings as may be reasonable and necessary.

42 U.S.C. § 300aa-13(12)(B).

In the case before this court, Special Master Corcoran's instructions to the parties at the beginning of the September 27, 2016 hearing were:

> [T]he expert testimony, the direct portion of their testimony will be considered to have been provided in the form of their expert report or reports. What I am going to allow each side to do is to very briefly, in less than five minutes, if not quicker, allow the expert to provide the essence of what their testimony is going to be or what their report says, and then we will go into cross examination and then we'll have redirect, and then, at that time, counsel will have the opportunity to follow up with their expert. That's the process that I'm going to follow today.

Although in advance of the hearing, Special Master Corcoran stated he would follow Special Master Moran's Order excluding direct, expert, oral testimony, he ultimately allowed brief, direct, expert oral testimony. The Special Master also allowed cross examination, as well as, re-direct examination of both expert witnesses. Moreover, at the hearing, the Special Master asked each witness multiple, clarifying questions, to better understand the testimony and the expert reports, which had been submitted for the record. Finally, the Special Master allowed Dr. Engstrand to file her original expert report and multiple supplements thereto, including one following the hearing.

The Vaccine Rules give the Special Master broad discretion to establish the manner in which evidence will be taken into the record, including the power to "determine the format for taking evidence and hearing argument based on the specific circumstances of each case and after consultation with the parties." Vaccine Rule 8(a). Special Master Corcoran did not abuse his broad discretion when he permitted only abbreviated direct oral testimony by the expert witnesses at the September 27, 2016 hearing and by accepting the experts' reports and supplemental reports as their primary direct testimony. As prescribed by Vaccine Rule 8, the previous Special Master "consult[ed] with the parties" regarding the format for taking evidence at the January 15, 2014 status conference and through issuance of draft and final Orders. See Vaccine Rule 8(a). Petitioner's argument that she had an absolute right to full direct examination of her expert witness at the hearing and that the failure of the Special Master to do so "set up the petitioner to fail" because it "prevent[ed] her expert from fully explaining her opinions" is meritless.

The court is satisfied that petitioner had a "full and fair opportunity to present [her] case." Vaccine Rule 3(b)(2). Contrary to petitioner's argument, the Special Master acted within the discretionary authority afforded him by Vaccine Rules 3 and 8. Additionally, because the Special Master offered both sides essentially equal opportunities, and his decision considered the evidentiary record in its entirety, his actions were not arbitrary or capricious, and the procedures he followed did not subject petitioner to any unfair prejudice. Petitioner, therefore, has failed to demonstrate that the Special Master's decision should be reversed as arbitrary and capricious because it failed to provide fundamental due process to the petitioner.

II. The Special Master Correctly Applied the Althen Standard to Petitioner's Case.

Petitioner's Motion for Review also alleges that the Special Master erred in finding that K.L. had not carried her burden of proof to meet all three Althen prongs. Petitioner claims that the Special Master improperly applied a heightened burden of proof, effectively requiring petitioner to prove her case with scientific certainty, rather than applying the preponderance of the evidence standard for causation, as required by the Vaccine Act and Althen v. Secretary of Health and Human Services, 418 F.3d at 1278. Petitioner further argues that, in any event, petitioner met her burden of proof satisfying all three prongs of the Althen standard. As noted above, for a non-Table injury such as petitioner alleges, petitioner carries the burden to satisfy all three elements established by the Federal Circuit in Althen, namely: "(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 proximate temporal relationship between vaccination and injury." Id. The court notes that, at the oral argument before this court on May 31, 2017, counsel for petitioner admitted that the Special Master correctly had applied Althen when petitioner's counsel stated that "the three prongs were appropriately applied."

Petitioner states that the Special Master improperly raised petitioner's burden of proof because he allegedly "review[ed] the evidence 'through the lens of the laboratorian,'" quoting Andreu ex rel. Andreu v. Secretary of Health and Human Services, 569 F.3d at 1378-79, instead of applying the preponderance of the evidence standard prescribed in Althen. Although petitioner's brief acknowledges that the Special Master "cit[ed] numerous precedents saying the special masters must be careful not to increase petitioners [sic] burden of proof," petitioner's counsel argues, however, that the Special Master's analysis of the evidence effectively required the petitioner to prove her causation theory with scientific certainty. Petitioner alleges that the Special Master "disallowed [petitioner's] claim because of its novelty and the fact that no specific scientific study conforms to the specific facts of this case" in violation of the Althen test, arguing in a footnote that the fact that petitioner's causation theory is scientifically unproven should not preclude her from compensation under the Vaccine Act.

Although petitioner is correct that the Special Master may not raise a petitioner's burden of proof to one of "scientific certainty," this does not lessen petitioner's burden to prove a plausible theory of causation supported by reliable scientific evidence. See Andreu ex rel. Andreu v. Sec'y of Health & Human Servs., 569 F.3d at 1379 ("Although . . . a claimant need not produce medical literature or epidemiological evidence to establish causation under the Vaccine Act, where such evidence is submitted, the special master can consider it in reaching an informed judgment as to whether a particular vaccination likely caused a particular injury." (citations omitted)); Capizzano v. Sec'y of Health & Human Servs., 440 F.3d at 1327 ("The proper inquiry is whether a petitioner in an off-Table injury case establishes a logical sequence of cause and effect . . . by a preponderance of the evidence."(citations omitted)); Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs., 35 F.3d at 548-49 ("The determination of causation in fact under the Vaccine Act involves ascertaining whether a sequence of cause and effect is 'logical' and legally probable, not medically or scientifically certain." (citations omitted)). The

Federal Circuit has found that it is not error for a Special Master to consider the medical literature offered by an expert witness in the context of a petitioner's alleged injury and after review find it does not support the petitioner's theory of causation, so long as the Special Master provides logical reasoning for finding certain articles unreliable. See Cedillo v. Sec'y of Health & Human Servs., 617 F.3d at 1345-46; see also K.T. v. Sec'y of Health & Human Servs., 132 Fed. Cl. 175, 186 (2017) (finding that the Special Master was not arbitrary or capricious when he considered the reliability and persuasiveness of scientific literature on which the experts relied "in evaluating the reliability of the expert's testimony," and that the literature petitioner cited did not persuasively support petitioner's theory of causation, nor did his analysis constitute a "heightened legal standard").

In the present case, Special Master Corcoran neither required petitioner to prove her case with scientific certainty, nor did he require petitioner to produce a scientific study that directly conformed to petitioner's causation theory. Special Master Corcoran's decision does not mention the "novelty" of petitioner's theory of causation, nor does it state that his decision was in any way related to the fact that no scientific study conforms to the facts of petitioner's case. Rather, the Special Master concluded that the literature petitioner cited "did not assist [her] case," because "much of the literature [Dr. Engstrand] offered either involved autoimmune forms of epilepsy (which are irrelevant under the facts of the case), different vaccines, or involved the relationship between the HPV vaccine and febrile seizures, which K.L. unquestionably never experienced," and, thus, were distinguishable from K.L.'s case. K.L. v. Sec'y Health & Human Servs., 2017 WL 1713110, at *14. Special Master Corcoran concluded that petitioner had failed to carry her burden of proof because "the weight of evidence does not support Petitioner's causation theory and there is insufficient evidence to support an award of compensation," not because petitioner's causation theory lacked scientific certainty. Id. at *17.

Special Master Corcoran also correctly applied the Althen standard to the facts of petitioner's case. The Special Master began his opinion by noting that he was applying Althen to petitioner's case, and acknowledging that, "[i]n attempting to establish an entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in Althen." K.L. v. Sec'y of Health & Human Servs., 2017 WL 1713110, at *10. The Special Master's opinion went on to explain and apply each prong of Althen to petitioner's case, specifically quoting the same language as petitioner did from Andreu ex rel. Andreu v. Secretary of Health and Human Services, 569 F.3d at 1377, and further noting that a Special Master "must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury." Id. at *13-14 (citation omitted). Specifically, at the end of this section of his opinion, which Special Master Corcoran titled "Althen Prong One," id. at *13, he concluded:

> Vaccine Act claimants are not required to prove a causation theory to a scientific certainty, but the theory must be based on 'sound and reliable medical or scientific explanation.' Knudsen [v. Sec'y of Health & Human Servs.], 35 F.3d at 548. I do not find that Petitioner has satisfied this standard.

Id. at *16. Furthermore, in the next section of his opinion, titled "Althen Prongs Two and Three," the Special Master analyzed K.L.'s medical records and doctors' visits, and determined that "K.L. has not successfully demonstrated with preponderant evidence that the HPV vaccine did cause her initial seizure as alleged, and thus has not satisfied the second Althen prong." Id. With respect to the third Althen prong, the Special Master noted that its "[r]esolution . . . [is] less easily accomplished," but determined that the evidence petitioner had presented on this prong did not "constitute particularly robust support for Petitioner's proposed timeframe," and, even "were [the Special Master] to find that the balance of evidence on this matter barely favored K.L., that determination would not alter [the Special Master's] ultimate decision about causation, because Petitioner's causation theory itself is too deficient, and unsupported by the actual medical history." Id. at *17. The record before the court establishes that the Special Master analyzed petitioner's case under the correct legal standard.

Petitioner's Motion for Review also asserts that the Special Master "failed to considered [sic] the relevant evidence of [sic] record, failed to draw plausible inferences from such evidence or failed to articulated [sic] a rational basis for the decision." Petitioner argues that the Special Master's reading of the record was arbitrary and capricious because he improperly "discounted," "misinterpreted," and/or did not discuss several of the studies cited by petitioner's expert, which allegedly supported her theory. At oral argument, petitioner's counsel again asserted that the Special Master's decision was arbitrary and capricious "primarily because of the way he reviewed some of the medical articles." In response, the government argues that "[f]inding petitioner's evidence unpersuasive does not mean that the Special Master misread the evidence or imposed a higher burden on petitioner than the law requires."

With respect to petitioner's argument that Special Master Corcoran "discounted" certain evidence, this court finds that the Special Master was not arbitrary or capricious because, based on his final opinion, he appears to have considered the relevant evidence in the record, and made reasonable determinations regarding the scientific reliability of the evidence offered by both parties. According to the relevant statute, the Special Master is required to weigh and consider "all . . . relevant medical and scientific evidence contained in the record," including evidence related to the petitioner's medical condition. 42 U.S.C. § 300aa-13(b)(1). The Vaccine Act further specifies that the evidence the Special Master must consider, "in addition to all other medical and scientific evidence contained in the record," includes "any diagnosis, conclusion, [or] medical judgment, . . . which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death . . . and the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." 42 U.S.C. § 300aa-13(b)(1)(A)-(B). After considering the relevant medical and scientific evidence in the record, the Special Master has discretion to determine the relative weight to give to evidence in the record, provided he or she offers a rational basis. See Andreu ex rel. Andreu v. Sec'y of Health & Human Servs., 569 F.3d at 1379 (finding that the Special Master may make a determination of witness credibility to determine the weight oral testimony should be afforded in relation to contemporaneous medical records); Capizzano v. Sec'y of Health & Human Servs., 440 F.3d at 1326 (finding the Special Master erred when he did not consider the diagnosis of the treating physician,

although the treating physician had affirmatively concluded the vaccine caused petitioner's injury); Burns v. Sec'y of Health & Human Servs., 3 F.3d at 417 (finding that the Special Master has discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, so long as the decision is based on a rational basis); Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1528-29 (Fed. Cir. 1993) (finding that when contemporaneous medical records conflict with later oral testimony, the Special Master was not arbitrary or capricious when he relied on the medical records to find that petitioner failed to satisfy her burden of proof).

Petitioner's motion specifically alleges that the Special Master "apparently did not review numerous exhibits, including Exhibit 31, Exhibit 33, and Exhibit 37." Dr. Engstrand's third expert report, Exhibit 31, however, was explicitly discussed in the Special Master's decision, which states, "[i]n the Spring of 2015, Dr. Engstrand filed her third report, which mainly sought to rebut points made by Respondent's expert, Dr. Shinnar, in his report. She maintained that autoimmune-related epilepsy was more common than Dr. Shinnar allowed, and that it could manifest without evidence on an EEG and without a prior or concurrent fever." K.L. v. Sec'y of Health & Human Servs., 2017 WL 1713110, at *5. The Special Master goes on to describe the literature cited by Dr. Engstrand in her third report, which included Exhibits 33 and 37. Thus, petitioner's argument that the Special Master failed to consider these exhibits is incorrect.

Petitioner also objects to the Special Master's treatment of the Li study, attached to Dr. Engstrand's affidavit filed on November 4, 2016 after the September 27, 2016 hearing, arguing that the Li study "specifically support[s]" and "confirm[s]" Dr. Engstrand's theory, "despite the special master misinterpreting it." Petitioner alleges in a separate section of the brief that "the special master simply emphasized a conclusory statement in the article discussing cytokine activation by seizures, without reviewing the details of the article which clearly shows that cytokines can indeed cause seizures." It remains unclear whether petitioner argues that the Special Master failed to consider the Li study entirely, or that the Special Master failed to give the article sufficient weight. Both of these allegations are specious, because Special Master Corcoran, in fact, referenced and analyzed the Li study two separate times in his opinion, including an in-depth analysis that quoted directly from the article. See id. at *6, 14. In the first instance, the Special Master's decision stated:

> The authors of [the] Li [study] reviewed studies involving cytokines's role in epilepsy. Li concluded that an array of different cytokines were involved – but more importantly (for present purposes), that the cytokines were activated only after the patient had suffered a seizure, as opposed to causing them, and it could not be fully ascertained in any event whether post-seizure cytokines exacerbated seizure activity. Li at 256 ("[cytokines] are activated by seizures, but their precise role in epilepsy is not yet clear"). (emphasis in original).

Id. at *6. In the second instance, the Special Master determined that the Li study "speaks more of the causative effect seizures have on the upregulation of cytokines than the other

way around, thus further undermining Dr. Engstrand's efforts to restore credibility to her theory." Id. at *14.

Moreover, a Special Master need not discuss in his or her final decision every piece of medical literature a petitioner files or references, and failing to discuss every piece of evidence will not alter the presumption that a Special Master has considered the entire record in his or her decision to grant or deny compensation. See Moriarty v. Sec'y of Health & Human Servs., 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision."). Therefore, the fact that Special Master Corcoran did not discuss every piece of evidence submitted into the record in his decision does not, in and of itself, constitute reversible error. In addition, petitioner has not identified a relevant, critical item of evidence in the record which was not addressed by the Special Master.

Furthermore, the level of scrutiny with which the Special Master reviewed the scientific studies the parties produced was appropriate. The Special Master is required to "consider all relevant and reliable evidence," Vaccine Rule 8(a), specifically, any medical records or reports "contained in the record regarding the nature, causation, and aggravation of the petitioner's . . . injury" and "all other relevant medical and scientific evidence contained in the record." 42 U.S.C. § 300aa-13(1). Moreover, if the Special Master considers certain items of medical evidence, but ultimately deems them unreliable, that does not constitute reversible error. See Cedillo v. Sec'y of Health & Human Servs., 617 F.3d at 1345-46 (no error found when the Special Master found one study petitioner cited unreliable because it was inconclusive, and found another insufficiently detailed in methodology and explanation of findings); see also Hines v. Sec'y of Health & Human Servs., 940 F.2d at 1527 (finding no error when the Special Master considered the entire record, although he did not give certain evidence "the controlling weight [the petitioner] urge[d] he should have"). As the factfinder, the Special Master has discretion to make determinations regarding the credibility of all the information provided orally and in writing by fact and expert witnesses, whether they testify in person at a hearing or submit reports or affidavits for the record. This discretion includes review of the medical literature submitted in support of a party's causation theories. See LaLonde v. Sec'y of Health & Human Servs., 746 F.3d at 1340-41 (finding no error when petitioner's expert posited a number of theories, but the Special Master found them unpersuasive because the theories were not supported by peer-reviewed medical literature).

In the present case, the Special Master considered and discussed each of Dr. Engstrand's four filed reports, Dr. Shinnar's reports, the experts' testimony at the hearing and the parties' arguments. In his opinion, the Special Master found the support for Dr. Engstrand's theory limited, stating: "[b]eyond Dr. Engstrand's qualifications, there is the issue of the reliability of the scientific basis for Petitioner's theory. While the individual articles offered proved reasonable and reliable individually, taken as a whole they do not assist Petitioner's case." K.L. v. Sec'y of Health & Human Servs., 2017 WL 1713110, at *14. By contrast, Special Master Corcoran found the literature Dr. Shinnar produced more persuasive. The Special Master stated in his decision:

> Respondent, by contrast, offered far more reliable and credible medical and scientific articles suggesting the HPV vaccine would not likely cause injuries of the kind experienced by K.L. Studies like Arnheim-Dahlstrom were more scientifically reliable (both given the larger population groups studied, as well as the fact that they involved observed cases rather than simply reported reactions) and more persuasively demonstrated no link between a number of neurological events, including epilepsy, and receipt of the HPV vaccine.

Id. at *15. From the opinion he issued, it is clear that the Special Master reviewed the medical literature submitted by both Dr. Engstrand and Dr. Shinnar, and the Special Master explained why he found that the studies Dr. Engstrand cited were either insufficiently related to petitioner's case or less scientifically reliable than those Dr. Shinnar cited. Contrary to petitioner's allegation that Special Master Corcoran "discounted" or "ignored" certain evidence, the Special Master stated in his decision that he had reviewed all evidence in the record in making his decision. See id. at *1 ("After considering the record as a whole, and for the reasons explained below, I find that Petitioner has failed to carry her burden in establishing causation, and therefore is not entitled to compensation under the Vaccine Program."). In the decision he laid out a thorough discussion and analysis of the evidence and the reasoning for his conclusions. The court finds that the Special Master did not act arbitrarily or capriciously and properly exercised his discretion.[22]

Regarding petitioner's argument that the Special Master "misinterpreted" certain evidence, petitioner appears specifically to highlight and object to the limited weight the Special Master gave to the Li article. At oral argument before this court, petitioner's counsel asserted that the Special Master had not "read the Li article thoroughly" because "there's a specific part of the Li article that addresses IL-1 beta." The thoroughness of the Special Master's decision and the fact that Dr. Engstrand herself abandoned the interleukin-1 beta theory during her testimony both demonstrate that petitioner's allegation is not supported by the record. Likewise, although counsel asserted that "the [Li] article says that the balance of the studies they looked at showed an increase in seizure activity," the Li study actually concludes:

[22] Petitioner's reliance on Moriarty v. Secretary of Health and Human Services, 844 F.3d 1322, cited to support her assertion that a Special Master committed reversible error when he allegedly failed to consider the entirety of the record is misplaced. In Moriarty, the Federal Circuit determined that "[t]here is thus no indication that the special master considered [petitioner's expert's] written testimony in his second report and the articles cited therein, and there is, in fact, an affirmative indication that he did not do so." Whereas the Special Master in Moriarty explicitly stated in his decision that he had not included certain of the expert's evidence in his analysis of petitioner's claim for compensation, Special Master Corcoran plainly considered Dr. Engstrand's oral and written testimony, as well as the articles she provided to the court. See K.L. v. Sec'y of Health & Human Servs., 2017 WL 1713110, at *14-15.

> A growing body of evidence suggests that there is an array of cytokines involved in epilepsy. These substances are activated by seizures, but their precise role in epilepsy is not yet clear . . . . Levels of these substances increase quickly after either generalized tonic-clonic or complex partial seizures . . . Seizures not only induce the expression of cytokines in the brain but also change peripheral cytokine levels.

See Gang Li et al., Cytokines and Epilepsy, 20 Seizure 249, 253 (emphasis added). Special Master Corcoran provided a rational basis for the lower evidentiary weight he gave the Li study, based on the study itself and the evidence in the record, when he stated that the Li study "speaks more of the causative effect seizures have on the upregulation of cytokines than the other way around, thus further undermining Dr. Engstrand's efforts to restore credibility to her theory after abandoning the opinion she initially offered in her first submitted expert report about the role of the IL-beta [sic] cytokine." K.L. v. Sec'y of Health & Human Servs., 2017 WL 1713110, at *14.

Petitioner additionally alleges that the Special Master acted arbitrarily and capriciously when, according to petitioner, he gave "little weight" to the fact that "numerous treating physicians considered the HPV vaccine to be a possible causative agent in their differential diagnosis." Petitioner's argument lacks merit on multiple grounds. First, by statute, the Special Master is not bound by "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary" that is "contained in the record regarding the nature, causation, and aggravation of the petitioner's illness," but rather has the discretion to "evaluat[e] the weight to be afforded to any such diagnosis" in the record, in light of "the entire record and the course of the injury, disability, illness, or condition." 42 U.S.C. § 300aa-13(1). Thus, Special Master Corcoran was not required to conclude that the Gardasil vaccination caused petitioner's epilepsy simply because it was noted in physicians' notes in the records, and in petitioner's case, only as a possible cause. Rather, the Special Master's decision reflects that he considered the entire record, including the medical records which recorded the progression of K.L.'s symptoms and illness over time, the opinions and the diagnoses of her treating physicians, including of Dr. Poduri, who was also an epilepsy specialist, as well as the opinions of the parties' expert witnesses.

Second, petitioner's brief asserts, "[t]he diagnosis of treating physicians is entitled to some weight," citing to Andreu ex rel. Andreu v. Secretary of Health and Human Services, 569 F.3d at 1367, and Capizzano v. Secretary of Health and Human Services, 440 F.3d at 1326. While petitioner's statement of the law is correct, the cases petitioner cites do not assist petitioner. In both Andreu and Capizzano, the treating physician unequivocally stated that the vaccine was the cause of petitioner's injury and the treating physician's conclusion was undisputed by the government's witness. See Andreu ex rel. Andreu v. Sec'y of Health & Human Servs., 569 F.3d at 1376; Capizzano v. Sec'y of Health & Human Servs., 440 F.3d at 1326. In the current case, in contrast to the facts in Andreu and Capizzano, the record before the court does not contain any conclusive statements by any of the petitioner's treating physicians that indicate that the Gardasil vaccination was the cause of petitioner's epilepsy. Instead, none of K.L.'s treating physicians concluded with any certainty that the vaccine was the causative agent. The

record before the court demonstrates that petitioner's treating physicians simply made note of K.L's recent HPV vaccine in K.L.'s medical history, and when any relationship between Gardasil and her seizures was indicated, it was in purely speculative terms. For example, at the time of K.L.'s first emergency room visit, her medical records noted that her recent HPV vaccine was one among several "potential contributors" for her first seizure. Similarly, the medical record from her February 12, 2010 treatment at FAHC states: "At transfer the cause of her seizure was thought to be multifactorial with potential contributors including a mild URI, OTC pharmacotherapy with benadryl and sudafed, and recent HPV vaccine administration." Dr. Volansky's notes from February 15, 2010 state: "Assessment: seizures, unclear etiology, may be new onset epilepsy, may have been effect of recent Gardasil and/or decongestants." Dr. Kalsner's notes from March 22, 2010 state: "Of note, she did receive the Gardasil vaccine two days prior to the first seizure. It was her third in a series of vaccinations." Dr. Poduri's notes from June 6, 2010 state: "She had also notably had her Gardasil vaccination two days prior to the first seizure." Dr. Volansky's notes from June 22, 2010, state: "There was some concern about having Gardasil vaccination, third dose, 2 days prior to having her first seizure onset and maybe that indicates the seizures should improve; however, would continue antiseizure medication for a total duration of 2 years and then gradually try to taper it off." As the Federal Circuit determined in Moberly v. Secretary of Health and Human Services, if contemporaneous physician's notes are "all speculative," the Special Master is permitted to find that such evidence is not dispositive. See Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d at 1323-25 (finding that speculative notations by treating physicians were properly not dispositive on causation because "[while] several of petitioner's treating physicians noted the temporal relationship between [petitioner's] vaccination and petitioner's initial brief seizures, none ever offered a solid statement that . . . [the] vaccination caused probably petitioner's condition"); see also Cedillo v. Sec'y of Health & Human Servs., 617 F.3d at 1348 ("The Special Master clearly articulated why he declined to afford significant weight to the notations made by [petitioner's] treating physicians, and we see no error in his treatment of that evidence.").

Finally, petitioner's arguments overlook the fact that Dr. Poduri was one of K.L.'s treating physicians, who had multiple appointments with petitioner, conducted a review of a detailed MRI study, and conducted a careful analysis of her medical history. Dr. Poduri diagnosed K.L. with idiopathic epilepsy and did not attribute her seizures to Gardasil. The Special Master did not err when he gave greater weight to Dr. Poduri and to the expert report of Dr. Shinnar.

Petitioner also argues in her brief, with little elaboration, that the Special Master erred because he did not address the "flaws" in the testimony of respondent's expert, Dr. Shinnar, but did so for petitioner's expert, Dr. Engstrand. According to petitioner, "[n]umerous critical comments of Dr. Engstrand appear in the Decision, without corresponding critical analysis of Dr. Shinnar." Petitioner alleges that Dr. Shinnar's testimony and report were unreliable because they contained "many errors," although petitioner fails to specify any particular errors in her filings before this court.[32] Petitioner

[32] K.L.'s Motion for Review simply referenced Petitioner's post-hearing brief, previously filed with Special Master Corcoran on November 14, 2016. During oral argument before

also argues that the Special Master erred when he "questioned the ability of Dr. Engstrand to even testify concerning her medical theory because she did not have 'specialized expertise in the condition of epilepsy' even though she is a highly qualified and experienced neurologist."

Contrary to petitioner's allegations, Special Master Corcoran did not treat the parties' experts disparately. Special Master Corcoran permitted both expert witnesses the opportunity to make clarifications in their testimonies at the September 27, 2016 hearing, and he directed clarifying questions to each witness. Additionally, after Dr. Engstrand abandoned her first theory of causation and offered a modified theory at the September 27, 2016 entitlement hearing, Special Master Corcoran permitted her to file a post-hearing affidavit to support her new theory, which he specifically discussed in his opinion. See K.L. v. Sec'y of Health & Human Servs., 2017 WL 1713110, at *6. In addition, Special Master Corcoran separately analyzed the articles cited by both experts in similar terms. See, e.g., id. at *6 ("Dr. Engstrand offered an article that she represented further supported the possibility of afebrile seizures following the HPV vaccine . . . . [The] Crawford [study], like the Valencian Article, involved a retrospective study of passive surveillance reporting of alleged vaccine adverse events, here based on the HPV vaccine's administration in Australia to young females."); id. at *8 ("Dr. Shinnar opined that the HPV vaccine could not affirmatively be linked to epilepsy. In support, he cited a large population study of young girls in Denmark and Sweden . . . . That study found no increased risk for autoimmune or neurological events among the nearly 300,000 patients who received multiple doses of the HPV vaccine.").

Petitioner's argument that the Special Master erred by questioning Dr. Engstrand's qualifications, but not Dr. Shinnar's, fails for several reasons. Petitioner has the burden of proof to establish causation. See 42 U.S.C § 300aa-13(a). Petitioner's expert, Dr. Engstrand, ultimately offered a causation theory that relied on an immunological mechanism and, logically, the Special Master compared it to the evidence Dr. Shinnar offered, in part, based on their relative expertise in immunology. See Milik v. Sec'y of Health & Human Servs., 822 F.3d 1367, 1381-82 (Fed. Cir. 2016) (finding that the Special Master did not act arbitrarily and capriciously when determining that the government expert's specific medical qualifications made his testimony more reliable than that of petitioner's expert); Porter v. Sec'y of Health & Human Servs., 663 F.3d at 1250 ("[T]his court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act."). In doing so, Special Master Corcoran acted within his proper discretion. The credibility of an expert witness is an appropriate matter for the Special Master to consider, given the importance of expert testimony in a petitioner's ability to carry his or her burden of proof when alleging a non-Table injury. See, e.g., Cedillo v. Sec'y of Health & Human Servs., 617 F.3d at 1347 (finding no error when the Special Master determined an expert witness lacked credibility when the Special Master explained his reason for so

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this court on May 31, 2017, when prompted by the court, petitioner's counsel conceded that of the four alleged "flaws," one was "minor" and he was unable to find support in the record for the others.

determining); Hazlehurst v. Sec'y of Health & Human Servs., 604 F.3d at 1349-50 (finding it was within the Special Master's discretion to admit and assess the reliability of expert testimony); H.L., on Behalf of A.I., v. Sec'y of Health & Human Servs., 129 Fed. Cl. 169, 175 (2016) (finding no error for the Special Master to find the government's witness more credible than petitioner's after he "thoroughly reviewed the record, expert testimony, and the articles each expert cited"). Because a Special Master acts within his discretion when he or she makes determinations regarding the credibility of any witness, including an expert witness, it was proper for Special Master Corcoran to consider the credentials of the expert witnesses in relation to the causation theories they posited and in relation to each other's expertise. So long as the Special Master provides a reasonable explanation in his opinion to show how he reached his conclusions regarding an experts' credibility, such credibility determinations will survive review. See, e.g., Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1347 (finding no error when the Special Master assessed the credibility of experts and found the government's more persuasive, and included a reasoned explanation in the opinion).

Special Master Corcoran's decision noted that Dr. Engstrand is a general neurologist, not an immunologist or epileptologist, and that Dr. Engstrand relied on an immunological mechanism which linked the Gardasil vaccine to petitioner's injury and a rare form of epilepsy based on an immunological mechanism, but that she did not have the relevant specialized expertise. See K.L. v. Sec'y of Health & Human Servs., 2017 WL 1713110, at *14. Special Master Corcoran stated:

> Dr. Engstrand is not an immunologist—although neither is Dr. Shinnar, for that matter. However, this lack of specific expertise on a matter relevant to the resolution of the case cuts more against Petitioner than Respondent, since Petitioner bears the initial, and ultimate, burden of proof.

Id. at *4 n.12. Special Master Corcoran found that the experts' respective areas of expertise cut against Dr. Engstrand, because her causation theory incorporated and required specialized knowledge of immunology, and in favor of Dr. Shinnar, whose alternative theory of causation was narrowly focused on epilepsy. Id. at *15. Contrary to what petitioner argues, the Special Master did not question Dr. Engstrand's qualifications as a neurologist, but rather her lack of qualifications as an immunologist. The Special Master expressed doubt as to the credibility of her expertise, specifically as it related to her theory of causation in K.L.'s case, which linked the Gardasil vaccine to petitioner's injuries, based on an immunological mechanism, and on her selection and discussion of relevant medical literature. Id. at *14-15. A Special Master may compare the evidence offered by each side's expert and make a decision "based on the credibility of the experts and the relative persuasiveness of their competing theories." Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1347 (quoting Lampe v. Sec'y of Health & Human Servs., 219 F.3d at 1362); see also Milik v. Sec'y of Health & Human Servs., 822 F.3d at 1381-82 (finding that the Special Master was not arbitrary and capricious when he determined that the government's expert's specific medical qualifications made his testimony more reliable than testimony of petitioner's expert); Porter v. Sec'y of Health & Human Servs., 663 F.3d at 1250 ("[S]pecial masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine

Act."); Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations," and the Special Master may analyze the credibility of experts); Copenhaver v. Sec'y of Health & Human Servs., 129 Fed. Cl. at 183 (finding that Special Masters may consider the expert's credentials when determining the relative weight to afford opinion testimony). Moreover, a Special Master's credibility findings are "virtually unchallengeable on appeal." Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d at 1347 (quoting Lampe v. Sec'y of Health & Human Servs., 219 F.3d at 1362); see also Cedillo v. Sec'y of Health & Human Servs., 617 F.3d at 1347 ("Under the Vaccine Act, Special Masters are accorded great deference in determining the credibility and reliability of expert witnesses."). This court, therefore, finds that Special Master Corcoran acted reasonably and within his discretion when he considered Dr. Engstrand's relative qualifications and the literature she included as part of her submissions in support of petitioner's theory, in comparison to the relative weight he gave to Dr. Shinnar's qualifications, expert report, and testimony, which were offered as a rebuttal to petitioner's theory.

Petitioner also argues that, based on the record before the Special Master, including Dr. Engstrand's expert opinion and the literature offered by petitioner's expert, she met her burden of proof under the Althen test and that the Special Master's failure to so find was in error. She asserts, again, as part of this argument, that the Special Master raised her burden of proof and that she should not be denied compensation merely because her theory is novel and "no specific scientific study conforms to the specific facts of this case." The government disagrees, arguing that petitioner failed to meet her burden of proof under Althen and did not prove, by a preponderance of the evidence, that the Gardasil vaccination caused her injuries. Respondent asserts that "the Special Master's conclusion was based on a thorough review of the evidence and is supported by both plausible inferences and a rational basis," so it should not be overturned.

Petitioner first argues that she satisfied her burden under prong one of the Althen test by showing a plausible theory of causation. Unfortunately for petitioner, her assertion that she has met Althen prong one with "clear plausibility" by showing a mechanism of causation that is "supported by credible medical studies" is based on a theory of causation that petitioner's own expert abandoned when pressed at the September 27, 2016 hearing. Even during oral argument before this court on May 31, 2017, petitioner's counsel asserted that the interleukin-1 beta theory was "Dr. Engstrand's entire theory." Moreover, the brief submitted by petitioner's counsel argues:

> Dr. Engstrand has stated that K.L. suffered from an autoimmune reaction stimulated by the HPV vaccine which caused release of cytokine interleukin 1 beta in the course of the immune response to the vaccine (the infectious agent), which in turn triggered a cluster of afebrile convulsions or seizures . . . .

As noted above, at the September 27, 2016 hearing before the Special Master, however, when asked about her interleukin-1 beta theory, Dr. Engstrand responded: "I'm not sure it's Interleukin-1 beta . . . the more I read about it and reread all the papers again, it is the

cytokine — I'm not certain which cytokine — that sets up an inflammatory reaction in K.L." Not only did petitioner's own expert abandon the original theory of causation that petitioner's counsel on behalf of petitioner asserts in the Motion for Review, the Special Master also found that the theory was unsupported by K.L.'s medical records or by any of the scientific literature petitioner cited, and that it was convincingly debunked by Dr. Shinnar's report and testimony. See K.L. v. Sec'y of Health & Human Servs., 2017 WL 1713110, at *16. The Special Master found Dr. Shinnar's explanation more credible because Dr. Shinnar supported his opinion with articles that were "more scientifically reliable (both given the larger population groups studied, as well as the fact that they involved observed cases rather than simply reported reactions) and more persuasively demonstrated no link between a number of neurological events, including epilepsy, and receipt of the HPV vaccine." Id. at *15.

In support of her argument, petitioner cites language from the United States Court of Federal Claims decision in Contreras v. Secretary of Health and Human Services that "[p]lausibility . . . in many cases *may* be enough to satisfy Althen prong one" (emphasis in original), suggesting that petitioner had a lowered burden of proof with respect to this prong. Contreras v. Sec'y of Health & Human Servs., 121 Fed. Cl. 230, 245 (2015). The United States Court of Federal Claims' Contreras decision petitioner cited, however, was ultimately vacated and remanded by the United States Court of Appeals for the Federal Circuit on January 3, 2017, three months before petitioner's counsel filed the Motion for Review on petitioner's behalf. See Contreras v. Sec'y of Health & Human Servs., 844 F.3d 1363 (Fed. Cir. 2017). Petitioner's counsel fails to note the Federal Circuit's decision to vacate and remand the case in the briefs he filed. Furthermore, petitioner's understanding of the Contreras decision in the Court of Federal Claims is also incomplete, because the Court of Federal Claims' Contreras decision separated a petitioner's burden with respect to Althen prong one from a petitioner's overall burden of proof, noting that even if plausibility may be sufficient for Althen prong one, this does not alter petitioner's overall burden to establish causation-in-fact by more than plausibility alone, stating, "while plausibility is not enough to show that a particular vaccine caused a particular injury, this is a separate question from the inquiry required by Althen prong one." 121 Fed. Cl. at 245 (citing Veryzer v. Sec'y of Health & Human Servs., 100 Fed. Cl. 344, 352 (2011)). In the present case, because the Special Master determined that petitioner had not produced sufficient evidence to meet her burden of proof to show a plausible theory of causation demonstrating that the vaccine caused her injury, and the Special Master supported this determination with a reasonable and thorough analysis of the evidence in his decision, the Special Master did not act arbitrarily or capriciously with respect to his conclusions on the Althen prong one.

In addition, petitioner argues in her Motion for Review that the Special Master erred when he found petitioner had failed to satisfy her burden to prove Althen prong two by a preponderance of the evidence. Specifically, petitioner alleges that Dr. Engstrand's explanation of the biological events in K.L.'s illness was sufficient to show a logical sequence of causation, that her medical records support this explanation, and that respondent's alternative theory of causation should be excluded. Under Althen prong two, a petitioner must show a logical sequence of cause and effect between the vaccine and petitioner's injuries, usually supported by evidence from petitioner's medical records. See

Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1278. In the present case, the Special Master found that petitioner did not sufficiently show that Gardasil caused her initial seizures, as alleged, because K.L.'s medical records showed no signs that K.L. had an autoimmune response contemporaneous with her initial seizure after the vaccination or an upregulation of cytokines, upon which Dr. Engstrand's causation theory relied. See K.L. v. Sec'y of Health & Human Servs., 2017 WL 1713110, at *16. The Special Master also found that the evidence presented by the treating physicians and the government's expert provided a more persuasive alternative explanation for K.L.'s illness. Id. In particular, the Special Master found that Dr. Shinnar had "effectively distinguished K.L.'s medical presentation with that of a patient with autoimmune epilepsy, who would likely have displayed abnormal EEG results demonstrating the presence of a neurologic injury, while at the same time being resistant to treatment." Id. Similarly, the Special Master found treating physician Dr. Poduri's diagnosis of idiopathic epilepsy to be persuasive because Dr. Poduri was K.L.'s continuing, treating physician, she reviewed numerous medical tests performed on K.L., and she had expertise in epilepsy. The Special Master stated in his opinion: "[i]n addition, particularly trustworthy treaters with significant epilepsy expertise, like Dr. Poduri, were aware of the vaccine's administration [to K.L.] but concluded, based on their review of the developing medical record, that more likely than not K.L.'s epilepsy was idiopathic." Id. (citations omitted). Provided the Special Master does so in a reasonable manner and "consider[s] the relevant evidence of record, draw[ing] plausible inferences and articulat[ing] a rational basis for the decision," it is within a Special Master's discretion to weigh the reliability and credibility of the evidence a petitioner provides to support his or her theory of causation. Broekelshen v. Sec'y of Health & Human Servs., 618 F.3d at 1348 (quoting Hines v. Sec'y of Health & Human Servs., 940 F.2d at 1528). Special Master Corcoran acted reasonably and did not err when he found the evidence from Drs. Shinnar and Poduri explaining K.L.'s medical records "more persuasive than Dr. Engstrand's statements to the contrary." K.L. v. Sec'y of Health & Human Servs., 2017 WL 1713110, at *16; see also Burns v. Sec'y of Health & Human Servs., 3 F.3d at 417 (finding no error when the Special Master found contemporaneous medical records more persuasive than later oral testimony, because "such a determination of credibility is uniquely within the purview of the special master").

Moreover, the government is permitted to present an alternative theory of causation to explain the petitioner's injury, which the Special Master may then consider in making his or her determination of whether the petitioner has met her burden of proof demonstrating that the vaccine caused petitioner's injury. See de Bazan v. Sec'y of Health & Human Servs., 539 F.3d at 1353 ("The government, like any defendant, 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."); see also Rus v. Sec'y of Health & Human Servs., 129 Fed. Cl. 672, 680 (2016) ("[R]egardless of whether the burden of proof ever shifts to the respondent, the special master may consider the evidence presented by the respondent in determining whether the petitioner has established a *prima facie* case." (citations omitted)). Therefore, it was proper for Special Master Corcoran to consider both Dr. Engstrand's causation theory and Dr. Shinnar's alternative causation theory in the context of K.L.'s medical records. The United States Court of Appeals for the Federal Circuit has interpreted 42 U.S.C § 300a-13(2)(b) to mean that a Special Master is expected to consider the record as a whole in making his or her decision regarding

entitlement to compensation, which includes all relevant evidence cited by both parties throughout the proceedings. See Moriarty v. Sec'y of Health & Human Servs., 844 F.3d at 1327-28 ("Thus, this statutory language indicates that a special master, reviewing the entire record of the case before him, must consider all *relevant* medical and scientific evidence contained in the record, which includes any *relevant* medical records or reports. It also instructs that the special master 'shall' consider the entire record, which includes this relevant evidence, when assigning the weight given to particular evidence." (emphasis in original)); see also Stone v. Sec'y of Health & Human Servs., 676 F.3d 1373, 1379 (Fed. Cir. 2012) ("Evidence of other possible sources of injury can be relevant not only to the 'factors unrelated' defense, but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question.").

Petitioner also argues that K.L.'s diagnosis of idiopathic epilepsy by Drs. Shinnar and Poduri should be discounted because evidence of idiopathic illnesses cannot be used to deny her recovery. In support of this argument, petitioner cites 42 U.S.C. § 300aa-13(a)(2)(A) and Wagner v. Secretary of Health and Human Services, 37 Fed. Cl. 134 (1997). Petitioner's argument misconstrues 42 U.S.C. § 300aa-13(a)(2)(A) and Wagner. The section of the statute petitioner relies on is only applied when the burden of proof is on the government to show that a petitioner's injuries were caused by a factor "unrelated to the administration of the vaccine," 42 U.S.C. § 300aa-13(2) either after causation is presumed because the injury is on-Table or after petitioner has proven causation-in-fact. See Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1281; see also Rus v. Sec'y of Health & Human Servs., 129 Fed. Cl. at 680 ("[I]f a petitioner establishes a *prima facie* case, the burden shifts to the respondent to show, by a preponderance of the evidence, that the injury was caused by a factor unrelated to the vaccine." (citations omitted)); Kotson v. Sec'y of Health & Human Servs., 974 F.2d 157, 158 (Fed. Cir. 1992) (finding that because the petitioner had an on-Table injury, causation was presumed, so per the statute an idiopathic illness could not defeat recovery); Doe ex rel. Estate of Doe v. Sec'y of Health & Human Servs., 83 Fed. Cl. 157, 169 (2008) (finding that the Special Master misallocated the burden of proof by failing to shift burden to government after petitioner proved a prima facie case per the statute). In K.L.'s case, 42 U.S.C. § 300aa-13(a)(2)(A) does not apply because the petitioner's alleged injury is an off-Table injury and she has failed to prove causation-in-fact. Therefore, the burden of proof has not shifted to the government to show that petitioner's injuries were caused by a factor unrelated to the vaccine.

The Wagner case also is not applicable to petitioner's claim because in Wagner, the Special Master determined that the petitioner had proven that her injuries were caused-in-fact by the vaccine by a preponderance of the evidence, and, therefore, that the burden had shifted to the government to prove that "factors unrelated to the administration of the vaccine" caused her injury. Wagner v. Sec'y of Health & Human Servs., 37 Fed. Cl. at 139. The court in Wagner held that an unknown cause could not be used to deny compensation after a determination that petitioner had proven causation-in-fact by a preponderance of the evidence. See id. at 138-39. In K.L.'s case, the Special Master determined that the petitioner has not met her burden of proof, and, thus, the burden of showing an alternative cause by "factors unrelated to the administration of the vaccine" by a preponderance of the evidence did not shift to the government. 42 U.S.C.

§ 300aa-13(2). Therefore, the Special Master did not act arbitrarily or capriciously with respect to Althen prong two because he appropriately considered the relevant evidence in the record regarding the causation of petitioner's alleged injury, including Dr. Shinnar's opinion that K.L.'s epilepsy was idiopathic and Dr. Poduri's diagnosis reflecting the same. This court should not re-weigh the evidence the Special Master reasonably reviewed and evaluated. See Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d at 1326.

Petitioner also alleges that she "clearly proved Prong 3" of the Althen test, arguing that she produced sufficient evidence to show a proximate temporal relationship between the vaccine and her injury, listing several of the articles Dr. Engstrand cited in her reports. Petitioner's motion additionally asserts that the Special Master made a "grudging admission that petitioner had a strong showing of proof" of Althen prong three. In support of this assertion, petitioner cites to the portion of the Special Master's opinion which reads: "At the same time, however, I acknowledge that a two-day period between vaccination and seizure has been deemed medically acceptable in other [Vaccine Injury] Program cases involving epilepsy." See K.L. v. Sec'y of Health & Human Servs., 2017 WL 1713110, at *15. Petitioner, therefore, argues that the Special Master indicated Althen prong three favored the petitioner, quoting the following language from the decision: "Yet even were I to find that **the balance of evidence on this matter barely favored K.L.,** that determination would not alter my ultimate decision about causation." Id. at *16 (emphasis added by petitioner).

Under Althen prong three, a petitioner must show a "proximate temporal relationship" between the vaccine and injury alleged that is "medically acceptable." Althen v. Sec'y of Health & Human Servs., 418 F.3d at 1281. To meet this standard, a petitioner must show by a preponderance of the evidence that "the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation," which also corresponds with petitioner's theory of how the vaccine caused her injury. de Bazan v. Sec'y of Health & Human Servs., 539 F.3d at 1352; see also Pafford v. Sec'y of Health & Human Servs., 451 F.3d at 1358-59 (finding that a temporal relationship is a required element of petitioner's claim under Althen). A petitioner, however, cannot rely on a temporal association between her vaccine and alleged injury alone to show causation. See Moberly ex rel. Moberly v. Sec'y of Health & Human Servs., 592 F.3d at 1323 ("[A] proximate temporal association alone does not suffice to show a causal link between the vaccination and the injury.") (quoting Grant v. Sec'y of Health & Human Servs., 956 F.3d at 1148); de Bazan v. Sec'y of Health & Human Servs., 539 F.3d at 1352 ("[T]he proximate temporal relationship prong requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact."); Pafford v. Sec'y of Health & Human Servs., 451 F.3d at 1358 (finding that the Special Master properly required evidence of a temporal relationship between the vaccine and petitioner's injury); see also K.T. v. Sec'y of Health & Human Servs., 132 Fed. Cl. at 186. Moreover, because a proximate temporal association alone cannot prove causation, consistency in the timing of the onset of symptoms with a theory that is itself scientifically unreliable will not cure the theory's unreliability or overcome petitioner's failure to satisfy her burden of proof. See, e.g., Moberly ex rel. Moberly v.

Sec'y of Health & Human Servs., 592 F.3d at 1323; see also K.T. v. Sec'y of Health & Human Servs., 132 Fed. Cl. at 186; Shapiro v. Sec'y of Health & Human Servs., 101 Fed. Cl. 532, 542 (2011).

Regarding petitioner's argument that the Special Master "made a grudging admission that petitioner made a strong showing of proof" regarding Althen prong three, petitioner misses the critical word "were" in the sentence cited from the Special Master's decision. The sentence[33] indicates that the Special Master was addressing the issue hypothetically, essentially thinking through the issues, not that he was ruling in petitioner's favor on prong three of Althen because of the absence of a provable theory of causation. Petitioner's counsel overstates the Special Master's findings regarding Althen prong three. The Special Master did not make a "grudging admission that petitioner made a strong showing of proof" on prong three, as petitioner alleges, but rather found that resolution of this prong was "less easily accomplished" because "Dr. Engstrand's theory proposed that cytokine upregulation would occur in the two-day timeframe at issue herein." K.L. v. Sec'y of Health & Human Servs., 2017 WL 1713110, at *16. Special Master Corcoran ultimately determined that petitioner had not proven prong three of Althen, and finding that, "[a]t bottom, Petitioner's theory is itself too unreliable to put stock in the fact that timing as evidenced by the facts herein is consistent with that theory." Id. at *17. As the factfinder, the Special Master had discretion to weigh the evidence presented, and it was not an abuse of that discretion for him to determine that petitioner also had not clearly met prong three because the medical literature Dr. Engstrand offered to show that the timeframe was "medically appropriate" was insufficient in K.L.'s case. Id. at *16. The Special Master provided the requisite "rational basis" for his determination. See, e.g., Hibbard v. Sec'y of Health & Human Servs., 698 F.3d at 1363. The Special Master pointed out in his opinion that the Crawford study Dr. Engstrand offered for the record related to patients with previously diagnosed epilepsy, and the Spiczak study Dr. Engstrand offered related to vaccines other than HPV. K.L. v. Sec'y of Health & Human Servs., 2017 WL 1713110, at *16. Thus, this court finds that the Special Master was not arbitrary or capricious in finding that the petitioner failed to meet her burden to prove Althen prong three.

CONCLUSION

Upon review of the record before this court, including testimony taken at the hearing before Special Master Corcoran, the medical records, exhibits, conflicting expert reports, and Special Master Corcoran's decision, this court finds that Special Master Corcoran employed the proper standards of proof and that his final decision, which concluded that petitioner failed to prove, by a preponderance of the evidence, a medical theory of causation between the Gardasil vaccination and petitioner's medical condition

[33] "Yet even were I to find that the balance of evidence on this matter barely favored K.L., that determination would not alter my ultimate decision about causation, because Petitioner's causation theory itself is too deficient, and unsupported by the actual medical history." K.L. v. Sec'y of Health & Human Servs., 2017 WL 1713110, at *17 (emphasis added).

was not arbitrary or capricious. The Special Master's ruling on entitlement denying compensation to petitioner is **AFFIRMED**.

IT IS SO ORDERED.

s/Marian Blank Horn
MARIAN BLANK HORN
Judge