In the United States Court of Federal Claims

No. 16-1505
(Filed Under Seal: December 8, 2021)
(Reissued for Publication: December 28, 2021)[1]

O.M.V.,	*	
	*	
	*	
Petitioner,	*	Entitlement; Influenza ("Flu") Vaccine;
	*	Off-Table Injury; Acute Disseminated
v.	*	Encephalomyelitis ("ADEM"); Multiple
	*	Sclerosis ("MS"); Demyelinating Condition.
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
	*	
Respondent.	*	
	*	

Edward M. Kraus, Law Offices of Chicago Kent, Chicago, IL, for Petitioner.

Emilie Williams, U.S. Department of Justice, Washington, DC, for Respondent.

ORDER AND OPINION

DIETZ, Judge.

Petitioner, O.M.V., seeks review of a decision by Special Master Nora Beth Dorsey, denying him compensation under the National Vaccine Injury Compensation Program ("Vaccine Act"). Petitioner alleges he was injured by an influenza ("flu") vaccine received on November 15, 2013. He filed for compensation on November 14, 2016. The Special Master denied relief on the ground that Petitioner failed to prove by a preponderance of the evidence that the vaccination caused his injury. Petitioner timely filed a motion for review. For the reasons stated below, Petitioner's Motion for Review is denied, and the Special Master's decision denying entitlement is sustained.

[1] Pursuant to Vaccine Rule 18(b) of the Rules of the United States Court of Federal Claims, the Court issued this Order and Opinion under seal on December 8, 2021 to provide the parties an opportunity to submit redactions. *See* ECF No. 137. The parties did not submit any redactions by the December 22, 2021 deadline. Accordingly, the Court now publishes this Order and Opinion without redactions.

I. BACKGROUND[2]

On November 15, 2013, Petitioner, at thirty-nine years old, received a trivalent flu vaccine upon returning from a medical trip in Bolivia. *O.M.V. v. Sec'y of Health & Hum. Servs.*, No. 16-1505V, 2021 WL 3183719, at *6 (Fed. Cl. Spec. Mstr. June 16, 2021). At the time Petitioner received the vaccine, he was working as a pediatrician. *Id.* at *17. Petitioner had no neurological symptoms prior to vaccination. *Id.*

A. Medical History

The day after he received the vaccine, Petitioner experienced an episode of confusion, weakness, problems with balance and tingling on the left side of his body, including scalp, face, arm, and leg. Pet'r's Mem. in Supp. of Mot. for Review at 2, ECF No. 127 [hereinafter Pet'r's Mot.]. Petitioner visited a nearby urgent care facility on the same day and complained of "bilateral facial numbness . . . and left arm weakness[.]" *O.M.V.*, 2021 WL 3183719, at *6. After being examined, Petitioner was diagnosed with generalized weakness and an acute severe migraine headache. *Id.*

The following week, Petitioner sought emergency treatment at a different urgent care facility complaining of left-side weakness, drooping in the face, and left arm weakness. *O.M.V.*, 2021 WL 3183719, at *6. The examining doctor diagnosed Petitioner with weakness of his left upper extremity and advised that he follow up with Dr. Mark Alan Simaga, a neurologist. *Id.* The next day, Petitioner's condition worsened, which prompted him to visit an emergency room where he complained of continued weakness in his arm and difficulty grasping items, focusing, and putting words together. *Id.* at *7. After rendering a physical examination, the examining doctor ordered multiple tests, including labs, electrocardiogram ("EKG"), and brain MRI—all of which came back normal. *Id.* The MRI showed no evidence of a demyelinating disorder. *Id.* Petitioner was diagnosed with paresthesia and stroke/cerebrovascular accident ("CVA") then discharged. *Id.*

On January 14, 2014, Petitioner was seen by Dr. Simaga, who diagnosed him with transient ischemic attack ("TIA") and hemiplegic migraine. *O.M.V.*, 2021 WL 3183719, at *7. Dr. Simaga also ordered numerous tests, including labs and MRIs, and prescribed Plavix for Petitioner. *Id.*

On January 29, 2014, Petitioner was evaluated by Dr. Krista Molina, a primary care physician. *O.M.V.*, 2021 WL 3183719, at *8. Dr. Molina diagnosed Petitioner with TIA, left arm weakness, left leg weakness, and left facial numbness. *Id.* Dr. Molina then re-ordered tests, referred Petitioner to the neurology department, and encouraged Petitioner to take Plavix daily and continue Pravachol. *Id.* Petitioner underwent an ultrasound and an EKG that day, both of

[2] The factual background is derived from the Special Master's Decision. *O.M.V. v. Sec'y of Health & Hum. Servs.*, No. 16-1505V, 2021 WL 3183719, at *6-20 (Fed. Cl. Spec. Mstr. June 16, 2021).

which came back normal. *Id.* Petitioner's symptoms were noted to have "started [one] day after flu shot, [two] days after a long plane trip." *Id.* On February 8, 2014, a brain MRI and blood tests were conducted, which were either normal or unremarkable. *Id.*

Petitioner's condition continued to worsen. *O.M.V.*, 2021 WL 3183719, at *8-9. On April 5, 2014, Petitioner was admitted to an emergency room where he complained of "[s]udden onset of left parietal headache associated with left facial numbness and left upper extremity numbness and weakness with abnormal gait." *Id.* at *9. Petitioner also reported that his "headache was much different than his usual migraine headache" and that it had lasted for about four hours. *Id.* Upon examination, the examining doctor diagnosed Petitioner with "left face numbness, left face and left-sided weakness and paresthesia, TIA versus complicated migraine, as well as borderline dyslipidemia." *Id.* Petitioner was admitted for observation. *Id.* The next day, however, Petitioner underwent a neurology consultation with Dr. Arkadiy Konyukhov, who noted that a repeat MRI of Petitioner's brain was normal, "except possible very small FLAIR hyperintensity in the right parieto-occipital white matter." *Id*. Petitioner was discharged with a diagnosis of "probable hemiplegic migraines or dyslipidemia." *Id.* MRIs of Petitioner's thoracic and cervical spines performed on May 6, 2014 were unremarkable, and no lesions were seen. *Id.*

In July 2014, Petitioner's treating physicians considered a diagnosis of a demyelinating disease. *O.M.V.*, 2021 WL 3183719, at *9. On July 1, Petitioner received a lumbar puncture, and Petitioner's cerebrospinal fluid ("CSF") showed five well-defined oligoclonal bands in the CSF that were not present in the corresponding serum sample. *Id.* Petitioner saw Dr. Konyukhov on July 14 for further evaluation of his ongoing left-sided weakness, numbness, and periods of confusion. *Id.* at *10. After reviewing Petitioner's test results, Dr. Konyukhov noted that Petitioner's "age might indicate demyelinating disease," though his MRIs were normal. *Id.* Petitioner was diagnosed with "disturbance of skin sensation and left hemiplegia." *Id.*

On July 30, Petitioner was admitted to a hospital for further care and observation where he complained of paresthesia, weakness, tingling, and loss of sensation on the left side of his body, and difficulty speaking, driving, and walking. *O.M.V.*, 2021 WL 3183719, at *10. While at the hospital, Petitioner had a neurology consultation with Dr. Syed Munzir, who suspected Petitioner had a complex migraine and recommended a brain MRI, which came back normal. *Id.* Petitioner was ultimately diagnosed with "left-sided paresthesia[] and weakness and possible hemiplegic migraine." *Id*. at *10-11. His examining doctor also noted that Petitioner's etiology was currently unclear, and he recommended Petitioner abstain from vaccinations until a clear diagnosis. *Id.* at *11.

On August 1, 2014, Petitioner saw Dr. Konyukhov. *Id.* Dr. Konyukhov observed subtle weakness in Petitioner's left arm, leg, and intrinsic muscles of hand, as well as some crossing of the reflexes at the knees. *O.M.V.*, 2021 WL 3183719, at *11. In light of the presence of oligoclonal bands along with left-sided weakness, Dr. Konyukhov found that Petitioner's recent complaint of "right-sided weakness could be [an] indication of [two] different attacks[,]" which could support a potential diagnosis of multiple sclerosis ("MS"). *Id*. However, he noted it "[is] so

unusual that there is still no lesion present on the MRI." *Id.* Dr. Konyukhov recommended Petitioner undergo an evaluation with an MS specialist. *Id.*

A few weeks later, Petitioner was evaluated by Dr. Jaison Grimes at Indiana University due to concern for demyelinating illness. *O.M.V.*, 2021 WL 3183719, at *11. After reviewing Petitioner's medical history, reported symptoms, and conducting a physical examination, Dr. Grimes found "[i]t a bit atypical that the patient's symptoms are so severe without a corresponding lesion on imagining, but the presence of oligoclonal bands is suggestive that this could be an atypical presentation of demyelinating disease." *Id.* Dr. Grimes recommended Petitioner "wean his corticosteroids and try an immunomodulating therapy, specifically Tecfidera."[3] *Id.* Additional imagining studies were recommended to assess for potential lesions "to aid in diagnosis of [MS.]" *Id.* On August 30, 2014, Petitioner underwent MRIs of the lumbar, cervical, and thoracic spine. *Id.* No lesions characteristic of MS were reported. *Id.* at *12.

Petitioner saw Dr. Molina on December 10, 2014, and he reported continued left-sided weakness, as well as a new onset of right-sided weakness. *O.M.V.*, 2021 WL 3183719, at *12. Upon examination, Dr. Molina diagnosed Petitioner with left-sided weakness, history of TIA, hyperlipidemia, and a Vitamin D deficiency. *Id.* Dr. Molina also provided a letter advising that Petitioner avoid future flu vaccines because he "had a severe reaction to the flu vaccine previously which resulted in long-lasting neurological deficits." *Id.* at *13.

In January 2015, Petitioner was evaluated by rheumatologist Dr. Heather Gillespie to assist with his diagnosis. *O.M.V.*, 2021 WL 3183719, at *13. Dr. Gillespie's assessment found weakness and pain in the face, upper extremity, and lower extremity, among other ailments. *Id.* She recommended intermittent steroid dosing and a follow up with Dr. Grimes. *Id.*

Petitioner followed up with Dr. Grimes on February 5, 2015. *O.M.V.*, 2021 WL 3183719, at *13. Upon a physical examination and review of prior MRIs, Dr. Grimes concluded that Petitioner did not meet the criteria for MS, but, if Petitioner did meet the criteria, "it would likely be a progressive form." *Id*. Nonetheless, he recommended Petitioner see a neuromuscular specialist. *Id.*

Petitioner followed up with Dr. Gillespie on March 20, 2015, and she observed the same symptoms from Petitioner's prior visit except "now with features of myopathy and labs consistent with myopathy." *O.M.V.*, 2021 WL 3183719, at *13. Dr. Gillespie ordered a muscle biopsy and MRI of the left lower extremity, both of which came back normal. *Id.* In April 2015, Petitioner had an electromyography ("EMG") study of the left arm and leg, which was also normal. *Id.* Petitioner returned to Dr. Gillespie on May 6 with complaints of persistent hip weakness, dorsiflexion weakness, persistent intermittent facial asymmetry, slower thought process, and drowsiness. *Id.* at *14. Dr. Gillespie agreed with Petitioner's continued use of prednisone and recommended additional labs and a muscle biopsy. *Id.* Petitioner next saw Dr. Gillespie on June 10, 2015, and, while he indicated his cognitive symptoms had improved, he

[3] Tecfidera is a drug used to treat MS patients. *Id.* at *11 n.35.

reported the weakness and pain on his left side persisted. *Id.* Petitioner's muscle biopsy showed no evidence of inflammatory changes, and Dr. Gillespie believed Petitioner had a "primary neurologic process." *Id.*

Near the end of October 2015, Petitioner saw Dr. Molina for a follow-up after an emergency room visit. *O.M.V.*, 2021 WL 3183719, at *14. Petitioner reported recurrent episodes of muscle pain and weakness, and indicated that he was taking Tecfidera for presumed MS, even though Dr. Grimes did not think Petitioner's symptoms were due to MS. *Id.*

On February 11, 2016, Petitioner returned to Dr. Gillespie reporting he started treatment for MS in the past six months with "some benefits." *O.M.V.*, 2021 WL 3183719, at *14. He reported an episode of upper extremity weakness, which improved with steroids. *Id.* He also complained of joint pain in his hands and chronic neck pain, which Dr. Gillespie attributed to an "[a]pparent response to MS treatment." *Id.*

Petitioner returned to Dr. Konyukhov on October 20, 2016 for "possible MS follow up." *O.M.V.*, 2021 WL 3183719, at *15. Petitioner reported his history of intermittent episodes of weakness, numbness, and tingling, mostly on the left side, which he "originally attributed to the [flu] vaccine." *Id.* Dr. Konyukhov noted that Petitioner's repeat MRIs did not show any abnormalities, and further noted that Dr. Grimes "considered [the] possibility of [MS] even without any lesions and therefore placed [Petitioner] on Tecfidera." *Id.* Dr. Konyukhov reviewed the imaging from September 2016 and did not see any nonspecific white matter lesions. *Id.* Petitioner's neurological exam was normal except for mild decreased strength in his left arm and leg. *Id.* In his assessment, Dr. Konyukhov wrote Petitioner's "intermittent episodes of weakness and numbness . . . could be suggestive of some kind of problem in the brain (MS), but so far MRIs [are] not showing any clear lesions." *Id.* He recommended Petitioner continue taking Tecfidera and have a repeat MRI in one year. *Id.*

In 2017, Petitioner was evaluated on numerous occasions in the emergency room for difficulty swallowing—which was thought to be due to an allergic reaction. *O.M.V.*, 2021 WL 3183719, at *15. In August 2017, Petitioner was referred to an allergist for allergy testing, and his test came back negative for everything except histamine. *Id.*

Petitioner returned to Dr. Molina on September 18, 2017 to report his recent difficulty swallowing and corresponding negative allergy test. *O.M.V.*, 2021 WL 3183719, at *15. Dr. Molina conducted a neurologic exam, which revealed "[m]ildly decreased grip strength in left hand [and] mildly decreased flexor strength in legs bilaterally[.]" *Id.* Her diagnoses included MS and dysphagia. *Id.* She ordered MRIs and labs, referred Petitioner to speech therapy and gastroenterology, and refilled his Tecfidera prescription. *Id.* Later that month, Petitioner underwent cervical, brain, and thoracic MRIs, and his brain MRI revealed small, faint FLAIR hyperintense foci in the white matter, with minimal changes from the previous exam. *Id.*

On October 10, 2017, Petitioner returned to Dr. Gillespie reporting an MS flare up, persistent weakness in the hands, and worsening difficulty with swallowing. *O.M.V.*, 2021 WL

3183719, at *16. Dr. Gillespie recommended Petitioner follow up with neurology for an "[a]pparent MS variant." *Id.* For the remainder of 2017, Petitioner continued to take the MS drug, Tecfidera, until he tested positive for John Cunningham ("JC") virus, at which time he was taken off Tecfidera. *Id*.

Petitioner saw John Emmett, a physician assistant to Dr. Grimes, for a follow-up on October 16, 2017. *O.M.V.*, 2021 WL 3183719, at *16. Mr. Emmett noted the "few nonspecific punctuate white matter hyperintensities" on Petitioner's September 2017 MRI that were unchanged from Petitioner's last MRI. *Id.* Petitioner's physical exam revealed no neurologic findings. *Id*. Mr. Emmett observed that Dr. Grimes had not previously suspected MS "given [the] lack of exam findings and relative lack of atypical MRI changes." *Id.*

During 2018 and 2019, Petitioner's condition remained unchanged, and he continued to receive conflicting diagnoses. *O.M.V.*, 2021 WL 3183719, at *16-17. On January 22, 2019, Petitioner returned to Dr. Konyukhov, who noted that there was "[n]o obvious diagnosis [so] far despite seeing multiple different physicians." *Id.* at *17. The next day, however, Petitioner saw Dr. Molina, who diagnosed Petitioner with "hyperlipidemia, MS, muscle spasm, Vitamin D deficiency, osteoporosis of lumbar spine, and '[a]dverse reaction to [flu] vaccine, sequela.'" *Id*.

B. Special Master's Decision

On November 14, 2016, Petitioner filed his petition requesting compensation under the Vaccine Act alleging that he suffered from permanent disabilities and permanent neurological deficits resulting from the flu vaccine. *See* Pet., ECF No. 1. Following numerous submissions of medical records and expert reports, a two-day entitlement hearing began on November 5, 2020. *See* ECF No. 74. During the hearing, Petitioner testified, Dr. Marcel Kinsbourne and Dr. M. Eric Gershwin also testified for Petitioner, and Dr. Subramaniam Sriram testified on behalf of Respondent. *See O.M.V.*, 2021 WL 3183719, at *32-38. Petitioner also submitted four expert reports authored by Dr. Kinsbourne, and two expert reports authored by Dr. Gershwin. *See id.* at *20 n.41 & *27 n.57. Respondent filed three expert reports authored by Dr. Sriram. *See id.* at *32 n.74.

After consideration of the facts and arguments, the Special Master found that Petitioner had not established by preponderant evidence that the vaccine caused his condition. *O.M.V.*, 2021 WL 3183719, at *49. The Special Master concluded that, while there was not preponderant evidence that Petitioner suffered from acute disseminate encephalomyelitis ("ADEM") or MS, Petitioner had "alleged that he suffered a demyelinating neurological condition of the CNS." *Id.* at *43. The Special Master then engaged in the *Althen* prong analysis, where she found Petitioner failed to meet his burden under each prong. *Id.* at *35-39. As a result, the Special Master denied Petitioner's request for compensation. Petitioner now seeks review of the Special Master's determination.

II. STANDARD OF REVIEW

This Court has jurisdiction under the Vaccine Act to review a special master's decision. 42 U.S.C. § 300aa-12(e)(2). In reviewing a special master's decision, this Court may:

> (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 of the findings of fact or conclusions of law of the special master found to be arbitrary, capricious, and 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)(A)-(C).

This Court reviews a special master's findings of fact 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. *Turner v. Sec'y of Health & Hum. Servs.*, 268 F.3d 1334, 1337 (Fed. Cir. 2001). The abuse of discretion standard applies to special master's evidentiary rulings, including the determinations as to the qualification of experts and the admissibility of their testimony. *Piscopo v. Sec'y of Health & Hum. Servs.*, 66 Fed. Cl. 49, 53 (2005) (citing *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)); *see Munn v. Sec'y of Health & Hum. Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992) ("The [abuse of discretion standard] will rarely come into play except where the special master excludes evidence."]; *Caves v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 119, 131 (2011), *aff'd*, 463 F. App'x 932 (Fed. Cir. 2012) ("The . . . abuse of discretion [standard] is applicable when the special master excludes evidence or otherwise limits the record upon which it relies."). With respect to the arbitrary and capricious standard, "no uniform definition . . . has emerged," but it is "a highly deferential standard of review" such that "[i]f 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." *Hines v. Sec'y of Health & Hum. Servs.*, 940 F.2d 1518, 1527-28 (Fed. Cir. 1991). This Court's role is not to "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." *Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011); *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000); *see also Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983) (a decision is arbitrary and capricious only if it is "so implausible that it could not be ascribed to a difference of view").

III. LEGAL STANDARDS

The Vaccine Act was established to compensate vaccine-related injuries and deaths after a showing that the vaccine caused the injury suffered. 42 U.S.C. § 300aa-11(a)(5)(B)(10). The Vaccine Act provides two ways for a petitioner to establish causation. *Munn*, 970 F.2d at 865. A petitioner may demonstrate causation through a statutorily prescribed presumption upon a showing that the alleged injury is one listed in the Vaccine Injury Table (the "Table"). 42 U.S.C.

§ 300aa-14. Or, when the alleged injury is not listed—an "off-Table injury"—the petitioner must prove "causation-in-fact" by a preponderance of the evidence—in other words, that they received a vaccine listed in the Table and that they suffered an injury as a result of the vaccine. *See* 42 U.S.C. §§ 300aa-11(c)(1)(C)(ii); *Lampe*, 219 F.3d at 1360.

In this case, because Petitioner's alleged injury—a demyelinating illness or other neurological condition—is not listed on the Table, he does not benefit from a presumption of causation, and he must specify his vaccine-related injury and shoulder the burden of proof on causation. *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1356 (Fed. Cir. 2010). More specifically, under the *Althen* test, he must:

> show by a preponderance of the 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 & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). This three-prong test "is intended to evaluate whether the vaccine actually caused the injury." *Locane v. Sec'y of Health and Hum. Servs.*, 685 F.3d 1375, 1380 (Fed. Cir. 2012). However, before applying the *Althen* test, the Vaccine Act requires a petitioner to show by preponderant evidence a "medically recognized injury" that is "more than just a symptom or manifestation of an unknown injury." *Lombardi v. Sec'y of Health & Hum. Servs.*, 656 F.3d 1343, 1352-53 (Fed. Cir. 2011) (explaining "if the existence and nature of the injury itself is in dispute," then "identification of a petitioner's injury is a prerequisite to an *Althen* analysis of causation").

IV. ANALYSIS

Petitioner identifies two perceived errors in the Special Master's decision. First, he argues that the Special Master erred by finding Petitioner did not establish that he suffered from a demyelinating illness or other neurological condition. Pet'r's Mot. at 17. Second, he argues that the Special Master "committed reversible error when she found against the weight of the evidence, that [P]etitioner's neurological condition could not be caused by an innate immune response and that he therefore did not meet his burden under *Althen* prong [one]." *Id.* at 20. The Court addresses each of Petitioner's concerns in turn.

A. Petitioner's injury

Petitioner asserts that he established by preponderant evidence that he suffered from a demyelinating condition post-vaccination based on the "overwhelming consensus of [P]etitioner's numerous treating physicians and the testimony of the medical experts." Pet'r's Mot. at 17-18. Petitioner's position is that, while the Special Master's conclusions that he did not suffer from ADEM or MS might be justified by the record, the Special Master erred in concluding that he did not establish that he suffered from any neurological condition at all. *Id.* at 19. The Special Master's failure to do so, Petitioner argues, was an abuse of discretion and warrants reversal. *Id.* at 19-20. Respondent counters arguing that the Special Master properly

determined that Petitioner did not provide preponderant evidence that he suffered from ADEM, MS, or any other defined neurological condition. Resp't's Resp. to Pet'r's Mot. at 10, ECF No. 131 [hereinafter Resp't's Resp.].

An off-Table petitioner—who does not benefit from a presumption of causation—must specify their vaccine-related injury and shoulder the burden of proving causation. *Broekelschen*, 618 F.3d at 1346. Identification of a vaccine-related injury is a prerequisite to the *Althen* analysis. *Id.* This is because "[m]edical recognition of the injury claimed is critical and by definition a 'vaccine-related,' i.e., illness, disability, injury, or condition, has to be more than just a symptom or manifestation of an unknown injury." *Id.* at 1349. An exact diagnosis, though, is not required for the special master to proceed to the *Althen* causation analysis. *See Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994) ("[T]o require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program."). When there is a dispute as to the nature of the injury, as in the present case, it is the duty of the special master to determine what injury, if any, is best supported by the evidence presented in the record before applying the *Althen* analysis to determine causation relative to that injury. *Broekelschen*, 618 F.3d at 1346; *Lombardi*, 656 F.3d at 1352 ("[I]f the existence and nature of the injury itself is in dispute, it is the special master's duty to first determine which injury was best supported by the evidence presented in the record before applying the *Althen* test to determine causation of that injury."); *see also Hibbard v. Sec'y of Health & Hum. Servs.*, 698 F.3d 1355, 1365 (Fed. Cir. 2012) (finding no error when the special master first focused on whether the petitioner had the injury she claimed was caused by the vaccine before addressing causation).

In this case, both parties read the Special Master's decision as concluding that Petitioner did not establish by preponderant evidence that he suffered from *any* neurological condition. *See* Pet'r's Mot. at 17; Resp't's Resp. at 7. However, the Court finds that the Special Master appropriately determined the nature of Petitioner's alleged injury based on the evidence presented in the record before proceeding with the *Althen* causation analysis. *See Broekelschen*, 618 F.3d at 1346. The parties dispute the nature of Petitioner's injury. Petitioner's expert Dr. Kinsbourne opined that Petitioner's diagnosis was "an inflammatory autoimmune encephalopathy that is most like MS with an ADEM-like onset, and with symptoms consistent with a demyelinating disorder." *O.M.V.*, 2021 WL 3183719, at *20. Respondent's expert Dr. Sriram opined that "the evidence does not support a diagnosis of MS, ADEM, or a demyelinating condition . . . [and] [P]etitioner's diagnosis remains ill-defined and unclear." *Id.* at *32. Thus, in a case like this, the Special Master appropriately determined which injury was best supported by the evidence presented in the record before applying the *Althen* test. *Broekelschen*, 618 F.3d at 1346.

The record shows the Special Master thoroughly considered whether Petitioner established, by preponderant evidence, that he suffered from ADEM, MS, or any other demyelinating disease. *See O.M.V.*, 2021 WL 3183719, at *40-43. In doing so, the Special Master first explicitly found Petitioner did not properly satisfy the diagnostic criteria for ADEM or MS—which Petitioner appears to acknowledge. *See* Pet'r's Mot. at 19 ("[W]hile the Special Master's conclusions that [P]etitioner did not suffer from ADEM or MS *per se* might be justified by the record . . . ."); *O.M.V.*, 2021 WL 3183719, at *40 (finding Petitioner did not suffer from

ADEM); *id.* at *42 (finding no preponderant evidence that Petitioner suffers from MS). The Special Master then proceeded to further analyze Petitioner's alleged "miscellaneous demyelinating or neurological conditions." *Id.* at *43. In consideration of Petitioner's expert reports and testimony, the Special Master found:

> Regardless of the phrase Dr. Kinsbourne use[d] to describe [P]etitioner's diagnosis, the totality of Dr. Kinsbourne's opinions boil[s] down to one category of neurological conditions—a demyelinating illness of the CNS. Thus, regardless of the name or phrase used, *the undersigned finds that [P]etitioner has alleged that he suffered a demyelinating neurological condition of the CNS.* Further, the undersigned finds that the petitioner has not established by preponderant evidence that he suffered a demyelinating illness post-vaccination.

Id. (emphasis added). From this, it is clear that the Special Master determined that Petitioner's alleged injury based on the record was a demyelinating neurological condition of the CNS. If the Special Master had concluded that Petitioner failed to meet his burden of identifying an injury, the Special Master could have stopped her analysis there. *See Hibbard*, 698 F.3d at 1364-65 ("If a special master can determine that a petitioner did not suffer [a vaccine-related injury], there is no reason why the special master should be required to undertake the separate (and frequently more difficult) [*Althen* analysis]."); *see also Lombardi*, 656 F.3d at 1353 ("In the absence of a showing of the very existence of any specific injury of which the petitioner complains, the question of causation is not reached."); *Locane*, 685 F.3d at 1381. The Special Master, instead, appropriately identified "demyelinating neurological condition of the CNS" as the injury—which aligns with the injury alleged by Petitioner[4]—before proceeding with the requisite causation analysis.[5] The Court also finds that the Special Master's identification of the Petitioner's alleged injury based on the record evidence was not arbitrary or capricious, an abuse of discretion, or otherwise not in accordance with law.

The confusion appears to arise from the following sentence in the Special Master's decision: "Further, the undersigned finds that the petitioner has not established by preponderant evidence that he suffered a demyelinating illness post-vaccination." *O.M.V.*, 2021 WL 3183719, at *43. This sentence may arguably be interpreted to mean that the Special Master determined that Petitioner failed to establish that he suffered from any demyelinating condition. However, the Court interprets this sentence to mean, not that Petitioner failed to demonstrate that he suffered from any neurological condition at all, but that Petitioner had not demonstrated that his neurological condition was caused by the vaccination. *See id.* (finding Petitioner failed to establish by preponderant evidence that he suffered a demyelinating illness *post-vaccination*).

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[4] In his motion, Petitioner argues that by a showing of preponderant evidence his alleged vaccine-related injury encompasses "a neurological illness, likely demyelinating in nature[,]" "neurological condition[,]" or "any CNS demyelinating condition." Pet'r's Mot. at 17, 19.

[5] This conclusion is further supported by the Special Master's elimination of "a number of other non-demyelinating conditions, including stroke (CVA), hemiplegic migraine, and CNS vasculitis" referenced within Petitioner's post-vaccination medical records. *O.M.V.*, 2021 WL 3183719, at *43. Because Petitioner "ha[d] not alleged, nor ha[d] his experts opined, that his alleged vaccine-related diagnosis [was] stroke, hemiplegic migraine, or vasculitis," she concluded that there was "insufficient evidence of *any other* neurological condition or diagnosis to support [P]etitioner's claim for compensation." *Id.* (emphasis added).

The inclusion of "post-vaccination" to qualify the remainder of the sentence speaks more to causation and serves as a preview of the Special Master's analysis under the *Althen* prongs.

B. *Althen* Prong One

Petitioner also asserts that the Special Master committed reversible error when she found against the weight of the evidence that Petitioner's neurological condition could not be caused by an innate immune response, and therefore concluded Petitioner failed to satisfy his burden under *Althen* prong one. Pet'r's Mot. at 20. Specifically, Petitioner argues the Special Master failed to acknowledge or explain why the role of the adaptive immune system rules out the ability of the innate immune system to produce neurological symptoms[] and ignore[d] petitioners' [sic] experts' cogent and reliable explanation of how it can do so, and within the time frame experienced by [Petitioner]." *Id.* at 21-22.

Under the first *Althen* prong, a petitioner must show by preponderant evidence a medical theory causally connecting the vaccine received and the injury sustained. *Althen*, 418 F.3d at 1278; *see Hibbard*, 698 F.3d at 1365 (requiring petitioner to show both the medical plausibility of their theory of causation and that the injury was consistent with that theory); *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006) (stating that the first *Althen* prong requires petitioner to show that the received vaccine caused the alleged injury). Petitioner's medical theory need not be medically or scientifically certain, but it must be a "sound and reliable" medical or scientific explanation. *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019) (citing *Knudsen*, 35 F.3d at 548-49).

The Federal Circuit has made clear that special masters, as the finders of fact, have the responsibility to weigh the persuasiveness and reliability of evidence presented to them, and if appropriate, the credibility of testimony. *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1325 (Fed. Cir. 2010); *see Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999) ("[T]he rules of evidence require that the trial judge determine whether the testimony has a reliable basis in the knowledge and experience of [the relevant] discipline.") (internal quotation marks omitted). The special master has broad discretion in determining the credibility of witnesses and weighing the evidence, and these credibility determinations are "virtually unreviewable" by the reviewing court. *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993). The reviewing court does not reweigh the evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses because all of these matters are within the purview of the factfinder. *Broekelschen*, 618 F.3d at 1349.

The record shows that the Special Master appropriately evaluated and weighed the evidence to reach the conclusion that Petitioner had not offered a sound and reliable medical theory causally connecting the flu vaccine to a demyelinating CNS illness. *O.M.V.*, 2021 WL 3183719, at *43. Based on the evidence, she determined that the prevailing mechanism causally associated with a demyelinating CNS illness is a T cell mediated adaptive immune system response, not an innate immune response. *Id*. The Special Master explained that, based on her experience, current medical literature, and expert testimony, molecular mimicry (an adaptive

immune system response) is the prevailing mechanism implicated in CNS demyelinating conditions. *Id.*

The Special Master properly assessed and considered the expert testimony presented by the parties. An assessment of the reliability of expert testimony is a determination that special masters are entitled—and expected—to make. *Porter*, 663 F.2d at 1250-51 ("[The Federal Circuit] has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act."); *Bradley*, 991 F.2d at 1575 (stating the factfinder has broad discretion in determining credibility because they see the witnesses and hear testimony). The Special Master's decision discusses Dr. Kinsbourne's testimony and notes that, while he opined that "vaccinations [generally] can cause demyelinating disorders . . . [he] deferred to Dr. Gershwin as to the mechanism." *O.M.V.*, 2021 WL 3183719, at *22. She further highlighted the fact that "Dr. Kinsbourne expressly rejected the mechanism of molecular mimicry in this case and opined that molecular mimicry would not occur within 24 hours." *Id.* at *23. The Special Master also addressed Dr. Gershwin's opinion of how the innate immune system can give rise to inflammation in the brain within twenty-four hours but considered it unpersuasive. *Id.* at *28-30. She found "Dr. Gershwin made a compelling argument that cytokines play a role in the pathological process of ADEM and MS[,]" but ultimately determined "[P]etitioner did not provide sound and reliable evidence that the innate immune system cytokine-induced inflammation explains CNS demyelination." *Id.* at *44-45. The Special Master explained the evidence supported the conclusion that "[i]t is the adaptive immune response that conducts the orchestra of various instruments that together play a role to cause CNS demyelination."[6] *Id.* (citing supporting sources).

Furthermore, the Special Master explained that she found Respondent's expert witness testimony by Dr. Sriram more persuasive because it was consistent with her experience, the medical literature, and prevailing case law. *O.M.V.*, 2021 WL 3183719, at *45. Specifically, Dr. Sriram testified that vaccination activates antigens in the lymph nodes where T cells proliferate, amplify, and subsequently enter the brain, which implicates an adaptive immune response. *Id.* The Federal Circuit has made clear that the special master's evaluation of the evidence—including its reliability and persuasiveness—is a "matter within the purview of the fact finder[,]" not the reviewing court. *Lampe*, 219 F.3d at 1364; *see Doe v. Sec'y of Health & Hum. Servs.*, 601 F.2d 1349, 1355 (Fed. Cir. 2010). Petitioner has not demonstrated that the Special Master erred. Most, if not all, of Petitioner's assertions relate to the weight assigned to certain evidence before the Special Master, and such factual findings are not to be second guessed by the Court. *Lampe*, 219 F.3d at 1362; *Hodges v. Sec'y of Health & Hum. Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993) (expressing the Vaccine Act "makes clear" that the reviewing court's purpose "is not to second guess" a special master's fact-intensive conclusions); *see Munn*, 970 F.2d at 870 ("It is, after all, the special masters to whom Congress has accorded the status of expert, entitling them to the special statutory deference in fact-finding normally reserved for specialized agencies.").

[6] The Special Master further noted that the medical literature supporting a finding of cytokines in clinically definite MS patients did not address whether cytokines caused or initiated the demyelinating disease. *O.M.V.*, 2021 WL 3183719, at *44 n.86.

In addition to weighing the evidence presented at the entitlement hearing, the Special Master agreed with the reasoning in prior vaccine cases where special masters rejected the theory of innate immunity as a sound and reliable mechanism in CNS demyelinating conditions. *See O.M.V.*, 2021 WL 3183719, at *43-44. The Court acknowledges that a special master may not exclusively rely on the fact-findings of other related vaccine cases to come to an ultimate determination. *See Contreras v. Sec'y of Health & Hum. Servs.*, 107 Fed. Cl. 280, 308 (2012). But that is not the case here. The Special Master's analysis was not "limited to a conclusory statement[,]" as Petitioner contends, rather the Special Master considered prior vaccine cases as lending additional support to the evidence before her. *See O.M.V.*, 2021 WL 3183719, at *43-45. The record shows that the Special Master relied on medical literature and expert testimony, in conjunction with her experience and case law, in coming to her conclusion that Petitioner in this case did "not offer a sound and reliable medical theory in support of his claim." *Id*. at *46; *see, e.g., Nunez v. Sec'y of Health & Hum. Servs.*, 144 Fed. Cl. 540, 548 (2019) (finding the special master appropriately reviewed the record as a whole and considered a similar vaccine case because she articulated a rational basis for her decision to reject petitioner's medical theory).

In sum, the record demonstrates that the Special Master appropriately analyzed the evidence, including Petitioner's experts, in determining whether an innate immune system can cause inflammation within twenty-four hours. After weighing the evidence and testimony, the Special Master rejected Petitioner's "novel theory" of innate immunity as a reliable mechanism in CNS demyelinating conditions. *See Lampe*, 219 F.3d at 1362 (noting the special master's assessment of witness credibility and their relative persuasiveness of competing medical theories are "uniquely deferential" and "virtually unchallengeable on appeal"). The Court finds that this conclusion was not arbitrary or capricious. Petitioner directs the Court to various points in the transcript that present evidence that "the flu vaccine can cause inflammation in the brain within 24 hours and that inflammation can occur independent of any T cell activation associated with an adaptive immune response." *See* Pet'r's Mot. at 22-23. The Court, however, declines Petitioner's invitation to reweigh evidence before the Special Master. *See Broekelschen*, 618 F.3d at 1349. This Court's role in reviewing the special master's decision "is not to second guess the [s]pecial [m]aster's fact-intensive conclusions[.]" *Locane*, 685 F.3d at 1380. 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. *Hines*, 940 F.2d at 1528. The record shows the Special Master considered all the evidence and, based on the evidence before her, concluded that Petitioner did not provide a "reliable medical or scientific explanation" sufficient to prove by preponderant evidence a medical theory linking the flu vaccine to his injury. *O.M.V.*, 2021 WL 3183719, at *43.

C. Remaining *Althen* prongs

Petitioner does not directly challenge the Special Master's findings under the remaining *Althen* prongs. Instead, he argues that the Special Master's "flawed reasoning rejecting that petitioner had a CNS demyelinating condition, or any neurological condition whatsoever, tainted her subsequent analysis." *See* Pet'r's Mot. at 20. Respondent argues that Petitioner challenges the Special Master's findings only under the first *Althen* prong, but his failure to meet his burden under the remaining *Althen* prongs is just as fatal. Resp't's Resp. at 12.

The Court is not persuaded by Petitioner's argument that the Special Master's analysis under the *Althen* prongs was "tainted" by a failure to find that Petitioner suffered a neurological condition and her further finding that such condition was not causally connected to his vaccine under the first *Althen* prong. As explained above, the Special Master's decision shows that she did in fact find that Petitioner had alleged that he suffered from a neurological condition—specifically a demyelinating illness of the CNS. The Special Master then proceeded to analyze such injury under the *Althen* prongs.

With respect to her analysis under the *Althen* prongs, the Court has reviewed the Special Master's decision under the first prong and, as discussed above, determined that her conclusions were not arbitrary or capricious, an abuse of discretion, or otherwise not in accordance with law. Petitioner does not provide any support for his argument that the Special Master's analysis on the second and third *Althen* prongs was arbitrary or capricious, aside from a conclusory statement that it was "tainted" by earlier findings. Because Petitioner failed to meet his burden of proof under the first *Althen* prong, he is not entitled to compensation under the Vaccine Act. *See Broekelschen*, 618 F.3d at 1350 (expressing that the Vaccine Act requires a petitioner to prove each prong of the *Althen* test by a preponderance of the evidence); *see also DePena v. Sec'y of Health & Hum. Serv.*, 133 Fed. Cl. 535, 549 (2017) ("[A] petitioner must satisfy all three prongs of the *Althen* test; a failure to satisfy one prong is fatal to the case."); *Doe/11 ex rel. Child/Doe/11 v. Sec'y of Dep't of Health & Hum. Servs.*, 87 Fed. Cl. 1, 14 (2009), *aff'd sub nom. Doe v. Sec'y of Health & Hum. Servs*., 601 F.3d 1349 (Fed. Cir. 2010) ("Failure to satisfy any of the three prongs prevents [p]etitioners from making their prima facie showing."). Thus, under these circumstances, the Court does not conduct a review of the Special Master's analysis and conclusions under the remaining *Althen* prongs.

V. CONCLUSION

In the conclusion of the Special Master's decision, she stated "[i]t is clear that [P]etitioner has had a very difficult struggle with his health since November 2013, and the undersigned extends her sympathy." The Court likewise acknowledges Petitioner's suffering and extends sympathy. However, because Petitioner has not demonstrated that the Special Master's decision was arbitrary or capricious, an abuse of discretion, or otherwise not in accordance with law, this Court must sustain the Special Master's decision.

For the reasons stated above, Petitioner's motion for review of the Special Master's decision is **DENIED**, and the Special Master's decision of June 26, 2021 is **SUSTAINED**. The Clerk of the Court is **DIRECTED** to enter judgment accordingly.

IT IS SO ORDERED.

s/ Thompson M. Dietz
THOMPSON M. DIETZ, Judge