

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: November 19, 2025

Refiled as Redacted: February 17, 2026

ANGELA MALAR,

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PUBLISHED

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Petitioner,

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No. 18-1429V

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v.

*

Special Master Nora Beth Dorsey

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SECRETARY OF HEALTH
AND HUMAN SERVICES,

*

Dismissal; Influenza (“Flu”) Vaccine;

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Neuromyelitis Optica (“NMO”);

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Neuromyelitis Optica Spectrum Disorder

Respondent.

*

(“NMOSD”).

Mark Theodore Sadaka, Law Offices of Sadaka Associates, LLC, Englewood, NJ, for Petitioner.
Felicia Langel, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION¹

On September 19, 2018, Angela Malar (“Petitioner”) filed a petition for compensation under the National Vaccine Injury Compensation Program (“Vaccine Act” or “the Program”), 42 U.S.C. § 300aa-10 *et seq.* (2018).² Petitioner alleges that as a result of receiving an influenza (“flu”) vaccine on October 4, 2015, she suffered neuromyelitis optica (“NMO”).³ Petition at

¹ When this Decision was originally filed, I advised my intent to post it on the United States Court of Federal Claims’ website, and/or at <https://www.govinfo.gov/app/collection/uscourts/national/cofc>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). In accordance with Vaccine Rule 18(b), Petitioner filed a motion to redact certain information. This Decision is being reissued with these redactions. Except for those changes and this footnote, no other substantive changes have been made. This Decision will be posted on the court’s website, and/or at <https://www.govinfo.gov/app/collection/uscourts/national/cofc>, with no further opportunity to move for redaction.

² The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to -34 (2018). All citations in this Decision to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

³ The petition also alleged an injury of migraine aura and a claim of significant aggravation. However, Petitioner’s filings and the joint submission specified the claim is a causation-in-fact for NMO. Therefore, the undersigned does not discuss migraine aura or significant aggravation.

Preamble (ECF No. 1). Respondent argued against compensation, stating that “this case is not appropriate for compensation under the terms of the [Vaccine] Act.” Respondent’s Report (“Resp. Rept.”) at 1 (ECF No. 62).

After carefully analyzing and weighing the evidence presented in this case in accordance with the applicable legal standards,⁴ the undersigned finds that Petitioner failed to provide preponderant evidence that her flu vaccine caused her NMO. Thus, Petitioner has failed to satisfy her burden of proof under Althen v. Secretary of Health & Human Services, 418 F.3d 1274, 1280 (Fed. Cir. 2005). Accordingly, Petitioner is not entitled to compensation.

I. ISSUES TO BE DECIDED

The parties agree that Petitioner received a flu vaccination on October 4, 2015 in the United States, and that following vaccination, her providers diagnosed her with NMO, an autoimmune condition.⁵ Joint Prehearing Submissions (“Joint Sub.”), filed Nov. 22, 2024, at 1 (ECF No. 133). The parties also stipulate that Petitioner suffered from NMO for more than six months following vaccination, that her petition was timely filed, and that there has been no prior award or settlement of a civil action for damages as a result of Petitioner’s NMO. Id.

The parties dispute Petitioner’s date of onset. Joint Sub. at 2. The parties also dispute whether Petitioner has provided preponderant evidence of all three Althen prongs. Id.

⁴ While the undersigned has reviewed all of the information filed in this case, only those filings and records that are most relevant will be discussed. See Moriarty v. Sec’y of Health & Hum. 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.”); see also Paterek v. Sec’y of Health & Hum. Servs., 527 F. App’x 875, 884 (Fed. Cir. 2013) (“Finding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered.”).

⁵ Although the parties identify Petitioner’s diagnosis as NMO, the experts interchangeably refer to Petitioner’s diagnosis as NMO and NMOSD. See Petitioner’s Exhibit (“Pet. Ex.”) 14 (consistently documenting Petitioner’s diagnosis as NMOSD except when citing to certain medical records that document diagnosis as NMO); Resp. Ex. A (opining “[t]here is little doubt as to the diagnosis of [NMOSD] in [Petitioner]” but otherwise characterizing her diagnosis as NMO); Resp. Ex. C (same). After a review of the expert reports, medical literature, as well as case law, the undersigned finds NMOSD more accurately reflects Petitioner’s pathology given her lack of spinal cord lesions. See Pet. Ex. 2 at 139 (“Limited forms of [NMO], such as isolated [optic neuritis] . . . have been referred to as NMO[SD].”) However, this distinction does not affect the undersigned’s Decision. Regardless of Petitioner’s diagnosis (NMOSD or NMO), the undersigned finds Petitioner has not provided preponderant evidence of causation. The undersigned will refer to Petitioner’s alleged vaccine-related injury as NMO in accordance with the parties’ Joint Submission.

II. BACKGROUND

A. Procedural History

Petitioner filed her petition on September 19, 2018, followed by medical records⁶ and an expert report from Dr. Alberto Martinez-Arizala from October 2018 to July 2020. Petition; Pet. Exs. 1-40. Respondent filed an expert report from Dr. Subramaniam Sriram on December 28, 2020. Resp. Ex. A. On February 25, 2021, Respondent filed his Rule 4(c) report, arguing against compensation. Resp. Rept. at 1.

On July 8, 2021, the undersigned held a Rule 5 conference. Rule 5 Order dated July 9, 2021 (ECF No. 70). The undersigned noted her concerns regarding onset and recommended further expert opinion from the parties on this issue. *Id.* at 2-4. Thereafter, Petitioner filed an expert report from Dr. David M. Yousem on March 28, 2023, and Respondent filed an expert report from Dr. Sriram on August 10, 2023. Pet. Ex. 54; Resp. Ex. C.

Afterwards, the parties filed a joint status report requesting to resolve entitlement through a hearing, which was set for December 2024. Joint Status Rept., filed Oct. 11, 2023 (ECF No. 116); Prehearing Order dated Nov. 28, 2023 (ECF No. 121). However, on October 16, 2024, Petitioner filed a status report requesting the December 2024 hearing be cancelled and that entitlement be resolved through a ruling on the record. Pet. Status Rept., filed Oct. 16, 2024 (ECF No. 127). On October 21, 2024, Respondent filed a status report indicating no objection to Petitioner's request. Resp. Status Rept., filed Oct. 21, 2024 (ECF No. 129). The entitlement hearing was cancelled and a briefing schedule issued. Order dated Oct. 21, 2024 (ECF No. 130).

Petitioner filed a motion for a ruling on the record on December 6, 2024. Pet. Motion for a Ruling on the Record ("Pet. Mot."), filed Dec. 6, 2024 (ECF No. 139). Respondent filed a response on January 6, 2025, and Petitioner filed a reply on January 27, 2025. Resp. Response to Pet. Mot. ("Resp. Response"), filed Jan. 6, 2025 (ECF No. 140); Pet. Reply to Resp. Response ("Pet. Reply"), filed Jan. 27, 2025 (ECF No. 141).

This matter is now ripe for adjudication.

B. Neuromyelitis Optica and Neuromyelitis Optica Spectrum Disorder

NMO is "a severe relapsing inflammatory [central nervous system ("CNS")] demyelinating disease that predominantly affects the optic nerves and spinal cord." Pet. Ex. 18 at 1;⁷ see also Pet. Ex. 2 at 139 ("NMO . . . is an immune-mediated chronic inflammatory disease that predominantly affects the optic nerve and spinal cord and presents with optic neuritis [] and myelitis.").

⁶ Medical records were filed throughout litigation.

⁷ P.J. Waters et al., Serologic Diagnosis of NMO: A Multicenter Comparison of Aquaporin-4-IgG Assays, 78 *Neurology* 665 (2012).

NMOSD includes patients with NMO as well as those who do not meet the criteria for NMO. See, e.g., Morgan v. Sec’y of Health & Hum. Servs., 850 F. App’x 775, 779 n.4 (Fed. Cir. 2021) (“[NMOSD] was first introduced in 2007 to cover patient groups with various clinical features and AQP4-IgG antibody test results. In 2013, . . . NMO [was] subsumed into the single descriptive term NMOSD because the clinical behavior, immunopathogenesis, and treatment of patients who have NMOSD are not demonstrably different than for those with NMO and patients with incomplete forms of NMO frequently later fulfill NMO criteria.” (internal citations and quotations omitted)); Inyang v. Sec’y of Health & Hum. Servs., No. 20-57V, 2024 WL 4063883, at *1 n.2 (Fed. Cl. Spec. Mstr. Aug. 8, 2024) (noting NMOSD includes NMO and acknowledging the experts used these terms interchangeably). Patients with only optic neuritis⁸ or transverse myelitis⁹ are classified under NMOSD since they have “incomplete forms of NMO.” Pet. Ex. 18 at 1; Resp. Ex. A, Tab 1 at 1;¹⁰ see also Pet. Ex. 17 at 8 (“[NMOSD] . . . may present with optic neuritis or transverse myelitis.”).¹¹ This expanded definition includes those with unilateral optic neuritis, like Petitioner. Resp. Ex. A, Tab 1 at 2; see Pet. Ex. 2 at 139 (“Limited forms of [NMO], such as isolated [optic neuritis] . . . have been referred to as NMO[SD].”).

Research shows that autoantibodies against aquaporin-4 (“AQP4”) are associated with NMO and NMOSDs. Pet. Ex. 2 at 139; Pet. Ex. 18 at 1; Pet. Ex. 31;¹² Resp. Ex. A, Tab 1; Resp. Ex. A, Tab 2.¹³ However, the exact role of these antibodies “is not clear.” Pet. Ex. 30 at 6;¹⁴ see also Resp. Ex. A, Tab 1 at 1; Resp. Ex. A, Tab 2.

⁸ Optic neuritis is “inflammation of the optic nerve.” Optic Neuritis, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=92519> (last visited Oct. 31, 2025).

⁹ Transverse myelitis is “myelitis in which the functional effect of the lesions spans the width of the entire cord at a given level.” Transverse Myelitis, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=91212> (last visited Oct. 31, 2025).

¹⁰ Brian G. Weinshenker et al., NMO-IgG: A Specific Biomarker for Neuromyelitis Optica, 22 Dis. Markers 197 (2006).

¹¹ Andrew J. Solomon, Diagnosis, Differential Diagnosis, and Misdiagnosis of Multiple Sclerosis, 25 Continuum 611 (2019).

¹² Vanda A. Lennon et al., A Serum Autoantibody Marker of Neuromyelitis Optica: Distinction from Multiple Sclerosis, 364 Lancet 2106 (2004).

¹³ Dean M. Wingerchuk et al., The Spectrum of Neuromyelitis Optica, 6 Lancet Neurol. 805 (2007).

¹⁴ Dimitrios Karussis & Panayiota Petrou, The Spectrum of Post-Vaccination Inflammatory CNS Demyelinating Syndromes, 13 Autoimmun. Revs. 215 (2014).

C. Factual History

1. Relevant Medical History¹⁵

Petitioner was forty-three years old when she received the subject flu vaccine on October 4, 2015. Pet. Ex. 6 at 1. Petitioner’s medical history included fibromyalgia, migraine without aura, intervertebral disc disease, depression and generalized anxiety, and [REDACTED]. Pet. Ex. 13 at 2-3; Pet. Ex. 40 at 1. Petitioner’s pharmacy records show that she was prescribed gabapentin from October 1, 2015 through March 8, 2016. Pet. Ex. 46 at 2; Pet. Ex. 47 at 1-2. The record does not reflect the purpose of Petitioner’s gabapentin prescription.¹⁶

Petitioner executed a declaration in which she averred she does not recall seeking medical care from October 4, 2015 until March 29, 2016. Pet. Ex. 41 at ¶ 2.

On March 28, 2016, Petitioner presented to her primary care provider (“PCP”) for an upper respiratory infection. Pet. Ex. 11 at 29. On examination, Petitioner had nasal discharge and swelling. Id. at 30. Her pupillary responses were normal. Id. She was diagnosed with an acute upper respiratory infection. Id. Petitioner had no additional complaints, and she was prescribed antibiotics. Id. at 29-31.

The next day, March 29, 2016, Petitioner presented to ophthalmology as a walk-in for vitreous floaters in her left eye. Pet. Ex. 8 at 1. On examination, Petitioner’s vision was mildly reduced in both eyes with the left eye worse than the right. Id. Petitioner reported that she was taking gabapentin, trazodone (antidepressant), and Wellbutrin (antidepressant). Id.

On April 3, 2016, six months post-vaccination, Petitioner presented to the emergency department (“ED”) at Thomas Jefferson University Hospital (“Thomas Jefferson”) reporting a one-day history of left eye “curtain” and flashes, left eye visual “black spots” for one week, right-sided lower lip numbness that “started this morning,” and bilateral foot paresthesias for two months. Pet. Ex. 2 at 15-16. Petitioner was admitted for possible optic neuritis. Id. at 38.

A brain magnetic resonance imaging (“MRI”) with and without contrast on April 4, 2016 showed “diffuse avid enhancement of the entire left optic nerve, consistent with optic neuritis,” as well as “scattered foci of abnormal hyperintense T2/FLAIR signal in the juxtacortical white matter and at the calloseseptal attachment, which most likely represent demyelination.” Pet. Ex. 2 at 155. Impression was “[l]eft optic neuritis in combination with demyelinating lesions in the juxtacortical and calloseseptal distribution, concerning for multiple sclerosis” (“MS”). Id. at 154. MR venography without contrast, conducted April 5, showed “[n]o evidence of major dural sinus or major deep vein thrombosis. Petitioner was treated with three days of solumedrol

¹⁵ This summary of medical records is largely taken from the parties’ briefs, as the undersigned finds the parties provided an accurate representation of the records. See Pet. Mot. at 2-5; Resp. Response at 3-8. The undersigned has edited the summary.

¹⁶ Petitioner maintains she had no visits with a medical provider during this period of time. See Pet. Ex. 41 at ¶ 2. Thus, the purpose of this prescription is not clear.

infusions, and “[she] felt that her vision was improving.” Id. at 38. On April 6, 2016, Petitioner was discharged on a tapering dose of prednisone and referred to outpatient neuro-ophthalmology. Id. At the time of discharge, NMO Immunoglobulin G (“IgG”) antibody testing was pending. Id.

Following her hospitalization, NMO IgG testing revealed abnormal levels of anti-AQP4 antibodies (6.8; reference range is less than 3.0 U/ml), “consistent with [NMO].” Pet. Ex. 2 at 138.

On April 12, 2016, Petitioner presented to her PCP reporting left eye blindness, mouth numbness, burning pain in her body, insomnia, and increased urinary frequency. Pet. Ex. 11 at 22. Petitioner also reported that she had been diagnosed with MS. Id. Petitioner’s PCP prescribed baclofen (antispasmodic) and a higher dose of gabapentin and referred her to neurology “asap.” Id. at 24.

On April 21, 2016, Petitioner presented to neurologist Tooba Fayyaz, D.O., reporting a diagnosis of MS two weeks prior. Pet. Ex. 3 at 21. Petitioner reported intermittent tingling in her legs and “a shooting sensation going down her back” that began “around Christmas time of 2015.” Id. At this visit, Petitioner complained of blurry vision in her left eye that “[was] much improved,” “constant pain down her back and into her upper arms,” “numbness and tingling down both her legs,” fatigue, urinary urgency, difficulty with balance, difficulty sleeping, and headaches. Id. Based on Petitioner’s clinical presentation and brain MRI, Dr. Fayyaz tentatively diagnosed her with MS. Id. at 22-23. Dr. Fayyaz noted that Petitioner “only had [one] attack” of MS, ordered a cervical spine MRI, and prescribed Copaxone (MS therapeutic). Id. at 23. Petitioner’s April 29, 2016 cervical spine MRI with and without contrast did not show demyelinating lesions and was normal. Id. at 54.

On May 3, 2016, Petitioner followed up with Dr. Fayyaz, who confirmed her diagnosis of NMO after review of her NMO antibody testing the previous month. Pet. Ex. 3 at 16-18. Petitioner reported ongoing body pain and blurry vision. Id. at 16. Dr. Fayyaz prescribed Imuran (immunosuppressive) and prednisone and ordered a thoracic spine MRI. Id. at 18. Petitioner’s May 10, 2016 thoracic spine MRI with and without contrast showed mild degenerative disc disease, did not show demyelination, and was otherwise normal. Id. at 52.

Petitioner presented to the ED at Cape Regional Medical Center on June 1, 2016, reporting pain in her *right* eye for three days. Pet. Ex. 4 at 936. Petitioner was admitted. Id. at 919. A repeat brain MRI with and without contrast on June 3, 2016 was unremarkable, showing no areas of abnormal enhancement. Id. at 919, 998. Cervical spine MRI, with and without contrast, conducted the same day showed mild disc bulging but was otherwise normal. Id. at 1000. She was discharged on June 4, 2016 in stable condition. Id. at 919. Her discharge

diagnoses were “[q]uestionable [NMO] with negative findings on [MRI]” and “[n]o evidence to prove this was [NMO],” with secondary diagnoses of chronic pain and [REDACTED].¹⁷ Id.

On July 14, 2016, Petitioner returned to Dr. Fayyaz. Pet. Ex. 3 at 12. Petitioner reported hand tremors, muscle spasms, and constant pain in her feet and ankles. Petitioner also reported that her left eye vision continued to improve. Id. Diagnosis remained NMO. Id. at 14. Petitioner continued her Imuran, prednisone, gabapentin, and baclofen. Id. at 14-15.

Petitioner had a lumber spine MRI on August 15, 2016 that showed mild degenerative disc disease. Pet. Ex. 4 at 879-80.

On October 4, 2016, one year post-vaccination, Petitioner presented to the ED at Cape Regional Medical Center reporting two days of blurry vision in both eyes (particularly the left), eye pain, generalized weakness, headache, and body pains. Pet. Ex. 4 at 758, 761, 772. Petitioner was admitted to the hospital. Id. at 765. An October 5 brain MRI with and without contrast showed “stable [findings] with no new abnormalities.” Id. at 801. Petitioner had a low vitamin B₁₂ (140.6 pg/ml; reference range 211-911 pg/ml) and was started on monthly vitamin B₁₂ injections.¹⁸ Id. at 742, 798. Petitioner was also treated with three days of solumedrol infusions. Id. at 742, 791. She was discharged on October 6 with diagnoses of “[a]cute exacerbation of [NMO],” vitamin B₁₂ deficiency, anxiety, and chronic post-traumatic stress disorder. Id. at 742.

Petitioner returned to Dr. Fayyaz on October 19, 2016, reporting ongoing whole-body pain, tremors in both hands, muscle spasms, and extreme fatigue. Pet. Ex. 3 at 6. She “sometimes” had a burning sensation in her face and behind her eyes, worsening blurry vision in left eye with stress, numbness in hands and feet, and “sometimes” had a tingling sensation throughout her body. Id. Dr. Fayyaz noted that Petitioner’s “overwhelming complaint [was] pain and her MRIs [] remained stable.” Id. at 8. Petitioner was referred to Thomas Jefferson neurology for evaluation. Id. Dr. Fayyaz also noted Petitioner’s vitamin B₁₂ deficiency and opined it was “a large contributing factor” to her complaints of numbness and tingling. Id.

Petitioner continued to report pain (“neuropathic pain” on December 12, 2016 and “pain in her legs” on March 22, 2017) and fatigue through 2016 and into the summer of 2017. See Pet. Ex. 4 at 361-69, 616-17. During this period, Petitioner also obtained treatment from pain management for her chronic pain. See generally Pet. Ex. 42. A repeat brain MRI with and

¹⁷ Later that day, on June 4, 2016, Petitioner was transported to the ED for [REDACTED]. Pet. Ex. 4 at 881-94. Petitioner was observed and then discharged to home without further treatment. Id.

¹⁸ A vitamin B₁₂ deficiency “can present with non-specific clinical features” and neurological manifestations, including paresthesias, peripheral neuropathy, and subacute combined degeneration of the spinal cord. Resp. Ex. A, Tab 4 at 1-2, 3 tbl.2 (Michael J. Shipton & Jacko Thachil, Vitamin B₁₂ Deficiency – A 21st Century Perspective, 15 Clin. Med. 145 (2015)). Additionally, “[s]equelae of untreated vitamin B₁₂ deficiency includes . . . permanent neurological symptoms.” Id. at 5.

without contrast on December 13, 2016 showed “[s]light progression in a white matter lesion” while “other scattered patchy hyperintensities remain[ed] stable,” “no new lesions,” and “no areas of abnormal enhancement.” Pet. Ex. 4 at 688. Overall, the findings were “nonspecific.” Id. Petitioner underwent an inpatient laparoscopic cholecystectomy on December 30, 2016 at Cooper University Hospital. Pet. Ex. 12 at 57-58. A neurology consultation noted “[no] evidence to suggest NMO exacerbation at the moment.” Id. at 61.

On August 29, 2017, almost two years post-vaccination, Petitioner presented to neurologist Vikram Bhise, M.D., at Robert Wood Johnson Medical School. Pet. Ex. 9 at 23. Petitioner reported that her symptoms “began in October 2015 following a flu shot.” Id. Symptoms at that time were “‘zapping’ going up and down her spine as well as burning of the feet.” Id. She reported she then lost her vision in her left eye in April 2016, after which she was diagnosed with NMO. Id. Petitioner complained of continued “mild blurred vision in her left eye” and “pseudo-flares.” Id. Under history of present illness, Dr. Bhise summarized pertinent medical records and documented a timeline of events. Id. at 23-24. The timeline indicated “10/2015 Lhermitte sign, paresthesias”¹⁹ followed by “04/2016 left optic neuritis, lip numbness.” Id. at 24. On examination, Petitioner had normal vision in both eyes and no neurological abnormalities. Id. at 27-28. Dr. Bhise diagnosed Petitioner with NMO, with an “initial symptom onset nearly [two] years ago” and “relapse free since April 2016.” Id. at 28. Dr. Bhise adjusted the dosage of Petitioner’s medications, ordered updated MRIs and labwork, and recommended physical therapy for her chronic pain. Id. at 28-29. On August 29, 2017, Petitioner’s AQP4 IgG was negative and her vitamin B₁₂ was normal. Id. at 36, 39.

Petitioner continued to report pain and fatigue in 2017 and 2018 and repeat MRIs, with and without contrast, were conducted. See, e.g., Pet. Ex. 4 at 49-59, 197-200, 248-51; Pet. Ex. 7 at 5-7. Repeat thoracic and lumbar spine MRIs on September 19, 2017 “show[ed] no areas of abnormal enhancement” and mild degenerative disc disease. Id. at 248-51. Repeat cervical spine MRI on November 27, 2017 was normal. Id. at 197. And repeat brain MRI on November 27, 2017 showed “[s]table white matter hyperintensities consistent with the patient’s history of [NMO]” and “the left optic nerve appear[ed] slightly enlarged, with peripheral and subtle central enhancement.” Id. at 199-200.

On December 7, 2017, Petitioner saw Elissa M. Wierman, PAC, to start care with a new PCP and for medication refills. Pet. Ex. 7 at 5. Petitioner reported “eye pain and periorbital pain” that occurred frequently as well as “muscle pain and joint pain.” Id. Assessment included NMO, for which PAC Wierman indicated medication refills would not be given at that time. Id.

¹⁹ Lhermitte’s sign is “the development of sudden, transient, electric-like shocks spreading down the body when the patient flexes the head forward; seen mainly in [MS] but also in compression and other disorders of the cervical cord.” Lhermitte Sign, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=106344> (last visited Oct. 31, 2025). “[S]ymptoms typical of spinal cord demyelination that are seen in [] [NMO] . . . include . . . Lhermitte’s symptom (spinal or limb dysaesthesias caused by neck flexion).” Resp. Ex. A, Tab 2 at 2. Lhermitte’s sign has also been reported in patients with vitamin B₁₂ deficiency. Resp. Ex. A, Tab 3 at 1 (William M. Butler et al., Lhermitte’s Sign in Cobalamin (Vitamin B₁₂) Deficiency, 245 JAMA 1059 (1981)).

at 7. Assessment also included vitamin B₁₂ deficiency and PAC Wierman opined this deficiency “[was] a large contributing factor in her . . . numbness/tingling.” Id.

At an ED visit on January 14, 2018, Petitioner reported feeling “exhausted weak and dehydrated. . . . She describe[d] her weakness as a sensation that her legs feel weak and she has burning in her legs and feet. She does not feel they will hold her up.” Pet. Ex. 4 at 49. Petitioner was noted to have “chronic pain issues” and was “followed by pain management.” Id. Petitioner further reported “[s]he did not get a flu vaccine this year as she state[d] the flu vaccine precipitated her [NMO].” Id. Repeat MRIs of the brain, cervical spine, and thoracic spine on January 15, 2018 “demonstrated no enhancing lesions.” Id. at 42, 74. She was discharged home the following day. Id. at 42.

In February 2018, Petitioner returned to the ED, reporting “nerve pain going up back, seeing flashes of light and black spots, stinging feeling all over.” Pet. Ex. 4 at 3. Testing was normal other than a urinary tract infection and high blood pressure. Id. at 13. Petitioner was discharged home that same day. Id.

On March 22, 2018, Petitioner presented to neurologist Donald Barone, D.O., who diagnosed Petitioner with “[r]esidual findings [of NMO] on exam[ination] [] but no definite clinical disease activity.” Pet. Ex. 1 at 1-4. Dr. Barone suspected that Petitioner’s “current visual symptoms [were] migraine aura without headache.” Id. at 5.

Petitioner’s next repeat MRIs were conducted on November 6, 2018, over three years post-vaccination. Pet. Ex. 13 at 37-43. Petitioner’s brain MRI without contrast showed a “potential mild right optic nerve T2 hyperintense signal and edema versus motion artifact. No diffusion restriction to specify an active lesion.” Id. at 37-38. Petitioner’s cervical spine MRI without contrast showed “no convincing cord signal abnormality.” Id. at 38-39. Similarly, no cord signal abnormalities were noted on Petitioner’s thoracic and lumbar spine MRIs. Id. at 39-43.

From 2019 through the spring of 2021, Petitioner periodically requested NMO medication refills from her PCP. Pet. Ex. 44 at 2-68. No additional medical records were filed.

2. Petitioner’s Declarations²⁰

Petitioner executed a declaration on December 5, 2024. Pet. Ex. 56. Petitioner received a flu vaccination on October 4, 2015. Id. at ¶ 3. She averred that she “first started experiencing burning/zapping sensation in [her] back and legs around Thanksgiving 2015.” Id. at ¶ 5. She felt “really fatigued” to the point she could not assist with Thanksgiving meal preparations and cleaning. Id. She first attributed the “burning/zapping sensations in [her] back and legs” to her new job, which she began a few months prior to vaccination, because she was on her feet all day and often would lift heavy items. Id. at ¶¶ 4, 6.

²⁰ Although titled affidavits, they were not notarized and are therefore referenced as declarations. See Pet. Exs. 41, 56.

Petitioner stated that she “then started experiencing issues with [her] vision.” Pet. Ex. 56 at ¶ 7. She first developed floaters and blurriness, which she attributed to age. *Id.* Her vision then began to get darker until she could no longer see out of her left eye. *Id.* Petitioner did not indicate when her vision issues began other than the fact they began sometime after the “burning/zapping sensations in [her] back and legs” and before she went to Thomas Jefferson University Hospital in April 2016. *See id.* at ¶¶ 6-8.

Regarding the lack of treatment following vaccination, Petitioner averred that she did not “recall seeking any medical care during the time period between October 4, 2015 and March 29, 2016.” Pet. Ex. 41 at ¶ 2. She did not have a PCP during this period of time, and she did not establish care with a PCP until April 21, 2016. *Id.* She did not seek medical treatment for her vaccine-related injury until April 4, 2016 at Thomas Jefferson University Hospital. *Id.* at ¶ 3.

D. Expert Reports

1. Petitioner’s Expert, Dr. Alberto Martinez-Arizala²¹

a. Background and Qualifications

Dr. Martinez-Arizala has been a professor of clinical neurology, neurosurgery, and physical medicine and rehabilitation at the University of Miami Miller School of Medicine for over 30 years. Pet. Ex. 14 at 1; Pet. Ex. 15 at 1-2. He obtained his M.D. from the university of Miami School of Medicine, after which he completed an internship and neurology residency through the U.S. Army and served until 1994. Pet. Ex. 14 at 1; Pet. Ex. 15 at 1-3. He is board certified in neurology and spinal cord medicine. Pet. Ex. 14 at 1; Pet. Ex. 15 at 1-2. Dr. Martinez-Arizala also worked as the Chief of the Spinal Cord Injury Service at the Miami VA Health Care System where he treated patients with spinal cord disorders, including patients with transverse myelitis and NMOSD. Pet. Ex. 14 at 1. Throughout his career, Dr. Martinez-Arizala has co-authored or authored various publications on the spinal cord and has been a member of professional organizations. Pet. Ex. 15 at 3-11. Since 2018, he has also served on the editorial board of The Journal of Spinal Cord Medicine. *Id.* at 10.

b. Opinion

Dr. Martinez-Arizala opined “[t]he weight of the evidence implicates the [flu] vaccine [Petitioner] was administered on [October 4, 2015] as triggering the optic neuritis and associated [NMO].” Pet. Ex. 14 at 5.

i. Althen Prong One

Dr. Martinez-Arizala opined the flu vaccine can cause optic neuritis and NMO via molecular mimicry. Pet. Ex. 14 at 4-6.

²¹ Dr. Martinez-Arizala provided one expert report. Pet. Ex. 14.

“Molecular mimicry i.e. the molecular similarity between the proteins of the viruses used for the vaccination and self antigens (for instance, CNS myelin components) [] represents one of the main immunopathogenetic mechanisms in post-vaccination CNS demyelination.” Pet. Ex. 30 at 7. Dr. Martinez-Arizala explained that with molecular mimicry, “components of the vaccine possess sequence similarities between it and specific human proteins that result in the cross-activation of autoreactive T or B cells,” which “causes a reaction of the immune system towards the pathogenic antigens that may harm the similar human proteins, essentially causing autoimmune disease.” Pet. Ex. 14 at 4. Specific to this case, “components of the vaccine resemble myelin in the optic nerve and [CNS] and trigger the inflammatory response that damage[] the optic nerve and cerebral white matter.” *Id.* at 6. He stated components of the flu vaccine in 2014-2015²² contained a protein that was cross-reactive with myelin oligodendrocyte glycoprotein (“MOG”),²³ which he contended is associated with optic neuritis. *Id.* at 4 (citing Pet. Ex. 18; Pet. Ex. 19 at 1 (noting “antibodies against MOG are found in patients with . . . [NMO]”)).²⁴

In his expert report, Dr. Martinez-Arizala discussed a literature review by Karussis and Petrou. Pet. Ex. 14 at 4 (citing Pet. Ex. 30). Karussis and Petrou conducted a PubMed search from 1979 to 2013 and found articles that reported 71 cases of CNS demyelinating diseases following vaccination. Pet. Ex. 30 at 1. Of the 71 cases, 21 were following flu vaccines. *Id.* However, none of the flu vaccination cases resulted in NMO. *Id.* at 4 tbl.2. NMO was the injury in seven of the 71 cases, and most of these cases were following human papillomavirus vaccination. *Id.* at 4-5 tbl.2, 6. In the 21 flu vaccination cases, eight developed optic neuritis and only four of the eight had a documented onset (three weeks, two weeks, 15 days, and two weeks). *Id.* at 4 tbl.2. The authors noted that “[u]sually the symptoms of the CNS demyelinating syndrome appear [a] few days following the immunization (mean: 14.2 days) but there are cases where the clinical presentation was delayed (more than [three] weeks or even up to [five] months post-vaccination) (approximately a third of all the reported cases).” *Id.* at 1. They concluded “[t]here is no absolute way to definitely link the onset or exacerbation of demyelination with the vaccine, but the close temporal association with the time of vaccination strongly argues in favor of such pathogenetic correlation.” *Id.* at 7. They noted the risk of onset or relapse of CNS demyelinating diseases following infections are “substantially higher.” *Id.*

²² For the strains used in 2014-2015 flu vaccination, see Pet. Ex. 17. However, the exact make up of Petitioner’s flu vaccination, or the package insert, was not provided.

²³ MOG “is a myelin protein localized at the surface of myelin sheath and is a potential target of demyelinating diseases,” including CNS demyelinating disorders. Pet. Ex. 28 at 1 (Kimihiko Kaneko et al., CSF Cytokine Profile in MOG-IgG+ Neurological Disease Is Similar to AQP4-IgG+ NMOSD but Distinct from MS: A Cross-Sectional Study and Potential Therapeutic Implications, 89 J. Neurol. Neurosurg. & Psychiatry 927 (2018)). It does not appear Petitioner was tested for MOG.

²⁴ Hideki Nakajima et al., Antibodies to Myelin Oligodendrocyte Glycoprotein in Idiopathic Optic Neuritis, 5 BMJ Open 1 (2015).

Dr. Martinez-Arizala noted the existence of case reports, citing seven articles discussing case reports of optic neuritis post-flu vaccination and one article discussing a case of NMOSD post-flu vaccination. Pet. Ex. 14 at 4 (citing Pet. Exs. 19-25, 39). However, he did not discuss these case reports or their applicability to this case.

He also cited case reports of NMO and other CNS demyelinating disorders following yellow fever, human papillomavirus, hepatitis B, 23-valent pneumococcal polysaccharide, Japanese encephalitis, and rabies vaccinations. Pet. Ex. 14 at 4-5 (citing Pet. Exs. 32-38). Dr. Martinez-Arizala also did not discuss any of these case reports. Nor did he discuss their applicability here or how they relate to the flu vaccine or his proposed theory.

Despite the fact that Dr. Martinez-Arizala did not discuss the case reports, the undersigned finds a brief review of the reports of optic neuritis and NMOSD post-flu vaccination informative.

Kawasaki et al.²⁵ reported two cases of bilateral optic disc edema following flu vaccination. Pet. Ex. 19. Both patients developed vision loss in one eye with eye pain or headache within four weeks of flu vaccination, with involvement of the second eye occurring shortly thereafter. *Id.* at 4. The authors believed “[a]n immune-mediated demyelinating injury of the optic nerve” was “an unlikely mechanism in [their] first patient.” *Id.* Instead, they “speculate[d]” the mechanism at play was an anterior ischemic optic neuropathy due to the temporal relationship to flu vaccination and bilateral involvement in both patients. *Id.*

The next case report is from Bienfang et al.²⁶ Pet. Ex. 20 at 1. Eleven days after H1N1 vaccination, the patient developed myalgias, arthralgias, and fever. *Id.* One week later, the symptoms worsened, and the patient began a course of oral prednisone. *Id.* On the third day of prednisone and about 20 days after vaccination, the patient developed blurred vision and eye pain. *Id.* He was diagnosed with iritis²⁷ in one eye and optic neuritis in the other eye. *Id.* The authors did not opine to the cause of the optic neuritis. *Id.* They did note that the time course between vaccination and systemic illness “is appropriate for an allergic reaction to injected foreign protein.” *Id.*

²⁵ Aki Kawasaki et al., Bilateral Anterior Ischemic Optic Neuropathy Following Influenza Vaccination, 18 J. Neuro-Ophthalmol. 56 (1998).

²⁶ Don C. Bienfang et al., Ocular Abnormalities After Influenza Immunization, 95 Arch. Ophthalmol. 1649 (1977).

²⁷ Iritis is “inflammation of the iris, usually marked by pain, congestion in the ciliary region, photophobia, contraction of the pupil, and discoloration of the iris.” Iritis, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=26154> (last visited Oct. 31, 2025).

Perry et al.²⁸ reported a case of bilateral optic neuritis that occurred in a patient 20 days following a flu vaccination and six days following a flu vaccination booster. Pet. Ex. 21 at 1. The authors noted the temporal relationship with vaccination but did not opine the bilateral optic neuritis was caused by flu vaccination. Id. at 5.

Similarly, Ray and Dreizin²⁹ reported a case of bilateral optic neuritis three weeks post-flu vaccination. Pet. Ex. 22 at 1. The authors ruled out various causes and concluded “[t]his case supports [flu] vaccine as a cause of optic neuropathy,” relying on the similar onset periods described in the Perry et al. and Bienfang et al. case reports. Id. at 3 (citing Pet. Exs. 20-21).

Cangemi and Bergen³⁰ documented a case of acute optic neuritis two weeks after swine flu vaccination. Pet. Ex. 23 at 1. They authors concluded the temporal relationship “may very well indicate a causal relationship. . . . However, we must emphasize that this is speculative.” Id. at 3.

Macoul³¹ described a case of bilateral optic nerve atrophy two to three weeks following swine flu vaccination. Pet. Ex. 24 at 1. Macoul opined that this three-week interval “correlates well with the period of viral replication” and concluded “[i]t is most probable” that the swine flu vaccine was causal. Id.

Lastly, Hull and Bates³² documented a case of bilateral optic neuritis in one patient on two consecutive occasions, both two weeks after flu vaccination. Pet. Ex. 25 at 2. The authors concluded “[their] case provides compelling clinical evidence that implicates [flu] vaccination as a cause of optic neuritis.” Id. The authors noted the cause of post-vaccination neuropathies are not known, acknowledged that molecular mimicry has been suggested, but found that theory “unlikely.” Id.

²⁸ Henry D. Perry et al., Reversible Blindness in Optic Neuritis Associated with Influenza Vaccination, 11 *Annals Ophthalmol.* 545 (1979).

²⁹ Cheryl L. Ray & Ivy J. Dreizin, Bilateral Optic Neuropathy Associated with Influenza Vaccination, 16 *J. Neuro-Ophthalmol.* 182 (1996).

³⁰ Francis E. Cangemi & Robert L. Bergen, Optic Atrophy Following Swine Flu Vaccination, 12 *Annals Ophthalmol.* 857 (1980).

³¹ Kenneth L. Macoul, Bilateral Optic Nerve Atrophy and Blindness Following Swine Influenza Vaccination, 14 *Annals Ophthalmol.* 398 (1982).

³² Thomas P. Hull & James H. Bates, Optic Neuritis After Influenza Vaccination, 124 *Am. J. Ophthalmol.* 703 (1997).

And for NMOSD post-flu vaccination, Dr. Martinez-Arizala cited Cho et al.,³³ who documented a case of longitudinally extensive transverse myelitis, later diagnosed as NMOSD following positive anti-AQP4 antibodies, that occurred three days after flu vaccination. Pet. Ex. 39 at 1. The patient had previously received the flu vaccine annually for years without side effects. Id. Two months prior to admission, the patient gave birth. Id. This patient did not develop optic neuritis. Id. at 1-3. The authors acknowledged that “the precise etiology and pathogenesis of NMOSD have not yet been established.” Id. at 3. Infections have been suggested as a trigger because 30% of NMOSD patients report an infection before the onset of neurological symptoms. Id. The authors also noted molecular mimicry has been suggested as a mechanism. Id. The authors did not opine the vaccine in the reported case was causal, noting “it is difficult to determine whether the relationship between vaccination and autoimmune disease is causal or coincidental.” Id.

ii. Althen Prongs Two and Three

Dr. Martinez-Arizala opined there is a logical sequence of cause and effect because Petitioner’s “[flu] vaccine contains components that triggered the optic neuritis” and “[t]he onset of her neurological symptoms was well within the time boundaries of the vaccine administration.” Pet. Ex. 14 at 5-6.

First, Dr. Martinez-Arizala did not explain how his theory, which relied upon the existence of MOG, applied here, when it appears Petitioner was not tested for MOG antibodies.

Second, regarding an alternative cause, he noted Petitioner had no evidence of optic neuritis prior to vaccination. Pet. Ex. 14 at 5. Dr. Martinez-Arizala also opined Petitioner had no other illness or infection that could have triggered her optic neuritis and NMO. Id.

Next, as to whether Petitioner’s course was consistent with vaccine causation, this turns on when Petitioner’s neurological symptoms of NMO began. Dr. Martinez-Arizala did not explain what he meant by “neurological symptoms.” However, he consistently cited records describing Petitioner’s reports of lower extremity paresthesias and zapping sensations. Thus, it appears the “neurological symptoms” he discusses and relies upon in regard to prongs two and three are Petitioner’s lower extremity paresthesias and burning/zapping sensations, and not her visual symptoms.

Dr. Martinez-Arizala provided conflicting opinions for onset of lower extremity paresthesias and zapping sensations. He opined Petitioner’s “contemporaneous medical records are consistent in pinning the start of her neurological symptoms about 4-8 weeks after vaccination.” Pet. Ex. 14 at 2, 5. Then, on the following page of his report, Dr. Martinez-Arizala concluded that “[t]he vaccination was administered on [October 4, 2015] and the onset of the neurological symptoms occurred approximately 8-12 weeks [after,] which is clearly within the expected time period reported in the published medical literature.” Id. at 6.

³³ Jeong Hee Cho et al., A Case of Neuromyelitis Optic Spectrum Disorder Following Seasonal Influenza Vaccination, 30 *Mult. Scler. & Relat. Disord.* 110 (2019).

To support his opinions as to onset, Dr. Martinez-Arizala cited to three of Petitioner's medical records. Pet. Ex. 14 at 2, 5. First, he cited to Petitioner's records from her first hospitalization on April 3, 2016, in which he maintained Petitioner's "neurological symptoms started shortly after receiving the vaccination." *Id.* at 5. However, as Dr. Martinez-Arizala acknowledged, the records from this hospitalization document Petitioner complained of bilateral foot paresthesias for two months, which would place onset approximately February 3, 2016, four months post-vaccination, not "shortly after" vaccination. *Id.* at 2, 5; *see* Pet. Ex. 2 at 15-16.

Dr. Martinez-Arizala also cited to records from Dr. Fayyaz and contended they also document Petitioner's "neurological symptoms started shortly after receiving the vaccination." Pet. Ex. 14 at 5. As he noted, however, Petitioner first saw Dr. Fayyaz on April 21, 2016 and reported intermittent tingling in her legs and "a shooting sensation going down her back" that began "around Christmas time of 2015." Pet. Ex. 3 at 21; *see also* Pet. Ex. 14 at 2. This would place onset around 11 to 12 weeks post-vaccination, not "shortly after" vaccination. *See* Pet. Ex. 14 at 2, 5.

And third, Dr. Martinez-Arizala cited to a record from Dr. Bhise, dated August 29, 2017, almost two-years post vaccination, that documented Petitioner reported her symptoms "[beginning] in October 2015 following a flu shot." Pet. Ex. 14 at 2, 5 (quoting Pet. Ex. 9 at 23). This would place onset the same month as Petitioner's flu vaccination. He opined "this clearly establishes that the onset of neurological symptoms preceded her optic neuritis and occurred approximately 4-8 weeks following the vaccination." *Id.* at 2.

Lastly, the cited case reports of optic neuritis following flu vaccination report an onset range of three days up to four weeks after vaccination. Kawasaki et al. reported two cases of bilateral optic disc edema within four weeks of flu vaccination. Pet. Ex. 19 at 4. Bienfang et al. and Perry et al. discussed patients who developed bilateral optic neuritis approximately 20 days post flu-vaccination. Pet. Ex. 20 at 1; Pet. Ex. 21 at 1. Ray and Dreizin reported a case of bilateral optic neuritis three weeks post-flu vaccination. Pet. Ex. 22 at 1. Cangemi and Bergen documented a case of acute optic neuritis two weeks after swine flu vaccination. Pet. Ex. 23 at 1. Macoul described a case of bilateral optic nerve atrophy two to three weeks following swine flu vaccination. Pet. Ex. 24 at 1. Hull and Bates discussed a patient who developed bilateral optic neuritis twice, both two weeks following flu vaccinations in consecutive years. Pet. Ex. 25 at 2.

And Cho et al. discussed a patient who received a flu vaccination, and three days later developed longitudinally extensive transverse myelitis, later confirmed as NMOSD. Pet. Ex. 39 at 1.

2. Petitioner's Expert, Dr. David M. Yousem³⁴

a. Background and Qualifications

Dr. Yousem is a board-certified radiologist with a subspecialty certification in neuroradiology. Pet. Ex. 54 at 1. After receiving his M.S. from University of Michigan, he

³⁴ Dr. Yousem provided one expert report. Pet. Ex. 54.

completed a diagnostic radiology residency at The Johns Hopkins Hospital, a general radiology/neuroradiology fellowship at The Johns Hopkins Hospital, and a neuroradiology fellowship at the Hospital of the University of Pennsylvania. Pet. Ex. 55 at 1. He has held positions at Johns Hopkins and University of Pennsylvania since 1990. Id. He has authored or co-authored almost 400 publications, he has held appointments on editorials and journals, he has been a member of numerous societies, and he has won various awards and honors throughout his career. Id. at 1-21, 29-34.

Dr. Yousem was retained to examine Petitioner's MRI studies. Pet. Ex. 54 at 1. He offered no opinions about vaccine causation. Id. at 5.

b. Opinion

Dr. Yousem opined Petitioner "had active left optic neuritis" seen on her April 3, 2016 brain MRI and "may have had additional flares" as demonstrated by her MRIs on October 5, 2016 and November 27, 2017. Pet. Ex. 54 at 5.

Petitioner's first brain MRI was conducted on April 3, 2016. Pet. Ex. 54 at 2; see Pet. Ex. 2 at 154-55. Dr. Yousem opined that the MRI "show[ed] non-specific periventricular and juxtacortical white matter lesions bilaterally that do not enhance and do not show restricted diffusion." Pet. Ex. 54 at 2. He explained these are not normal findings for an individual of Petitioner's age (44). Id. Because there was no evidence of enhancement, he opined that the lesions seen "[were] not active or recent in age" and "[were] more likely than not greater than days to [two] weeks old." Id.

Secondly, he opined that the April 3, 2016 MRI images of her orbits showed enhancement of the left optic nerve, meaning Petitioner "had active left optic neuritis" on April 3, 2016. Pet. Ex. 54 at 3, 5.

Petitioner's next brain MRI, done June 2016, showed the left optic nerve was no longer enhancing and was otherwise unchanged. Pet. Ex. 54 at 3.

Additionally, Petitioner's next brain MRI in October 2016 was stable. Pet. Ex. 54 at 3. Dr. Yousem noted the left optic nerve was "slightly brighter" and "smaller" than the right optic nerve in this study, which he opined "could be [evidence of] faint enhancement on the left." Id. However, because there was no orbital study to clearly identify these findings, Dr. Yousem explained he would need clinician confirmation of visual complaints at this time to determine whether Petitioner was having active disease. Id. at 3-4.

The next brain MRI from December 2016, according to Dr. Yousem, was stable with no new abnormalities or enhancement. Pet. Ex. 54 at 4.

With regard to the November 2017 brain MRI, Dr. Yousem had concerns about Petitioner's left optic nerve on one image. Pet. Ex. 54 at 4. Again, he noted orbital views were not performed and thus, he would need clinical confirmation. Id.

In January 2018, an orbital MRI examination was conducted and showed no enhancement of the left optic nerve. Pet. Ex. 54 at 4.

He also reviewed Petitioner's cervical, thoracic, and lumbar spine MRIs from 2016 to 2020 and noted no areas of demyelination were seen. Pet. Ex. 54 at 5.

Dr. Yousem concluded Petitioner "had active left optic neuritis" on April 3, 2016, as depicted by her MRI. Pet. Ex. 54 at 5. Dr. Yousem did not offer an opinion as to the onset of Petitioner's optic neuritis or NMO. See id. at 1-5.

3. Respondent's Expert, Dr. Subramaniam Sriram³⁵

a. Background and Qualifications

Dr. Sriram currently works as a Professor of Neurology and Microbiology Immunology and Director of the MS Clinic at Vanderbilt Medical Center. Resp. Ex. A at 1. He received his M.B. and B.S. from University of Madras in India in 1973. Resp. Ex. B at 1. Thereafter, he was an intern and internal medicine resident at Wayne State University in Michigan, as well as a neurology resident, chief neurology resident, and post-doctoral fellow in neuroimmunology at Stanford University. Id. Dr. Sriram is board certified in internal medicine and psychiatry and neurology, and is licensed to practice in California, Vermont, and Tennessee. Id. He has authored or co-authored over 150 publications. Id. at 9-22. "[He] follow[s] approximately 50 patients with [NMO]" and is "a recognized expert in the field of Neuroimmunology and MS." Resp. Ex. A at 1.

b. Opinion

Dr. Sriram opined "to a reasonable degree of medical certainty that the development of NMO in [Petitioner] was not caused by the receipt of the flu vaccine on October 4, 2015." Resp. Ex. A at 7; see also Resp. Ex. C at 5.

i. Althen Prong One

Dr. Sriram did not discuss or address Petitioner's theory of molecular mimicry in detail. See Resp. Exs. A, C. In response to Dr. Martinez-Arizala's opinions about MOG and its relevance here, Dr. Sriram opined that MOG is not the antigen known to cause NMO. Resp. Ex. A at 7. He further opined there is no known cross-reactivity between the flu vaccine and AQP4, the autoantigen that causes NMO. Id.

Dr. Sriram responded to the medical literature discussed in Dr. Martinez-Arizala's expert report.³⁶ Resp. Ex. A at 7. As to the paper authored by Karussis and Petrou, Dr. Sriram noted

³⁵ Dr. Sriram provided two expert reports. Resp. Exs. A, C.

³⁶ One article from Mealy et al. was mentioned in Dr. Martinez-Arizala's expert report but was not cited or otherwise filed by Petitioner.

the authors did not identify any cases of NMO following the flu vaccine. *Id.* (citing Pet. Ex. 30 at 4 tbl.2).

ii. Althen Prongs Two and Three

Dr. Sriram opined the flu vaccination administered on October 4, 2015 did not cause Petitioner’s NMO. Resp. Ex. A at 5-7. He opined the cause of Petitioner’s optic neuritis was well identified—AQP4 antibodies. Resp. Ex. C at 2.

He explained that “loss of myelin is the dominant feature of NMO,” but with AQP4, “the destruction of myelin is indirect since the [AQP4] antibodies are present on another CNS cell type, the astrocytes.”³⁷ Resp. Ex. A at 4. More specifically, “[b]inding by antibodies to [AQP4] antigens leads to the fixation of complement proteins on astrocytes leading to loss of astrocytes. Since astrocytes are necessary for the functioning of the oligodendrocytes, loss of myelin is therefore the result of collateral damage done to the astrocytes by the [AQP4] antibodies.” *Id.*

Regarding the onset of Petitioner’s NMO, Dr. Sriram looked to “[t]he cardinal feature of the neurologic deficit, optic neuritis associated with inflammation of the optic nerve seen on subsequent neuroimages,” which was around April 4, 2016. Resp. Ex. C at 4. He opined that Petitioner’s earlier neurologic complaints (i.e., paresthesias) were not attributable to her NMO. *Id.* at 4-5; Resp. Ex. A at 6.

With regard to the foot paresthesias and “zapping” sensation Petitioner described, Dr. Sriram opined these symptoms were not consistent with NMO. Resp. Ex. A at 4-6; Resp. Ex. C at 4. Dr. Sriram agreed NMO can cause lesions in the spinal cord, which could lead to the neurological symptoms described by Petitioner. Resp. Ex. A at 6. However, Petitioner had numerous MRIs of her entire spine and each was normal. *Id.* Petitioner’s expert, Dr. Yousem agreed there was a lack of any evidence of spinal cord inflammation. Resp. Ex. C at 4 (citing Pet. Ex. 54 at 5). Further, no contemporaneous medical records document that Petitioner experienced “neurologic deficits between the receipt of the vaccine and the development of optic neuritis.” *Id.* at 4-5. Dr. Sriram opined this lack of clinical evidence does not support spinal cord involvement related to NMO which could explain Petitioner’s complaints of paresthesias or “zapping” sensations. Resp. Ex. A at 6.

Dr. Sriram next noted that “[e]ven if we assume[d] that her lower extremity paresthesias was the earliest evidence of NMO, . . . the historical record is inconsistent with the onset of her paresthesias of her legs.” Resp. Ex. A at 6. Dr. Sriram cited to the same three medical records as Dr. Martinez-Arizala and noted these records document Petitioner reporting three different dates for onset of her lower extremity paresthesias. *Id.* First, during her April 2016 hospitalization, Petitioner reported two months of neurological symptoms (bilateral foot paresthesias), placing onset in February 2016, four months after vaccination. *Id.* Then, at her

³⁷ An astrocyte is “a neuroglial cell of ectodermal origin, characterized by fibrous, protoplasmic, or plasmatofibrous processes.” *Astrocyte*, Dorland’s Med. Dictionary Online, <https://www.dorlandsonline.com/dorland/definition?id=4587> (last visited Oct. 31, 2025).

first visit to Dr. Fayyaz, later in April 2016, Petitioner reported her symptoms began around Christmas of 2015, which is 11 to 12 weeks post-vaccination. Id. Lastly, Dr. Bhise's records from August 2017 described Petitioner's neurological symptoms as beginning in October 2015. Id. Overall, he concluded "[t]here is [] a wide discrepancy on the date of onset of [these] symptoms" in her medical records. Id.

Even if onset was in October 2015, the earliest date mentioned in her medical records, though not the date of onset identified in her most contemporaneous medical records, Dr. Sriram maintained this "does not establish that the symptoms she had were due to the vaccine" as there was a "normal MRI of the spine and lack of clinical evidence of myelitis." Resp. Ex. A at 6. Furthermore, there was no medical record evidence between vaccination (October 2015) and the development of optic neuritis (April 2016) documenting Petitioner's neurologic deficits. Resp. Ex. C at 4-5.

As stated earlier, Dr. Sriram explained Petitioner did not have signs or symptoms of optic neuritis until April 2016, six months after vaccination. Resp. Ex. A at 5. He maintained there is no indication in Petitioner's medical records that she suffered symptoms of optic neuritis prior to then. Id. This time interval of six months "is much longer than what would be considered a causal connection for a logical sequence of cause and effect," making "a causal connection" between vaccination and NMO unlikely. Id. at 5-6.

Dr. Sriram agreed with Dr. Yousem that Petitioner's April 2016 brain MRI showed enhancement (active inflammation) of the left optic nerve. Resp. Ex. C at 3. Dr. Sriram opined it was "unlikely" that this inflammation was present for months prior to Petitioner's onset of visual symptoms. Id. at 4. Thus, he opined Petitioner's April 2016 brain MRI abnormality seen in the optic nerve "occurred hand-in-hand with the clinical symptoms of decreased vision." Id. Petitioner first complained of issues with her vision on March 29, 2016, when she had floaters in her left eye, and a few days later, she presented to the ED for a one-day history of left eye "curtain" and flashes. Resp. Ex. A at 2 (citing Pet. Ex. 2 at 15; Pet. Ex. 8 at 1).

Regarding Petitioner's Lhermitte's-like symptoms, Dr. Sriram opined these symptoms can be seen in both NMO and vitamin B₁₂ deficiency. Resp. Ex. A at 4-6; Resp. Ex. C at 4. Spinal cord demyelination seen in NMO can result in symptoms consistent with Lhermitte's sign. Resp. Ex. A, Tab 2 at 2. However, Petitioner had no evidence of demyelination seen on spinal cord MRI, and thus, Dr. Sriram opined that Petitioner's vitamin B₁₂ deficiency can cause Lhermitte's-like symptoms, including tingling of the feet and the "zapping" sensation described by Petitioner. Resp. Ex. A at 4-6; Resp. Ex. C at 4; see Resp. Ex. A, Tabs 3-4. He explained that severe cases of vitamin B₁₂ deficiency can cause neurological abnormalities, including "[n]umbness, tingling of extremities, weakness[,] and sometimes electric shock like sensations of the back due to spinal cord involvement." Resp. Ex. A at 4-5 (citing Resp. Ex. A, Tabs 3-4). And these "clinical symptoms of B₁₂ deficiency [] match the symptoms that [Petitioner] described in her spine and extremities." Id. at 5.

III. DISCUSSION

A. Standards for Adjudication

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 10(a). “Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award ‘vaccine-injured persons quickly, easily, and with certainty and generosity.’” Rooks v. Sec’y of Health & Hum. Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner’s burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. Moberly v. Sec’y of Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec’y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). Petitioner need not make a specific type of evidentiary showing, i.e., “epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect.” Capizzano v. Sec’y of Health & Hum. Servs., 440 F.3d 1317, 1325 (Fed. Cir. 2006). Instead, Petitioner may satisfy her burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

In particular, Petitioner must prove that the vaccine was “not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury.” Moberly, 592 F.3d at 1321 (quoting Shyface v. Sec’y of Health & Hum. Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); see also Pafford v. Sec’y of Health & Hum. Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). The received vaccine, however, need not be the predominant cause of the injury. Shyface, 165 F.3d at 1351. A petitioner who satisfies this burden is entitled to compensation unless Respondent can prove, by a preponderance of the evidence, that the vaccinee’s injury is “due to factors unrelated to the administration of the vaccine.” § 13(a)(1)(B). However, if a petitioner fails to establish a prima facie case, the burden does not shift. Bradley v. Sec’y of Health & Hum. Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

“Regardless of whether the burden ever shifts to the [R]espondent, the special master may consider the evidence presented by the [R]espondent in determining whether the [P]etitioner has established a prima facie case.” Flores v. Sec’y of Health & Hum. Servs., 115 Fed. Cl. 157, 162-63 (2014); see also Stone v. Sec’y of Health & Hum. Servs., 676 F.3d 1373, 1379 (Fed. Cir. 2012) (“[E]vidence 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.”); de Bazan v. Sec’y of Health & Hum. Servs., 539 F.3d 1347, 1353 (Fed. Cir. 2008) (“The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the [P]etitioner’s evidence on a requisite element of the [P]etitioner’s case-in-chief.”); Pafford, 451 F.3d at 1358-59 (“[T]he presence of multiple potential causative agents makes it difficult to attribute ‘but for’ causation to the vaccination. . . . [T]he Special Master properly introduced the presence of the other unrelated contemporaneous events as just as likely to have been the triggering event as the vaccinations.”).

B. Factual Issues

A petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding her claim. § 13(a)(1)(A). To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See Burns v. Sec’y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records, “in general, warrant consideration as trustworthy evidence.” Cucuras v. Sec’y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). But see Kirby v. Sec’y of Health & Hum. Servs., 997 F.3d 1378, 1382 (Fed. Cir. 2021) (rejecting the presumption that “medical records are accurate and complete as to all the patient’s physical conditions”); Shapiro v. Sec’y of Health & Hum. Servs., 101 Fed. Cl. 532, 538 (2011) (“[T]he absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance.” (quoting Murphy v. Sec’y of Health & Hum. Servs., 23 Cl. Ct. 726, 733 (1991), aff’d per curiam, 968 F.2d 1226 (Fed. Cir. 1992))), recons. den’d after remand, 105 Fed. Cl. 353 (2012), aff’d mem., 503 F. App’x 952 (Fed. Cir. 2013).

There are situations in which compelling testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. Campbell v. Sec’y of Health & Hum. Servs., 69 Fed. Cl. 775, 779 (2006) (“[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking.”); Lowrie v. Sec’y of Health & Hum. Servs., No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) (“[W]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent.” (quoting Murphy, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness’s credibility is needed when determining the weight that such testimony should be afforded. Andreu v. Sec’y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley, 991 F.2d at 1575.

Despite the weight afforded to medical records, special masters are not rigidly bound by those records in determining onset of a petitioner’s symptoms. Valenzuela v. Sec’y of Health & Hum. Servs., No. 90-1002V, 1991 WL 182241, at *3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); see also Eng v. Sec’y of Health & Hum. Servs., No. 90-1754V, 1994 WL 67704, at *3 (Fed. Cl. Spec. Mstr. Feb. 18, 1994) (noting Section 13(b)(2) “must be construed so as to give effect also to § 13(b)(1) which directs the special master or court to consider the medical records (reports, diagnosis, conclusions, medical judgment, test reports, etc.), but does not require the special master or court to be bound by them”).

C. Causation

To receive compensation through the Program, Petitioner must prove either (1) that she suffered a “Table Injury”—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that she received, or (2) that she suffered an injury that was actually caused by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); Capizzano, 440 F.3d at 1319-20. 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.” Moberly, 592 F.3d at 1321 (quoting Shyface, 165 F.3d at 1352-53).

Because Petitioner does not allege she suffered a Table Injury, she must prove a vaccine she received caused her injury. To do so, Petitioner must establish, by preponderant evidence: “(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, 418 F.3d at 1278.

The causation theory must relate to the injury alleged. Petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be “legally probable, not medically or scientifically certain.” Knudsen v. Sec’y of Health & Hum. Servs., 35 F.3d. 543, 548-49 (Fed. Cir. 1994). Petitioner cannot establish entitlement to compensation based solely on her assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In determining whether a petitioner is entitled to compensation, the special master shall consider all material in the record, including “any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation.” § 13(b)(1)(A). The undersigned must weigh the submitted evidence and the testimony of the parties’ proffered experts and rule in Petitioner’s favor when the evidence weighs in her favor. See Moberly, 592 F.3d at 1325-26 (“Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence.”); Althen, 418 F.3d at 1280 (noting that “close calls” are resolved in Petitioner’s favor).

Testimony that merely expresses the possibility—not the probability—is insufficient, by itself, to substantiate a claim that such an injury occurred. See Waterman v. Sec’y of Health & Hum. Servs., 123 Fed. Cl. 564, 573-74 (2015) (denying Petitioner’s motion for review and noting that a possible causal link was not sufficient to meet the preponderance standard). The Federal Circuit has made clear that the mere possibility of a link between a vaccination and a petitioner’s injury is not sufficient to satisfy the preponderance standard. Moberly, 592 F.3d at 1322 (emphasizing that “proof of a ‘plausible’ or ‘possible’ causal link between the vaccine and the injury” does not equate to proof of causation by a preponderance of the evidence); Boatmon v. Sec’y of Health & Hum. Servs., 941 F.3d 1351, 1359-60 (Fed. Cir. 2019). While certainty is by no means required, a possible mechanism does not rise to the level of preponderance. Moberly, 592 F.3d at 1322; see also de Bazan, 539 F.3d at 1351.

IV. ONSET ANALYSIS

Here, the parties disagree as to Petitioner’s onset of NMO. For the following reasons, the undersigned finds onset was April 2, 2016.

Petitioner reported two different neurologically related signs and symptoms. The first set of symptoms related to her lower extremity paresthesias and “zapping”-like sensations. The second set of symptoms related to vision in her left eye.

Regarding the symptoms related to paresthesias and “zapping” sensations, Petitioner offered four conflicting reports. The first contemporaneous medical record evidence is dated April 3, 2016, when Petitioner reported two months of lower extremity paresthesias, placing onset in February 2016, four months after vaccination. Pet. Ex. 2 at 15-16. Later that month, on April 21, Petitioner reported intermittent tingling in her legs and “a shooting sensation going down her back” that began “around Christmas time of 2015,” which is an onset of 11 to 12 weeks after vaccination. Pet. Ex. 3 at 21. Moving forward to August 29, 2017, Petitioner reported her zapping and burning symptoms “began in October 2015 following a flu shot,” which would place onset within 30 days of vaccination. Pet. Ex. 9 at 23. Seven years later, in December 2024, Petitioner executed a declaration reporting her burning/zapping symptoms began around Thanksgiving 2015 (November 26, 2015), approximately seven to eight weeks after vaccination. Pet. Ex. 56 at ¶ 5.

Petitioner’s declaration, placing onset of her burning/zapping sensations around Thanksgiving 2015, was not documented in any medical record. Moreover, Petitioner’s declaration was executed more than nine years after vaccination and after this case was filed. See, e.g., Zumwalt v. Sec’y of Health & Hum. Servs., No. 16-994V, 2019 WL 1953739, at *19 (Fed. Cl. Spec. Mstr. Mar. 21, 2019) (rejecting opinion from a treating provider when he presented an opinion two-and-one-half years after treatment and after litigation was initiated), mot. for rev. den’d, 146 Fed. Cl. 525 (2019).

Further, the declaration is inconsistent with the contemporaneous medical records, and thus, the undersigned finds it reasonable to give greater weight to the contemporaneous medical records. See Cucuras, 993 F.2d at 1528 (noting that “the Supreme Court counsels that oral testimony in conflict with contemporaneous documentary evidence deserves little weight”); Doe/70 v. Sec’y of Health & Hum. Servs., 95 Fed. Cl. 598, 608 (2010); Stevens v. Sec’y of Health & Hum. Servs., No. 90-221V, 1990 WL 608693, at *3 (Cl. Ct. Spec. Mstr. Dec. 21, 1990) (noting that “clear, cogent, and consistent testimony can overcome such missing or contradictory medical records”); Vergara ex rel. J.A.V. v. Sec’y of Health & Hum. Servs., No. 08-882V, 2014 WL 2795491, at *4 (Fed. Cl. Spec. Mstr. May 15, 2014) (“Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recorded in later medical histories, affidavits, or trial testimony.”); Campbell, 69 Fed. Cl. at 779 (“It is, of course, true that where later testimony conflicts with earlier contemporaneous documents, courts generally give the contemporaneous documentation more weight.”); Ricci v. Sec’y of Health & Hum. Servs., 101 Fed. Cl. 385, 391 (2011) (“Medical records from years later, merely chronicling a timeline between vaccination and injury, are not worthy of the same consideration as contemporaneous records.”).

Moreover, the differing time periods reported by Petitioner for the onset of her paresthesias and “zapping” sensations renders her reports less persuasive. In medical records from April 2016, which are the most contemporaneous records, Petitioner reports her lower extremity paresthesias and “zapping” sensations began two months prior (February 2016) and around Christmas 2015. Over a year later, in August 2017, Petitioner reported her symptoms dating back to vaccination. Yet, no medical records document these symptoms between October 2015 and February 2016. Therefore, the undersigned finds Petitioner’s statements less

persuasive. See Cucuras, 993 F.2d at 1528 (noting that “the Supreme Court counsels that oral testimony in conflict with contemporaneous documentary evidence deserves little weight”).

The experts disagree as to whether Petitioner’s paresthesias and “zapping” sensations were the first manifestations of her NMO.

Petitioner’s expert, Dr. Martinez-Arizala, relates the onset of Petitioner’s NMO to her reports of paresthesias and burning/zapping sensations. As described above, Dr. Martinez-Arizala relies upon medical records in April 2016 and August 2017 referring to onset of lower extremity paresthesias in October 2015, around Christmas 2015, and in February 2016. See Pet. Ex. 14 at 2, 5. His inconsistency renders his opinion less persuasive.

Respondent’s expert, Dr. Sriram, opines that Petitioner’s lower extremity paresthesias and zapping sensations were not due to her NMO. He bases his opinion on the fact that Petitioner’s spinal cord MRIs do not show abnormalities that would explain symptoms of paresthesias or abnormal zapping sensations. Additionally, because of this lack of spinal cord evidence, such symptoms are not consistent with NMO. Lastly, he opines that Petitioner’s lower extremity paresthesias were caused by her vitamin B₁₂ deficiency and cited supportive medical literature discussing Lhermitte’s-like symptoms, including tingling of the feet and the “zapping” sensation, is seen in patients with vitamin B₁₂ deficiency. See Resp. Ex. A, Tabs 3-4

The undersigned finds Dr. Sriram’s opinions about the significance of Petitioner’s lower extremity paresthesias and abnormal sensations to be persuasive for several reasons.

First, Petitioner’s spinal cord MRIs consistently showed no abnormality that would explain her reports of burning/zapping sensations and paresthesias. Petitioner received numerous spinal cord MRIs from 2016 to 2020 and none showed evidence of inflammation or demyelination. Both parties’ experts, Dr. Yousem and Dr. Sriram, agreed.

Second, Dr. Sriram and Petitioner’s treating physicians related her burning/zapping sensations and paresthesias to her vitamin B₁₂ deficiency. Dr. Fayyaz opined Petitioner’s vitamin B₁₂ deficiency was “a large contributing factor” to her complaints of numbness and tingling. Pet. Ex. 3 at 8. An examination and assessment from PAC Wierman included Petitioner’s vitamin B₁₂ deficiency as “a large contributing factor in her . . . numbness/tingling.” Pet. Ex. 7 at 7.

For these reasons, the undersigned finds that Petitioner’s complaints of leg paresthesias and zapping sensations were not manifestations of her NMO. The undersigned finds that Petitioner’s complaints on April 2, 2016, including the “curtain” over her left eye, were the initial manifestations of her NMO.

Petitioner received her flu vaccine on October 4, 2015. The first neurological abnormality characteristic of NMO documented in her medical records was on April 3, 2016, when she presented to the ED reporting a one-day history of left eye “curtain” and flashes, placing onset on April 2. Pet. Ex. 2 at 15. A brain MRI the following day, April 4, showed

“[l]eft optic neuritis in combination with demyelinating lesions.” *Id.* at 154-55. NMO IgG antibody testing confirmed her diagnosis of NMO.

The undersigned’s finding regarding onset is also supported by expert testimony of Dr. Sriram as discussed above.

Therefore, based on the most contemporaneous medical records, the undersigned finds Petitioner’s onset of NMO occurred April 2, 2016, approximately six months after her October 4, 2015 flu vaccination.

V. CAUSATION ANALYSIS

A. Althen Prong One

Under Althen prong one, Petitioner must set forth a medical theory explaining how the received vaccine could have caused the sustained injury. Andreu, 569 F.3d at 1375; Pafford, 451 F.3d at 1355-56. Petitioner’s theory of causation need not be medically or scientifically certain, but it must be informed by a “sound and reliable” medical or scientific explanation. Boatmon, 941 F.3d at 1359; see also Knudsen, 35 F.3d at 548; Veryzer v. Sec’y of Health & Hum. Servs., 98 Fed. Cl. 214, 223 (2011) (noting that special masters are bound by both § 13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both “relevant” and “reliable”). If Petitioner relies upon a medical opinion to support his theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. See Broekelschen v. Sec’y of Health & Hum. Servs., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (“The special master’s decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories.”); Perreira v. Sec’y of Health & Hum. Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating that an “expert opinion is no better than the soundness of the reasons supporting it” (citing Fehrs v. United States, 620 F.2d 255, 265 (Ct. Cl. 1980))).

The experts do not dispute the theory of molecular mimicry generally, or that it is sound and reliable. However, they dispute whether the flu vaccine specifically can cause NMO via molecular mimicry.

First, the undersigned notes that Petitioner’s onset, April 2, 2016, is not compatible with vaccine causation or with the theory of molecular mimicry. See, e.g., Barone v. Sec’y of Health & Hum. Servs., No. 11-707V, 2014 WL 6834557, at *13 (Fed. Cl. Spec. Mstr. Nov. 12, 2014) (“[S]pecial masters have never gone beyond a two-month (meaning eight week) interval in holding that a vaccination caused a demyelinating illness.”).

The undersigned also notes Petitioner failed to provide evidence to show that components of the flu vaccination “resemble myelin in the optic nerve and [CNS] and trigger the inflammatory response” so as to cause NMO. Pet. Ex. 14 at 6. Simply asserting a causal theory without context or a supportive factual framework based on medical literature, research, or other evidence is insufficient. The causal theory must be specific to Petitioner’s case. Moberly, 592 F.3d at 1322. Merely identifying a mechanism for a disease process without additional evidence

specific to Petitioner’s case is insufficient to preponderantly show causation. See Monzon v. Sec’y of Health & Hum. Servs., No. 17-1055V, 2021 WL 2711289, at *29 (Fed. Cl. Spec. Mstr. June 2, 2021); Baron v. Sec’y of Health & Hum. Servs., No. 14-341V, 2019 WL 2273484, at *17 (Fed. Cl. Spec. Mstr. Mar. 18, 2019); Duncan v. Sec’y of Health & Hum. Servs., No. 16-1367V, 2020 WL 6738228, at *11 (Fed. Cl. Spec. Mstr. Oct. 19, 2020), aff’d, 153 Fed. Cl. 642 (2021); Boatmon, 941 F.3d at 1360; LaLonde v. Sec’y of Health & Hum. Servs., 746 F.3d 1334, 1339 (Fed. Cir. 2014) (citing Moberly, 592 F.3d at 1322); W.C. v. Sec’y of Health & Hum. Servs., 704 F.3d 1352, 1356 (Fed. Cir. 2013).

Further, although molecular mimicry is an accepted scientific mechanism, generally opining that molecular mimicry is a causal theory, without more, is insufficient. See, e.g., Loyd ex rel. C.L. v. Sec’y of Health & Hum. Servs., No. 16-811V, 2021 WL 2708941, at *31 (Fed. Cl. Spec. Mstr. May 20, 2021) (“[T]hrough molecular mimicry is a generally accepted scientific concept, and is frequently invoked in Program cases, the mere mention of it does not constitute satisfaction of the preponderant evidentiary standard. Rather, it must be shown that the mechanism likely does link the vaccine in question to the relevant injury.” (internal citations omitted)); McKown v. Sec’y of Health & Hum. Servs., No. 15-1451V, 2019 WL 4072113, at *50 (Fed. Cl. Spec. Mstr. July 15, 2019) (explaining that “merely chanting the magic words ‘molecular mimicry’ in a Vaccine Act case does not render a causation theory scientifically reliable, absent additional evidence specifically tying the mechanism to the injury and/or vaccine in question” (emphasis omitted)); Sheets v. Sec’y of Health & Hum. Servs., No. 16-1173V, 2019 WL 2296212, at *17 (Fed. Cl. Spec. Mstr. Apr. 30, 2019) (determining Petitioner had not satisfied Althen prong one when he did not relate molecular mimicry “to either the vaccines in question or Petitioner’s own specific condition”).

Moreover, as illustrated by the medical literature, mechanisms other than molecular mimicry have been discussed in association with vaccinations. Bienfang et al. suggested “an allergic reaction to injected foreign protein.” Pet. Ex. 20 at 1. Macoul described viral replication. Pet. Ex. 24 at 1. And Hull and Bates acknowledged the theory of molecular mimicry but opined it was “unlikely.” Pet. Ex. 25 at 2.

Even assuming Petitioner has proven a sound and reliable causal mechanism under Althen prong one, the undersigned finds Petitioner did not provide preponderant evidence of a logical sequence of cause and effect or a proximate temporal relationship between the flu vaccination and Petitioner’s NMO. Due to the facts and circumstances of this case, specifically the fact that Petitioner developed symptoms of NMO months after receipt of a flu vaccine, the undersigned’s determination as to causation turns on an analysis of Althen prongs two and three, and thus, the undersigned focuses on Althen prongs two and three. See Vaughan ex rel. A.H. v. Sec’y of Health & Hum. Servs., 107 Fed. Cl. 212, 221-22 (2012) (finding the special master’s failure to rule on Althen prong one not fatal to his decision because Althen prong two was fatal to Petitioner’s case); Hibbard v. Sec’y of Health & Hum. Servs., 698 F.3d 1355, 1364 (Fed. Cir. 2012) (“discern[ing] no error in the manner in which the special master chose to address the Althen [prongs]” when he focused on Althen prong two after “assuming the medical viability of [the] theory of causation”).

B. Althen Prong Two

Under Althen prong two, Petitioner must prove by a preponderance of the evidence that there is a “logical sequence of cause and effect showing that the vaccination was the reason for the injury.” Capizzano, 440 F.3d at 1324 (quoting Althen, 418 F.3d at 1278). “Petitioner must show that the vaccine was the ‘but for’ cause of the harm . . . or in other words, that the vaccine was the ‘reason for the injury.’” Pafford, 451 F.3d at 1356 (internal citations omitted).

In evaluating whether this prong is satisfied, the opinions and views of the vaccinee’s treating physicians are entitled to some weight. Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326 (“[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a ‘logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.’” (quoting Althen, 418 F.3d at 1280)). Medical records are generally viewed as trustworthy evidence, since they are created contemporaneously with the treatment of the vaccinee. Cucuras, 993 F.2d at 1528. Petitioner need not make a specific type of evidentiary showing, i.e., “epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect.” Capizzano, 440 F.3d at 1325. Instead, Petitioner may satisfy her burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325-26.

The undersigned finds there is not preponderant evidence in the record to support a logical sequence of cause-and-effect showing the October 4, 2015 flu vaccine to be the cause of Petitioner’s NMO. See Althen, 418 F.3d at 1278.

First, Petitioner’s clinical course is not consistent with a vaccine-related condition. Petitioner received the flu vaccine on October 4, 2015. Petitioner did not see a medical provider for almost six months, until March 28, when she complained of an upper respiratory infection. The following day, March 29, she presented to ophthalmology as a walk-in for vitreous floaters in her left eye. And on April 3, 2016, Petitioner presented of the ED, reporting a one-day history of left eye “curtain” and flashes, placing onset on April 2, 2016. Pet. Ex. 2 at 15-16. She was diagnosed with optic neuritis during her hospitalization and later diagnosed with NMO following antibody testing results.

Second, none of Petitioner’s treating physicians offered an opinion associating her NMO with flu vaccination. In cases with such evidence, it can be considered in an analysis of Althen prong two. See Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326 (“[M]edical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a ‘logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.’” (quoting Althen, 418 F.3d at 1280)). Here, there is no such supportive evidence.

Further, to the extent that Petitioner asserts that her neurological symptoms of lower extremity paresthesias and zapping sensations relate to her NMO, there is evidence of an alternative cause—vitamin B₁₂ deficiency—based on the opinions of Petitioner’s treating physicians and Dr. Sriram as well as medical literature.

Dr. Fayyaz opined Petitioner's vitamin B₁₂ deficiency was "a large contributing factor" to her complaints of numbness and tingling. Pet. Ex. 3 at 8. An examination and assessment from PAC Wierman Assessment included Petitioner's vitamin B₁₂ deficiency as "a large contributing factor in her . . . numbness/tingling." Pet. Ex. 7 at 7.

Dr. Sriram explained severe cases of vitamin B₁₂ deficiency can cause neurological abnormalities, including "[n]umbness, tingling of extremities, weakness[,] and sometimes electric shock like sensations of the back due to spinal cord involvement," and these "clinical symptoms of B12 deficiency [] match the symptoms that [Petitioner] described in her spine and extremities." Resp. Ex. A at 4-5. For support, he cited literature confirming a vitamin B₁₂ deficiency can present with neurological manifestations, including Lhermitte's sign. See Resp. Ex. A, Tab 3 at 1; Resp. Ex. A, Tab 4 at 1-2, 3 tbl.2, 5.

Accordingly, the undersigned finds that Petitioner has not satisfied her burden under Althen prong two.

C. Althen Prong Three

Althen prong three requires Petitioner to establish a "proximate temporal relationship" between the vaccination and the injury alleged. Althen, 418 F.3d at 1281. That term has been defined as a "medically acceptable temporal relationship." Id. The Petitioner must offer "preponderant proof that the onset of symptoms occurred within a time frame for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." de Bazan, 539 F.3d at 1352. The explanation for what is a medically acceptable time frame must also be consistent with the theory of how the relevant vaccine can cause the injury alleged (under Althen prong one). Id.; Koehn, 773 F.3d at 1243; Shapiro, 101 Fed. Cl. at 542; see Pafford, 451 F.3d at 1358.

As discussed above, the undersigned finds Petitioner's NMO onset was April 2, 2016, almost six months after her October 4, 2015 flu vaccination.

The undersigned finds this six-month period is not a medically acceptable time frame for the posited theory of molecular mimicry, or for any other proffered theory relevant to a post-vaccination autoimmune illness. Petitioner's experts provided no literature or evidence to suggest a flu vaccine can cause NMO six months following a flu vaccination. In fact, a review

of all optic neuritis and NMO case reports post-flu vaccination provided by Petitioner show onset periods between three days and four weeks.³⁸

Lastly, Vaccine Program cases have found such a long onset interval is not medically appropriate in demyelinating diseases, including CNS diseases, and/or cases where the proffered causal theory is molecular mimicry. See, e.g., Barone, 2014 WL 6834557, at *13 (noting eight weeks/two months is the longest reasonable timeframe for a flu/GBS injury); Corder v. Sec’y of Health & Hum. Servs., No. 08-228V, 2011 WL 2469736, at *27-29 (Fed. Cl. Spec. Mstr. May 31, 2011) (finding petitioner failed to prove that the flu vaccine can cause GBS four months after vaccination); Lopez ex rel. Lopez v. Sec’y of Health & Hum. Servs., No. 14-270V, 2014 WL 2584436, at *1 (Fed. Cl. Spec. Mstr. May 20, 2014) (dismissing a case of Tdap/TM due to a three-month onset and listing cases where a petition in a demyelinating injury case was dismissed for an onset period greater than two months); Doe/29 v. Sec’y of Health & Hum. Servs., No. [Redacted]V, 2009 WL 180078, at *3-4 (Fed. Cl. Spec. Mstr. Jan. 21, 2009) (granting entitlement in an NMO case where the theory was molecular mimicry and onset was either 18 days or two months/eight weeks).

Therefore, the undersigned finds the temporal association is not appropriate given the mechanism of injury. Petitioner has failed to satisfy the third Althen prong.

VI. CONCLUSION

The undersigned extends her sympathy to Petitioner for all that she has suffered. Her Decision, however, cannot be decided based upon sympathy, but rather on the evidence and law.

For the reasons discussed above, the undersigned finds that Petitioner has failed to establish by preponderant evidence that the flu vaccination she received caused her to develop NMO. Therefore, Petitioner is not entitled to compensation and the petition must be dismissed.

In the absence of a timely filed motion for review pursuant to Vaccine Rule 23, the Clerk of Court **SHALL ENTER JUDGMENT** in accordance with this Decision.

³⁸ This also includes the Nakamura et al. article cited by Petitioner’s counsel. See Pet. Ex. 57 (Yoshikazu Nakamura et al., Influenza-Associated Monophasic Neuromyelitis Optica, 50 *Inter. Med.* 1605 (2011)). Nakamura et al. reported a case of NMO post-flu infection. Id. Petitioner’s experts failed to explain the relationship between flu infection and an inactivated flu vaccination. “An expert may ‘extrapolate from existing data,’ and use ‘circumstantial evidence,’ [b]ut the reasons for the extrapolation should be transparent and persuasive.” K.O. v. Sec’y of Health & Hum. Servs., No. 13-472V, 2016 WL 7634491, at *12 (Fed. Cl. Spec. Mstr. July 7, 2016) (internal citations omitted) (first quoting Snyder v. Sec’y of Health & Hum. Servs., 88 Fed. Cl. 706, 743 (2009); and then quoting Althen, 418 F.3d at 1280); see also, e.g., Zikeli v. Sec’y of Health & Hum. Servs., No. 20-564V, 2025 WL 2306208, at *29 (Fed. Cl. Spec. Mstr. July 16, 2025) (finding Petitioner’s expert “failed to explain how data from the live flu virus could be extrapolated to the inactivated flu vaccine at issue.”).

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master