In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: October 22, 2025

MICHAEL WAKILEH,	*	PUBLISHED
Petitioner,	*	No. 21-1136V
v.	*	Special Master Nora Beth Dorsey
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Dismissal; Tetanus, Diphtheria, and Acellular Pertussis ("Tdap") Vaccine; Multiple Sclerosis ("MS"); Significant Aggravation.
Respondent.	*	

Bradley S. Freedberg, Bradley S. Freedberg, P.C., Denver, CO, for Petitioner.
Mark Kim Hellie, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION[1]

On March 30, 2021, Michael Wakileh ("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 a tetanus, diphtheria, and acellular pertussis ("Tdap") vaccination administered on April 25, 2018, significantly aggravated his multiple sclerosis ("MS"). Second Amended ("Am.") Petition at Preamble (ECF No. 89); see also Petition (ECF No. 1); Am. Petition (ECF No. 88). Respondent argued against

[1] Because this Decision contains a reasoned explanation for the action in this case, the undersigned is required 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). **This means the Decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

[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) ("Vaccine Act" or "the Act"). All citations in this Decision to individual sections of the Vaccine Act are to 42 U.S.C.A. § 300aa.

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. 48).

After carefully analyzing and weighing the evidence presented in this case in accordance with the applicable legal standards,[3] the undersigned finds that Petitioner has failed to provide preponderant evidence that his Tdap vaccination significantly aggravated his MS. Thus, Petitioner has failed to satisfy his burden of proof under Loving v. Secretary of Health & Human Services, 86 Fed. Cl. 135, 142-44 (2009). Accordingly, the petition must be dismissed.

I. ISSUES TO BE DECIDED

The parties agree that Petitioner suffers from MS[4] and that Petitioner had MS prior to his Tdap vaccination. Joint Submission, filed Sept. 18, 2024, at 8 (ECF No. 96); Resp. Response to Motion for Ruling on the Record ("Resp. Response"), filed Dec. 4, 2024, at 3 (ECF No. 103).

The parties dispute all six Loving factors. Joint Submission at 8 (citing Loving, 86 Fed. Cl. at 44). Specifically, Respondent disagrees that Petitioner has demonstrated a significant aggravation of his MS; disagrees that Petitioner has provided preponderant evidence that the Tdap vaccine can aggravate MS; and disagrees that Petitioner has provided preponderant evidence of a proximate temporal relationship between his Tdap vaccination and significant aggravation of MS. Resp. Response at 6, 8, 11. Further, Respondent contends that "any aggravation or worsening of Petitioner's MS symptoms is due to his refusal to receive appropriate treatment . . . and the natural progression of his untreated MS." Id. at 10.

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[3] 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.").

[4] MS is a chronic disease of the central nervous system ("CNS") that results in increased impairment and disability over time. See Resp. Exhibit ("Ex.") A, Tab 9 at 2 (Lamiae Grimaldi et al., Vaccines and the Risk of Hospitalization for Multiple Sclerosis Flare-Ups, 80 JAMA Neuro. 1098 (2023)). It is characterized by "monophasic clinical episode[s] with patient-reported symptoms and objective findings reflecting a focal or multifocal inflammatory demyelinating event in the CNS, developing acutely or subacutely, with a duration of at least 24 h[ours], with or without recovery, and in the absence of fever or infection." Resp. Ex. A, Tab 1 at 2 (Alan J. Thompson et al., Diagnosis of Multiple Sclerosis: 2017 Revisions of the McDonald Criteria, 17 Lancet Neuro. 162 (2018)). Diagnosis is made when both dissemination in time ("development or appearance of new CNS lesions over time") and dissemination in space ("development of lesions in distinct anatomical locations within the CNS") are met, and other diagnoses are ruled out. Id. at 2, 7. Objective evidence of lesions on magnetic resonance imaging ("MRI") and oligoclonal bands in the cerebral spinal fluid ("CSF") aid in the diagnosis of MS. Id. at 5.

Additionally, Respondent disputes facts contained in Petitioner's declarations that are not supported by the medical records. Joint Submission at 8.

II. BACKGROUND

A. Procedural History

On March 30, 2021, Petitioner filed a petition and declaration, followed by medical records between April 2021 and December 2022.[5] Petition; Pet. Exs. 1-28. The case was reassigned to the undersigned in December 2022. Notice of Reassignment dated Dec. 20, 2022 (ECF No. 40). Respondent filed his Rule 4(c) report on June 6, 2023, arguing against compensation. Resp. Rept. at 1.

On September 13, 2023, Petitioner filed an expert report from Dr. William L. Conte. Pet. Ex. 31. On February 2, 2024, Respondent filed an expert report from Dr. Harold Moses. Resp. Ex. A. Dr. Conte did not provide a responsive expert report.[6]

The undesigned held a Rule 5 conference on May 16, 2024. Order dated May 16, 2024 (ECF No. 84). She preliminarily found "the evidence insufficient to rule in favor of Petitioner." Id. at 3. The undersigned recommended Petitioner file additional medical records if available. Id.

Petitioner filed a joint status report on June 20, 2024, stating his attempts to "recover additional medical records ha[d] not yielded any results." Joint Status Rept., filed June 20, 2024 (ECF No. 86). Petitioner wished to submit his case for adjudication based on the available record. Id. In July 2024, Petitioner filed an amended petition followed by a second amended petition. Am. Petition; Second Am. Petition; Pet. Status Rept., filed July 30, 2024 (ECF No. 90) (noting the second amended petition clarified that "the injury claimed in this case is . . . [MS,] a type of CNS demyelinating disease").

On September 3, 2024, Petitioner filed a motion for ruling on the record. Pet. Motion for Ruling on the Record ("Pet. Mot."), filed Sept. 3, 2024 (ECF No. 91); Pet. Supporting Brief ("Pet. Br."), filed Sept. 3, 2024 (ECF No. 92). Respondent filed a response and Petitioner filed a reply. Resp. Response; Pet. Reply to Resp. Response ("Pet. Reply"), filed Dec. 16, 2024 (ECF No. 105).

This matter is now ripe for adjudication.

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[5] Petitioner continued to file medical records and declarations throughout litigation.

[6] Petitioner filed a non-expert response to Dr. Moses' report as he was unable to retain Dr. Conte for a responsive expert report. See Pet. Non-Expert Response to Resp. Expert Rept., filed Mar. 25, 2024, at 1 (ECF No. 80).

B. Factual History

1. Stipulated Medical History[7]

The parties agreed to the following stipulated medical history in their Joint Submission. See Joint Submission at 1-8.

a. Pre-Vaccination Medical History

Petitioner's medical records only contain two medical visits before his subject Tdap vaccination. Pet. Ex. 3 at 402; Pet. Ex. 7 at 5, 9-10. On May 13, 2015, Petitioner saw a dermatologist as a new patient. Pet. Ex. 3 at 395. On August 24, 2017, Petitioner sought emergency care for a cough and sore throat. Pet. Ex. 7 at 10. Petitioner was diagnosed with pharyngitis (sore throat) and prescribed amoxicillin and Motrin. Id. at 7, 13.

b. Vaccination and Post-Vaccination Medical History

On April 25, 2018, Petitioner sought emergency care because a cat bit him on his face about two hours earlier. Pet. Ex. 16 at 1. Petitioner's examination showed superficial scratches on his nose without bleeding, swelling, or erythema. Id. at 2. Petitioner was given a Tdap vaccine, an injection of Ceftiaxone (an antibiotic), and prescribed Amoxicillin. Id. at 1. At the time of his vaccination, Petitioner was thirty-three years old. Id.

On May 16, 2018, three weeks after his vaccination, Petitioner sought emergency care for dizziness and gait instability. Pet. Ex. 16 at 3-4. Petitioner related these symptoms to his Tdap vaccination. Id. Petitioner's treater, Brett Larson, P.A., noted that Petitioner stated his symptoms were a "possible side effect from Tdap." Id. at 3. PA Larson also noted that Petitioner's "[symptoms] of dizziness and gait instability occurred [three] days after he was seen [for his cat bite]." Id. Upon examination, Petitioner's deep tendon reflexes and strength were normal.[8] Id. at 4. He had a positive Romberg's sign[9] and diminished pinprick sensation on the left side of his face. Id. PA Larson diagnosed Petitioner with dizziness, altered gait, and decreased sensation, and referred him for follow up with his primary care physician and a neurologist. Id. at 3. PA Larson also noted that Petitioner's affect and mood were abnormal but did not note any specific behavioral issues. Id.

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[7] While the stipulated medical history is taken from the parties' joint submission, the undersigned has made minor edits for style and added definitions of medical terms where appropriate.

[8] The undersigned notes that the neurological examination also documented intact cranial nerves. Pet. Ex. 16 at 4.

[9] Romberg sign is the "swaying of the body or falling when standing with the feet close together and the eyes closed; the result of loss of joint position sense, seen in . . . diseases affecting the posterior columns." Romberg Sign, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=106448 (last visited Sept. 29, 2025).

That same day, PA Larson's office submitted a Vaccine Adverse Event Reporting System ("VAERS")[10] report. Pet. Ex. 15 at 1. The VAERS form noted that Petitioner "received TDAP vaccine on [April 25, 2018] and returned to facility on [May 16, 2018] with complaints of dizziness, altered gait, [and] decreased sensation but all tests and examination showed no deficits." Id. The box on the VAERS report form indicating that Petitioner had recovered was also checked. Id.

On January 6, 2019, more than eight months after his vaccination and more than seven months after his last medical visit, Petitioner sought emergency care. Pet. Ex. 4 at 9, 12. Petitioner's treating doctor, Thomas Lebby, M.D., noted that Petitioner complained that, for seven months he felt lightheaded, nauseated, and had a "cluttered mind." Id. at 12. Petitioner also claimed that he went to a different hospital several times for these symptoms and was told that there was nothing wrong with him. Id. Dr. Lebby further noted, "feeling bad since cat bite about [eight] months ago, had bite to nose, the same day he went to an [emergency room], had Tdap and Rocephin shots, immediately he felt bad, has been bad since. Dizzy, weak[,] and gradually not able to work." Id. Petitioner reported that his symptoms were constant and severe. Id. He also reported weight loss, headache, and nausea. Id. Petitioner's examination was normal. Id. at 13. Dr. Lebby did not observe any focal neurological deficits. Id. Petitioner had normal coordination, gait, strength, and speech. Id. His blood labs and metabolic panel were normal. Id. at 14-15. Dr. Lebby diagnosed Petitioner with improved dizziness and prescribed Zofran and tramadol. Id. at 15.

On February 20, 2019, Petitioner established care with a new primary care physician, Ahmed Alsadek, M.D. Pet. Ex. 21 at 23. Petitioner reported dizziness, nausea, confusion, blurry vision, and loss of balance since April 2018. Id. Petitioner's neurological exam was negative. Id. Dr. Alsadek ordered additional labs and imaging and referred Petitioner to a cardiologist. Id.

On March 2, 2019, Petitioner sought emergency care from Christopher E. McCoy, M.D., for dizziness and "multiple complaints." Pet. Ex. 3 at 339. Petitioner reported that he fell and hit his head last week. Id. Petitioner also reported that he had seen several other doctors who could not identify the cause of his reported symptoms. Id. Upon examination, Petitioner's cranial nerves were intact, and he displayed 5/5 strength in all extremities. Id. at 340-41. Petitioner's sensation was intact, his finger-to-nose test was negative, and his heel-to-shin test was negative. Id. at 341. Dr. McCoy's assessment was that Petitioner was stable and in no apparent distress. Id. Dr. McCoy discussed the results with Petitioner and informed him "that there was no acute emergency that was found that warranted admission at this time." Id. Petitioner requested medication "for dizziness if it recurs when he gets home." Id.

[10] VAERS, the Vaccine Adverse Event Reporting System, is "a national early warning system to detect possible safety problems in U.S.-licensed vaccines. . . . VAERS is a passive reporting system . . . [and] is not designed to determine if a vaccine caused a health problem, but is especially useful for detecting unusual or unexpected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine." About VAERS, U.S. Dep't of Health & Hum. Servs., https://vaers.hhs.gov/about.html (last visited Oct. 15, 2025).

On March 7, 2019, Petitioner followed up with Dr. Alsadek to review his labs. Pet. Ex. 21 at 22. Petitioner's labs were normal. Id. He refused to let the nurse copy the lab results. Id. Dr. Alsadek noted that Petitioner had horizontal nystagmus.[11] Id. Dr. Alsadek's assessment was benign positional vertigo, paresthesia, normal blood pressure, Guillain-Barré syndrome ("GBS"), and allergic rhinitis. Id. Dr. Alsadek referred Petitioner to a neurologist. Id.

On March 13, 2019, Petitioner sought emergency care from Sangeeta S. Sakaria, M.D., for several ongoing complaints. Pet. Ex. 3 at 252-53. Dr. Sakaria noted that Petitioner complained of ataxia,[12] blurry vision, shortness of breath, exhaustion, fatigue, nausea, vomiting, extremity weakness, and a pins-and-needles sensation in his feet. Id. at 253. Petitioner's examination was mostly normal except for nystagmus, ataxia, and hyperreflexia.[13] Id. at 254. Dr. Sakaria's assessment noted, "33 [year old] [male] [with] no [prior medical history] (chart states GBS but this is just presumed by patient) who presents with ataxia, blurry vision, subjective weakness of extremities, fatigue. On exam[,] patient has significant nystagmus, ataxia and hyperreflexia." Id. Dr. Sakaria's differential included MS, myasthenia gravis, intracerebral hemorrhage, stroke, metabolic derangement, GBS, muscular dystrophy[,] and less likely tertiary syphilis or conversion disorder. Id. Dr. Sakaria ordered several labs and scans. Id. Petitioner's labs were normal except for his urinalysis which had elevated mucous and hemoglobin. Id. at 259-69. Petitioner's chest X-ray and head computed tomography ("CT") (with and without contrast) were normal. Id. at 270, 273-77.

During his emergency room visit, Petitioner also saw neurologist, Genevieve H. Cruz, M.D. Pet. Ex. 3 at 240. Dr. Cruz's neurological exam was normal except for his previously observed nystagmus. Id. at 243. Dr. Cruz also noted that Petitioner had "Hyperactive speech and [was] inattentive. High anxiety and easily startled. Pressured thoughts, easily irritated." Id. at 243. Dr. Cruz further noted that Petitioner had "[e]xaggerative leaning in all directions with fully corrective recovery to upright station. Normal casual gait when patient is not aware of being watched." Id. Dr. Cruz did not think Petitioner had GBS because his reflexes were intact, his proprioception was intact, and there were no other peripheral findings. Id. at 244. Dr. Cruz noted that Petitioner was "able to walk and complete all [activities of daily living]." Id. Her assessment further stated, "[e]xaggerative imbalance on exam without actual loss of balance[,] seemed functional in nature[,] and embellished without any other findings of cerebellar

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[11] Nystagmus is "an involuntary, rapid, rhythmic movement of the eyeball." Nystagmus, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=34565 (last visited Sept. 29, 2025).

[12] Ataxia is "failure of muscular coordination" or "irregularity of muscular action." Ataxia, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=4630 (last visited Oct. 1, 2025).

[13] Hyperreflexia is "dysreflexia characterized by exaggeration of reflexes." Hyperreflexia, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=23992 (last visited Oct. 6, 2025). Dysreflexia is the "disordered response to stimuli." Dysreflexia, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=15288 (last visited Oct. 6, 2025).

pathology." Id. Dr. Cruz recommended an MRI to rule out cerebellar pathology. Id. Petitioner refused to have the MRI because he did not want to have the contrast. Id. at 251. Petitioner's record specifically stated, "You have been seen and evaluated by a neurologist, it was recommended you have an MRI with contrast however you did not complete the work up in the emergency department. You are leaving against medical advice." Id. at 305.

On March 15, 2019, Petitioner saw Dr. Alsadek and requested referrals to several specialists including ears, nose, and throat ("ENT"), ophthalmology, and cardiology. Pet. Ex. 21 at 21.

On April 11, 2019, Petitioner saw neurologist, Manisha K. Korb, M.D at University of California, Irvine ("UCI") Health. Pet. Ex. 3 at 221. Upon examination, Petitioner's sensation, coordination, strength, and deep tendon reflexes were all normal. Id. at 224. Dr. Korb noted Petitioner's right eye nystagmus. Id. Dr. Korb also noted, "[p]rominent functional gait with intentional falls." Id. He had a normal station and base and was able to tiptoe, heel walk, and stand and hop on one foot without any difficulty. Id. The neurologist recommended an MRI and electromyography ("EMG"). Id. at 225.

On April 12, 2019, Petitioner saw Dr. Alsadek, requesting forms for a disabled-persons placard. Pet. Ex. 21 at 20. Petitioner refused a referral to a psychiatrist. Id.

On May 1, 2019, Petitioner followed up with Dr. Korb for an EMG; however, the EMG was not performed due to Petitioner's lack of cooperation. Pet. Ex. 3 at 209. According to Dr. Korb's notes, Petitioner requested to have his medical records changed because he felt they were inaccurate. Id. "He began to raise his voice and fling his hands." Id. Dr. Korb and a medical fellow "left the room at that point and got Risk Management and Security involved." Id.

On May 3, 2019, Dr. Korb's practice sent Petitioner a registered letter stating,

> Our staff have reported that [you] were non-compliant and verbally aggressive. Staff informed you that our test needed to be rescheduled since you arrived 30 minutes late to your appointment and you started to hit your hand on the counter demanding to be seen. When the physician agreed to see you and attempted to conduct the test, you refused to cooperate. You also made a comment to staff stating "I would pay $100,000 to tear this place up" and "I'll be back to get you guys."

Pet. Ex. 3 at 212.

On May 4, 2019, Petitioner went to a different neurological practice and saw Christina M. Nguyen, M.D. Pet. Ex. 5 at 2. Dr. Nguyen's examination revealed normal strength, normal coordination, and no ataxia. Id. at 3-4. Petitioner's cranial nerves were normal, and he had normal sensation except vibration decreased below his knees. Id. at 4. His reflexes were symmetric. Id. Dr. Nguyen diagnosed Petitioner with weakness, paresthesias, and post-concussive syndrome. Id. at 4-5. Dr. Nguyen recommended an EMG, MRI, and electroencephalogram ("EEG"). Id. at 4.

On May 7, 2019, a telephone note from Dr. Korb indicated that Mitchell Berner, M.D., called about Petitioner's MRI results.[14] Pet. Ex. 3 at 204. Dr. Berner was concerned because Petitioner's MRI showed "extensive supratentorial lesions, both enhancing and non-enhancing, that were suspicious for possible end stage[] MS." Id.

On May 8, 2019, Petitioner had an EMG/nerve conduction study ("NCS") which was normal. Pet. Ex. 5 at 6. "There was no electrodiagnostic evidence of neuropathy, left cervical or left lumbar radiculopathy, or irritable myopathy." Id.

On May 12, 2019, Petitioner sought emergency care after crashing his electric scooter into some shelves at a grocery store. Pet. Ex. 13 at 3. He was diagnosed with a hernia which was manually reduced. Id. at 5. He was recommended to see his primary care physician for a referral hernia surgery. Id.

On May 22, 2019, Petitioner saw Dr. Alsadek for assistance with filling out forms requesting in-home support. Pet. Ex. 21 at 18. Dr. Alsadek noted Petitioner "had not been compliant with medical management and referrals." Id. Dr. Alsadek also noted that Petitioner had a recent brain MRI suggesting advanced MS. Id. Dr. Alsadek further noted that Petitioner "has been hostile with the staff in the office." Id.

Later that day, May 22, 2019, Petitioner sought emergency care for his MS. Pet. Ex. 4 at 18. The emergency room administered IV solumedrol, and Petitioner's condition improved. Id. However, when he was about to be admitted to the hospital, Petitioner became verbally aggressive, uncooperative, and said that he wanted to go home. Id. After changing his mind several times, he finally decided to be discharged home, against medical advice. Id.

On June 3, 2019, Petitioner saw neurologist, Michael Sy, M.D., Ph.D. Pet. Ex. 3 at 192. Dr. Sy's assessment was MS with active inflammation. Id. at 197. He recommended that Petitioner be admitted to the hospital to start a three-day course of IV solumedrol. Id. Dr. Sy also ordered cervical and thoracic MRIs and additional labs. Id.

From June 4, 2019 to June 6, 2019, Petitioner was admitted to the hospital for his IV solumedrol course and other procedures. Pet. Ex. 3 at 49-50. Petitioner's thoracic MRI revealed "multiple T2 hyperintense lesion in the thoracic cord most consistent with reported history of [MS]." Id. at 102. The thoracic MRI also showed a "[p]ossible tiny focus of enhancement in the thoracic cord at the level of T1-T2, only seen on the sagittal images, acute demyelination not

[14] On May 7, 2019, Dr. Korb at UCI Health received a call from Dr. Berner at West Coast Radiology regarding MRI results. Pet. Ex. 3 at 204. The UCI Health records document that Petitioner received an "outside" MRI on May 6, 2019. Id. at 205. Dr. Korb requested a complete report and disc with images be sent to his clinic; however, a complete copy of Dr. Berner's radiology report does not appear in the UCI Health records. See id. at 204. In his expert report, Dr. Conte stated he reviewed three pages of records from West Coast Radiology dated May 6, 2019. Pet. Ex. 31 at 5. These records do not appear to have been filed by Petitioner.

excluded." Id. Petitioner's cervical MRI showed "[p]laques throughout the cerebellum, brain stem, and visualized spinal cord." Id. at 99. Petitioner's labs were normal except for low vitamin D, a positive antinuclear antibodies ("ANA") titer of 1:80, and hepatitis B surface antibody reactivity. Id. at 79, 87, 88; see generally id. at 68-95 (labs). During his admission, Petitioner continued to display aggressive behavior and other mental-health issues. Id. at 59, 61-62, 143-44. Petitioner's discharge diagnosis was MS and "[u]nderlying psychiatric diagnosis (schizophrenia, bipolar, etc.)." Id. at 49.

On June 12, 2019, Petitioner was discharged from Dr. Nguyen's practice because he called after missing an appointment and was verbally threatening. Pet. Ex. 5 at 9-10.

On June 24, 2019, Petitioner saw Dr. Alsadek, requesting several procedures including STD screening, a lumbar puncture, and blood work. Pet. Ex. 21 at 17. After Dr. Alsadek advised Petitioner to follow up with his neurologist and that he did not need blood work, Petitioner became "hostile and loud" with Dr. Alsadek and his staff, who ultimately called 911. Id.

In July 2019, Petitioner continued to see neurologists for his care. Pet. Ex. 3 at 9-12; Pet. Ex. 9 at 7-10, 14-20. Although he was discharged from Dr. Nguyen's care, Petitioner returned to Dr. Nguyen's office, and security was called to remove Petitioner after he became disruptive. Pet. Ex. 5 at 10. Petitioner had a visual evoked potential[15] test. Pet. Ex. 9 at 14. His visual evoked potential test was abnormal with prolonged P100 latencies, indicating severe bilateral optic neuritis.[16] Id. Petitioner also had lumbar puncture with CSF oligoclonal bands, high immunoglobulin ("IgG") synthesis rate, an elevated IgG index, and elevated protein. Pet. Ex. 8 at 86-89.

In August and September 2019, Petitioner continued to receive neurological care both from his clinicians and on an emergency basis. Pet. Ex. 3 at 5; Pet. Ex. 9 at 3; Pet. Ex. 8 at 51-55; Pet. Ex. 13 at 67, 71, 108, 123, 131-32. He continued to be aggressive with his treating doctors and their staff. Pet. Ex. 9 at 3; Pet. Ex. 8 at 54-55; Pet. Ex. 13 at 123; Pet. Ex. 13 at 131-32. From September 23, 2019 to September 25, 2019, Petitioner was hospitalized and received IV steroids. Pet. Ex. 4 at 173. The treating neurologist noted, "At this time although there is the possibility that [Petitioner] could have had a proximal vaccination demyelinating reaction[,] he seems to have the clinical picture and MRI as evidence suggesting of demyelinating diseases such as [MS] and probably less of a picture of [acute disseminated encephalomyelitis]." Id. at 175. Petitioner's discharge summary noted that Petitioner has paranoia and was not receptive to

[15] In visual evoked potential studies, a "visual stimulus to the eye causes an electrical response in the occipital area that can be recorded using 'EEG-like' electrodes . . . . Ninety percent of patients with [MS] show abnormal latencies in [visual evoked potential studies], a phenomenon attributed to the demyelination of nerve fibers." Evoked Potential Studies, Mosby's Manual of Diagnostic and Laboratory Tests 503-04 (6th ed. 2018).

[16] 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. 20, 2025).

any treatment. Id. at 164. The discharge summary also noted, "Allergy and Adverse reactions: tetanus toxoid." Id. at 169.

In October 2019, Petitioner had a second lumbar puncture. Pet. Ex. 13 at 176-82. He had CSF oligoclonal bands, high IgG synthesis rate, an elevated IgG index, positive tetanus toxoid IgG Ab, and elevated protein. Id. These results were similar to his previous lumbar puncture and compatible with MS. Id. at 185; Pet. Ex. 8 at 86-89.

In 2020, Petitioner continued to seek both clinical and emergency neurological care. Pet. Ex. 8 at 22-25; Pet. Ex. 12 at 2-3; Pet. Ex. 13 at 208-14, 349-52. He was given IV steroids throughout the year. Pet. Ex. 13 at 225; Pet. Ex. 2 at 108, 116. On June 27, 2020, while he was hospitalized, Petitioner had a brain MRI, cervical MRI, and thoracic MRI. Pet. Ex. 12 at 16-17. The MRIs were consistent with MS. Id.

Petitioner continued to receive treatment in 2021 and 2022. He continued to receive IV steroids. Pet. Ex. 20 at 36; Pet. Ex. 23 at 182, 197-98, 219, 234, 249, 322, 332-33, 341, 344. In April and May 2022, Petitioner also had seven therapeutic plasma exchange sessions. Pet. Ex. 23 at 3, 104-05. On April 14, 2022, Petitioner had a brain MRI and cervical MRI. Id. at 127. The MRI results were consistent with MS and appeared to be slightly progressed from MRIs taken in 2019. Id. The last MRIs were taken on June 23, 2022 and did not have any significant changes from the April 13, 2022 MRIs. Pet. Ex. 25 at 2-7.

2. Other Relevant Medical Records

In addition to the above stipulated medical history, the undersigned finds the following medical records relevant.

On May 13, 2015, Petitioner presented to UCI Dermatology for a skin check. Pet. Ex. 3 at 399. Petitioner's vital signs and body measurements were taken, and Petitioner reported he had no pain. Id. No physician examination was recorded, and no history of present illness was recorded. See id. at 399-402. No other information was provided regarding this visit. Id.

Petitioner's next documented encounter was on August 24, 2017 at Anaheim Regional Medical Center with a chief complaint of sore throat. Pet. Ex. 7 at 10. Past medical history stated "[n]o serious illness." Id. Review of systems was normal besides a "sore throat and [d]ifficulty of swallowing." Id. at 11. Neurological examination documented "[Cranial nerves] II-XI intact, Speech normal, Motor and [sensory] strength normal, and Symmetric." Id. Petitioner's differential diagnosis was strep throat, pharyngitis, tonsillitis, and abscess. Id. at 12.

At the March 7, 2019 visit with Dr. Alsadek, Petitioner also reported he had fatigue for "about [a] couple months" but could not "recall exact date." Pet. Ex. 21 at 22. Petitioner reported lower and upper extremity "tingling associated with weakness" since his Tdap vaccine and Rocephin injection in April 2018. Id. Petitioner also complained of dizziness when moving

his head. Id. Dr. Alsadek performed an Epley's maneuver[17] after which Petitioner felt a "little better." Id.

Petitioner was seen by neurologist, Dr. Cruz, during his March 13, 2019 hospital visit. Pet. Ex. 3 at 241. History of present illness noted Petitioner "[w]as vaccinated against Tetanus almost one year ago on [April 25, 2018] and was told he may experience dizziness afterwards. Was fine for a few days up to a week when first noted imbalance while walking." Id.

On April 11, 2019, an evaluation done by Jonathan Cauchi, M.D., noted Petitioner's dizziness "started acutely when [Petitioner] received a vaccination for TDAP when he has bitten by a cat. He said it began as soon as the needle entered his arm." Pet. Ex. 3 at 221.

At the June 3, 2019 appointment, Dr. Sy noted "there seems to be a progressive decline in function" with Petitioner "using a cane to get around and [] unsteady on his feet." Pet. Ex. 3 at 192.

On July 29, 2019, Petitioner was again seen by neurologist, Dr. Sy, for follow-up of his MS. Pet. Ex. 3 at 9. In history of present illness, Petitioner "[a]gain relay[ed] that symptoms really started to deteriorate after the tetanus vaccine . . . . They then worsened after a concussion shortly after that." Id. On examination, Petitioner had nystagmus, diminished facial sensations, ataxic gait, difficulty with heel walking, and difficulty with tandem walking. Brain, cervical, and thoracic spine MRIs showed "plaques throughout the cerebellum, brainstem, and visualized spinal cord." Id. at 12. Under impression, Dr. Sy stated,

> 34 [year old] man with MS. He has aggressive disease and would recommend aggressive management. . . . Of note, he was declining rapidly after vaccination. Various vaccinations are known to be associated with triggering MS relapses. When he received the vaccine, he was not on disease modifying therapy, so he was at even more risk. Most likely, the tetanus shot in April 2018 was related to worsening of MS which caused deterioration in his functioning.
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> Thankfully, he has made some recovery with IV solumedrol but mostly like[ly] he will not recover all of his function. In addition to ataxia[] [and] nystagmus, he has issues with fatigue, short term memory, processing speed, headache, [and] sleep disturbances. All of these are related to MS.

Id.

Petitioner next followed-up with Dr. Sy (attending) and Jonathan Chou, M.D., (Resident) on November 8, 2020. Pet. Ex. 20 at 224. History of the present illness noted Petitioner

[17] Epley's maneuver is a "canalith-repositioning maneuver" that involves "moving the head through a series of specific positions" and is used in the treatment of benign paroxysmal positional vertigo. Mickie Hamiter, Benign Paroxysmal Positional Vertigo, Merck Manual, https://www.merckmanuals.com/professional/ear-nose-and-throat-disorders/inner-ear-disorders/benign-paroxysmal-positional-vertigo (last visited Oct. 20, 2025).

"suspects symptoms started to deteriorate after tetanus vaccine in April [2018]. They then worsened after a concussion shortly after that." Id. Neither Dr. Sy nor Dr. Chou commented on the casual role of Tdap vaccination on Petitioner's MS at this visit. See id. at 224-27. Dr. Sy continued to treat Petitioner through 2022. See Pet. Ex. 23 at 149, 170, 303, 308. At these subsequent visits, Dr. Sy noted that Petitioner stated symptoms began after the April 2018 Tdap vaccine, but Dr. Sy did not comment on the casual role of Tdap vaccination on Petitioner's MS. See id.

No additional relevant records were filed.

3. Petitioner's Declarations

Petitioner submitted three declarations in support of his claim. Pet. Exs. 1, 26, 41. In his first and second declaration,[18] Petitioner described his experience after receiving the Tdap vaccine. Pet. Ex. 1 at ¶¶ 2-49; Pet. Ex. 26 at ¶¶ 2-49.

Prior to vaccination, Petitioner averred he was able to walk, able to drive to work, and "was in the process of creating another company." Pet. Ex. 1 at ¶ 2. He was also remodeling his home and backyard. Id. Petitioner would work out four times a week and "went out on weekends." Id. Petitioner averred he can no longer do "any of these tasks mentioned" because of his instability in his gait and because of his blurry or double vision. Id.

On April 25, 2018, Petitioner went to HealthCare Partners after a cat bite and was given a Tdap shot. Pet. Ex. 1 at ¶ 3.

Addressing his onset of symptoms, Petitioner explained that soon after he received the vaccine he had a headache, eye pressure, and the "feeling of concussion." Pet. Ex. 1 at ¶ 4. A nurse told him he "did not look too well" and put him an observation room. Id. The next day, on April 26, 2018, he "woke up to symptoms of delayed functioning and dizziness and photosynthesis to light." Id. at ¶ 5. As discussed below, Petitioner later retracted these statements regarding onset of symptoms. See Pet. Ex. 41.

Petitioner stated he next sought medical care on May 16, 2018. Pet. Ex. 1 at ¶ 6. He returned to HealthCare Partners and was seen by PA Larson. Id. He felt "dizzy . . . pressure . . . stinging pain in [his] scalp and uncoordinated." Id. He also had "an altered gait, decreased sensation, delayed movements, and dizziness." Id. PA Larson recommended Petitioner see a neurologist. Id.

[18] Petitioner's second declaration was almost identical to his first declaration. Compare Pet. Ex. 1 at ¶¶ 1-49, with Pet. Ex. 26 at ¶¶ 1-49. Petitioner's second declaration clarified that he met jurisdictional requirements. Pet. Ex. 26 at ¶ 50.

Petitioner averred he made an appointment in May 2018 with Isaac Beshay, a primary care provider, to "tell him about [his] condition that started since [he] got a Tdap vaccine.[19] Pet. Ex. 1 at ¶ 7. Petitioner was told "that's not what [the primary care provider] does." Id. Petitioner stated he attempted to see another primary care provider in June 2018 as he was "very dizzy" and had blurry visions, pain in his scalp and hearing loss, but he could not get an appointment. Id. at ¶ 8.

Petitioner averred he made an appointment to see Dr. John Molina in July 2018.[20] Pet. Ex. 1 at ¶ 9. Petitioner reported he was having visions problems, dizziness, and balance problems since his April vaccine. Id. Petitioner also stated that the "nerve area of [his] arms and legs [felt] like they were burning." Id. Petitioner felt that Dr. Molina "did not believe [him] and wanted to look into other matters" so Petitioner "could not continue with this doctor" and "went to look for other care somewhere else." Id.

Following the July appointment, Petitioner reported his symptoms "got to the point where [he] was so fatigued and weak that [he] gave up and [he] stayed in bed for approximately [five] months." Pet. Ex. 1 at ¶ 10. He stated he was bedridden, unable to walk to the bathroom, and was only able to eat one to two meals a day due to his nausea and dizziness. Id. He averred he "stopped working due to the state [he] was in." Id.

Petitioner reported he next sought medical care in January 2019. Pet. Ex. 1 at ¶ 11. The balance of Petitioner's first and second declarations recounted his visits with different providers and facilities between January 2019 and 2021. Id. at ¶¶ 11-49. Petitioner recounted the progression of his symptoms over this time period. See id. Petitioner also noted various incidents and visits where he felt he was misdiagnosed or mistreated by his medical providers. See, e.g., id. at ¶¶ 11, 14, 17, 21-22, 24, 27, 33, 37, 44-45, 48.

On December 11, 2024, Petitioner executed a third declaration retracting portions of his previous declarations. Pet. Ex. 41. Petitioner retracted two statements. First, he retracted item four in his first and second declaration:

> Soon after I received the vaccine, I felt a rushing headache, as well as eye pressure/feeling of eyes being squeezed and burning, and simultaneously my eyes were intermittently turning off black. I had a feeling of a concussion like someone hit me in the back of the head. The nurse said I did not look too well so she put me in the observation room and my sight was blurry to where I could not see in the lowest of light. I went home in the hopes of getting some rest and everything was to go away.

Pet. Ex. 41 at ¶ 5 (quoting Pet. Ex. 1 at ¶ 4; Pet. Ex. 26 at ¶ 4). Petitioner averred that after receiving the vaccine, he "did not have a sudden headache or eye pressure" nor "did [he] feel as

[19] No medical records were filed from this appointment.

[20] No medical records were filed from this appointment.

though [he] suffered a concussion." Id. at ¶ 6. Further, the nurse did not make the statements he described in his previous declarations, and he was not placed in an observation room. Id. at ¶ 7.

Next, Petitioner retracted item five in his first and second declaration:

> On April 26, 2018, I woke up to symptoms of delayed functioning and dizziness and photosynthesis to light. These progressed. After bumping my head on the kitchen cabinet several times over the course of three weeks from losing my head space placement several times in the kitchen, I finally said that I would need to go back to the emergency room to see what was happening with me.

Pet. Ex. 41 at ¶ 10 (quoting Pet. Ex. 1 at ¶ 5; Pet. Ex. 26 at ¶ 5). Petitioner averred this was not the earliest manifestation of his symptoms. Id. at ¶ 11. Instead, his symptoms "would not appear until three or more days after received the vaccine." Id. at ¶ 12.

He explained that his retracted statements were "motivated by [an] attempt to bolster [his] case without knowing that making such assertions would work against [his] actual claim" and he further explained that "without any medical observations or witnesses to support what was happening to [him,] . . .[he] took liberties in making [his] condition appear worse after only a single day of receiving the vaccine." Pet. Ex. 41 at ¶¶ 8, 11.

Petitioner stated that the symptoms he "eventually experienced after the Tdap vaccine were in fact real" and he has been "left disabled because of it." Pet. Ex. 41 at ¶ 9. Petitioner expressed his regret for misstating the facts of his case. See id. at ¶¶ 3, 8, 11, 13-14.

C. Expert Reports

1. Petitioner's Expert, Dr. William L. Conte[21]

a. Background and Qualifications

Dr. Conte is a board-certified neurologist. Pet. Ex. 31 at 4. He is an MS specialist at Methodist Hospitals, Neuroscience Institute Comprehensive MS Center in Merrillville, IN. Pet. Ex. 32 at 1. Dr. Conte received his M.D. from Loyola University Chicago. Id. He completed a neurology residency at Loyola University followed by a fellowship in MS and neuroimmunology at the University of Chicago. Id. Dr. Conte also holds a M.S. in public health sciences. Id. He currently has an "active, full-time neurology practice" where he "provide[s] ambulatory and inpatient care." Pet. Ex. 31 at 4. Additionally, Dr. Conte serves as an adjunct clinical assistant professor of neurology at Indiana University School of Medicine. Pet. Ex. 32 at 1. He has authored or co-authored several peer reviewed articles on MS and conducted research related to "various MS disease modifying therapies." Id. at 1-3.

[21] Dr. Conte submitted one expert report. Pet. Ex. 31.

b. Opinion

Dr. Conte opined, "more likely than not," Petitioner had dormant and asymptomatic MS prior to his 2018 vaccination. Pet. Ex. 31 at 8. Dr. Conte opined, "to a reasonable degree of medical certainty," "the April 25, 2018 Tdap vaccination causally triggered symptoms and the clinical worsening of MS" in Petitioner. Id.

i. Loving Factors One, Two, and Three

With regard to Loving factor one (Petitioner's condition prior to vaccination), Dr. Conte opined it was "more likely than not" that Petitioner had MS lesions prior to vaccination since Petitioner "had so many lesions within a year of the vaccination." Pet. Ex. 31 at 12. He explained that the lesion load and brain atrophy present on Petitioner's initial MRI from May 6, 2019[22] supported the presence of MS prior to 2018. Id. at 8. However, while Petitioner had MS lesions prior to vaccination, his MS was "dormant and asymptomatic." Id. at 12. Based on Petitioner's reports, Dr. Conte noted that Petitioner had "no prior neurological signs or symptoms" and was "able to work and exercise regularly" prior to his Tdap vaccination. Id. at 6.

Dr. Conte opined it was not possible to know when Petitioner's MS began. Pet. Ex. 31 at 11. There is often a lag between the onset of demyelination (lesions) and clinical symptoms, and many patients will "go years or decades" without symptoms of MS. Id. Moreover, Dr. Conte explained that one phenotype of MS, known as radiologically isolated syndrome ("RIS"), is characterized by patients with lesions in the brain or spine without current or past neurological symptoms. Id. He did not opine that Petitioner had RIS. See id.

Next, Dr. Conte discussed Loving factors two and three, Petitioner's post-vaccination condition and whether Petitioner experienced a "significant aggravation."

At the time of vaccination, Petitioner reported he was able to "work and exercise" and was not experiencing neurological signs and symptoms. Pet. Ex. 31 at 6. Within the first few weeks following vaccination, Petitioner experienced "issues with cognition and sensitivity to light" as well as "dizziness and problems walking." Id. At Petitioner's neurology visit in April 2019 (approximately one year after the Tdap vaccination), the neurologist noted sustained nystagmus and documented Petitioner's difficulty walking. Id. The May 6, 2019 MRI showed "extensive innumerable" areas of lesions throughout the brain that were consistent with MS. Id. "The clinical status of [Petitioner] ha[d] continued to worsen, and he ha[d] difficulty walking along with fatigue, vision problems, urinary and bowel incontinence, and vertigo. He [] had multiple falls and [was] unable to maintain employment." Id. at 7.

As of Dr. Conte's September 2023 report, Petitioner "ha[d] multiple lesions in disease-typical areas of the brain and spine, [] had multiple episodic flare-ups or relapses, and ha[d] [CSF] studies consistent with findings in people with MS." Pet. Ex. 31 at 8. Dr. Conte opined

[22] Dr. Conte stated he reviewed three pages of records from West Coast Radiology dated May 6, 2019. Pet. Ex. 31 at 5. These records do not appear to have been filed by Petitioner.

that Petitioner's "current symptoms are permanent, and he is unlikely to regain his pre-vaccination function." Id.

Finally, Dr. Conte opined that "through cause and effect," Petitioner's "MS was significantly aggravated by the April 25, 2018, Tdap vaccine." Pet. Ex. 31 at 12.

ii. Loving Factor Four/Althen Prong One

Dr. Conte provided a brief overview of MS. Pet. Ex. 31 at 9-10. He explained MS is an autoimmune disease and demyelinating condition that affects the CNS when "the altered immune system causes the myelin sheath surrounding the nerves to degrade." Id. at 9. Dr. Conte acknowledged that the "exact cause of MS is currently unknown" but noted it "likely involves multiple complex biological and environmental factors" such as infection. Id. (citing Pet. Ex. 33).[23]

Dr. Conte opined that the concept of molecular mimicry supports infection and vaccination as a cause or trigger of MS. Pet. Ex. 31 at 9-11. He explained molecular mimicry is

> the process in which a foreign antigen triggers autoreactive t- or b-cells in a susceptible host. A foreign antigen may cross-react with antigens in the body (self-antigens), thus inducing autoimmunity with the result that the individual's own immune system attacks itself. Normally, individuals are tolerant of their own self-antigens, meaning the body destroys or inactivates the abnormal cells that recognize self-antigens. However, people with autoimmune disease have abnormal functioning and decreased number of regulatory cells, such as Tregs (which are notably altered in people with MS). . . . [M]olecular mimicry can occur even when a single t-cell cross-reacts with various peptides and t-cell receptors that have a similar shape.

Id. at 10 (citing Pet. Ex. 34;[24] Pet. Ex. 35).[25] Dr. Conte explained that the mechanism of molecular mimicry has been "extensively researched" to explain the causal role of Epstein-Barr

[23] Jock Murray, Infection as a Cause of Multiple Sclerosis, 325 BMJ 1128 (2002).

[24] Abul Abbas et al., Immunologic Tolerance and Autoimmunity, in Cellular and Molecular Immunology 315 (8th ed. 2015).

[25] Kedar Mahajan & Don J. Mahad, Pathology and Pathophysiology of Multiple Sclerosis, in Multiple Sclerosis and Related Disorders 15 (R.J. Fox et al. eds., 2nd ed. 2019).

Virus ("EBV") in MS. Id. (citing Pet. Ex. 36;[26] Pet. Ex. 37;[27] Pet. Ex. 39).[28] Broadly, EBV peptides share a similar shape to myelin basic protein[29] and EBV can cross-react with myelin basic protein. Id. Dr. Conte noted that epidemiological studies have demonstrated the clinical association of EBV and MS. Id. (citing Pet. Ex. 38).[30] In Bjornevik et al., the authors found the risk of MS "increased 32-fold after infection with EBV but was not increased after infection with other viruses." Pet. Ex. 38 at 1. The authors concluded that their finding "suggest[ed] EBV as the leading cause of MS." Id.

Turning to vaccination and molecular mimicry, Dr. Conte made no "distinction between the foreign antigen as a natural virus [e.g., EBV] and the foreign antigen as a vaccine." Pet. Ex. 31 at 11. He opined that a "vaccine-antigen" could "presumably" induce autoimmunity through the above-described process of molecular mimicry "but at a much lower rate" as a vaccine cannot "change its structure on its own as a virus can." Id.

Of note, none of the above-referenced literature describing molecular mimicry in the context of EBV and MS discussed a causal role for vaccines in MS. See Pet. Exs. 35-39.

Reviewing medical literature, Dr. Conte acknowledged that the clinical data regarding vaccines as a cause for MS is "small and controversial." Pet. Ex. 31 at 11. He attributed this to the "rarity of the phenomenon" and noted that most papers are either "small, retrospective case reports" or "case-control studies heterogeneous in study design." Id. Dr. Conte noted that one "relatively large case-control study" by Langer-Gould et al.[31] found an increased risk of MS and other CNS demyelinating syndromes "30 days after any type of vaccination in individuals younger than 50 (which is consistent with [Petitioner's] situation)." Id. (citing Pet. Ex. 40).

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[26] Christian Münz et al., Antiviral Immune Responses: Triggers of or Triggered by Autoimmunity?, 9 Nat. Rev. Immunol. 246 (2009).

[27] Samanatha Soldan & Paul Lieberman, Epstein-Barr Virus and Multiple Sclerosis, 21 Nat. Rev. Microbiol. 51 (2022).

[28] Hartmut Wekerle & Reinhard Hohlfeld, Molecular Mimicry in Multiple Sclerosis, 349 New Eng. J. Med. 185 (2003).

[29] Myelin basic protein is "a basic protein . . . that constitutes about 30 per cent of myelin proteins; elevated levels of [myelin basic protein] occur in acute exacerbation of [MS]." Myelin Basic Protein, Dorland's Med. Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=100535 (last visited Oct. 15, 2025).

[30] Kjetil Bjornevik et al., Longitudinal Analysis Reveals High Prevalence of Epstein-Barr Virus Associated with Multiple Sclerosis, 375 Science 296 (2022).

[31] Annette Langer-Gould et al., Vaccines and the Risk of Multiple Sclerosis and Other Central Nervous System Demyelinating Diseases, 71 JAMA Neurol. 1506 (2014).

The study by Langer-Gould et al. focused on whether vaccinations of any type increased the risk of MS or other CNS demyelinating syndromes. Pet. Ex. 40 at 1. The authors found "[v]accination of any type was associated with an increased risk of CNS [acute demyelinating syndrome] onset within the first 30 days after vaccination only in younger (< 50 years) individuals." Id. However, the "association disappeared after 30 days." Id. at 5. They concluded that a "short-term increase in risk suggests that vaccines may accelerate the transition from subclinical to overt autoimmunity in patients with existing disease." Id. at 1. The authors explained that vaccines could "theoretically" increase the risk of CNS acute demyelinating syndromes through "mechanisms similar to those induced by infection" including molecular mimicry. Id. at 6.

iii. Loving Factor Five/Althen Prong Two and Loving Factor Six/Althen Prong Three

Dr. Conte opined "through cause and effect" Petitioner's "MS was significantly aggravated by the April 25, 2018, Tdap vaccine." Pet. Ex. 31 at 12.

Based on the lesion load and level of brain atrophy on Petitioner's May 2019 MRI, Dr. Conte opined that Petitioner had MS prior to his April 2018 vaccination. Pet. Ex. 31 at 8. This MS was "dormant and asymptomatic." Id. "Following the administration of the Tdap booster, [Petitioner] experienced a headache and visual disturbance. Over the next few weeks, the symptoms progressed to issues with cognition and sensitivity to light." Id. at 6.

Reviewing Petitioner's clinical course, Dr. Conte noted Petitioner first sought care on May 16, 2018, when he reported dizziness and problems walking. Pet. Ex. 31 at 6. Petitioner also reported numbness and tingling in his extremities and decreased sensation in the left side of his face. Id. He had positive Romberg's sign and decreased sensation to pinprick on the left side.[32] Id. Petitioner was referred to a neurologist. Id.

Dr. Conte stated Petitioner was seen by a neurologist in April 2019.[33] Pet. Ex. 31 at 6. Petitioner was examined by Dr. Cauchi and Dr. Korb who noted sustained nystagmus and that Petitioner had difficulty walking. Id. They recommended further workup due to concerns of a CNS issue. Id. Petitioner underwent an MRI on May 6, 2019 that showed "extensive innumerable" areas of lesions that the radiologist interpreted as consistent with MS. Id. at 7.

In support of his opinion that Petitioner's MS was significantly aggravated "through cause and effect," Dr. Conte opined that the MRI taken May 6, 2019 (over one year after vaccination) showed lesions with "contrast enhancement, meaning there was active inflammation occurring." Pet. Ex. 31 at 12. Dr. Conte did not explain how active inflammation on an MRI

[32] Dr. Conte did not opine that a positive Romberg's sign and decreased sensation were objective neurological symptoms.

[33] Petitioner's medical records show he first saw a neurologist during his March 13, 2019 hospital visit.

taken in May 2019 related to the April 2018 vaccination. In further support, Dr. Conte noted that "[j]ust over a year after the vaccination, [Petitioner] had a large number of lesions within his CNS."[34] Id. Finally, he noted the temporal association between Petitioner's symptoms and his April 2018 vaccination. Id.

Discussing temporal association, Dr. Conte opined that Petitioner became "symptomatic very shortly after vaccination." Pet. Ex. 31 at 12. He noted Petitioner experienced headache and visual disturbances following vaccination with the symptoms progressing to "issues with cognition and sensitivity to light" over "the next few weeks." Id. at 3. While Dr. Conte did not provide a specific onset date, he opined that Petitioner's symptoms began within the 30-day time frame discussed in Langer-Gould et al. Id. In Langer-Gould at al., the authors identified four cases of acquired CNS demyelinating syndromes that occurred within 14 days after vaccination and 19 cases that occurred within 30 days after vaccination. Pet. Ex. 40 at 6 fig.2. Looking only at MS patients, the authors identified two cases of MS that occurred within 14 days after vaccination and three cases that occurred within 30 days after vaccination. Id. The authors did not provide any additional data on the specific onset date for these cases.

Dr. Conte concluded "if it were not for the vaccination, [Petitioner] would not be in the position he is in now." Pet. Ex. 31 at 12.

2. Respondent's Expert, Dr. Harold Moses, Jr.[35]

a. Background and Qualifications

Dr. Moses is a board-certified neurologist. Resp. Ex. A at 1; Resp. Ex. B at 1. He is an associate professor of neurology in the division of neuroimmunology and MS at Vanderbilt Medical Center. Resp. Ex. A at 1. He received his M.D. from the University of North Carolina, Chapel Hill. Resp. Ex. B at 1. He then completed a neurology residency at the Mayo Clinic followed by a fellowship at Vanderbilt Medical Center. Id. In his clinical neurology practice, he sees approximately 1600 patients. Resp. Ex. A at 1. Ninety percent of his patients have MS. Id. Dr. Moses has also been "involved in several clinical trials in MS and [has] been for more than 25 years." Id. In addition to his clinical practice, he has "published on both the clinical and immune aspects of MS." Id.; Resp. Ex. B at 8-10.

b. Opinion

Dr. Moses opined that Petitioner's Tdap vaccination "did not trigger or worsen his MS." Resp. Ex. A at 11. Dr. Moses concluded there is "no evidence to support the claim" that Petitioner's "recurrent and ongoing MS symptoms and MRI findings resulted from his Tdap immunization." Id. at 12.

[34] There is no MRI prior to vaccination to serve as a baseline comparison.

[35] Dr. Moses filed one expert report. Resp. Ex. A.

i. Loving Factors One, Two, and Three

With regard to Loving factor one (Petitioner's condition prior to vaccination), Dr. Moses agreed with Dr. Conte's opinion that Petitioner "likely" had MS prior to vaccination. Resp. Ex. A at 12. Dr. Moses explained it was "difficult to determine" whether Petitioner had onset of MS silent lesions prior to his 2018 Tdap vaccination; however, he noted the "extensive number of lesions" on Petitioner's May 2019 MRI support the possibility that Petitioner's MS preceded vaccination. Id. at 9. While Dr. Moses did not personally review the May 2019 MRI imaging, he noted that Petitioner's treating providers described the MRI as having "characteristics of end-stage MS disease." Id. at 1, 9. Clinically, MS presents with neurological deficits "that pertain to either the optic nerves, brainstem, or spinal cord. Id. at 8. Dr. Moses explained that it is also possible for a patient to have extensive lesions "which are silent, not causing clinical symptoms." Id.

Turning to Petitioner's post-vaccination condition, Dr. Moses acknowledged that Petitioner described his initial symptoms of "imbalance and neuritis" beginning "anywhere from the time of injection to [three] days after his Tdap vaccination." Resp. Ex. A at 12-13. However, Dr. Moses opined that Petitioner's complaints of dizziness and imbalance at his first post-vaccine visit on May 16, 2018 "did not correspond to objective abnormalities" on examination. Id. at 9 (citing Pet. Ex. 15 at 1). He noted Petitioner had normal deep tendon reflexes and strength as well as intact cranial nerves. Id. At Petitioner's next appointment in January 2019, he had "no abnormalities on exam, no focal neurological deficits, [and] normal coordination, gait, strength." Id. at 2. Dr. Moses noted that Petitioner's March 2, 2018 emergency room visit also reflected a normal physiological and neurological examination. Id. at 2, 9.

Dr. Moses explained that the "first neurological event constitutes the first attack of the disease, in a patient later diagnosed with MS." Resp. Ex. A at 8 (citing Resp. Ex. A, Tab 1). In the 2017 McDonald diagnostic criteria described by Thompson et al., the authors defined objective clinical or paraclinical evidence of an MS attack as "[a]n abnormality on neurological examination, imaging (MRI or optical coherence tomography), or neurophysiological testing (visual evoked potentials) that corresponds to the anatomical location suggested by the symptoms." Resp. Ex. A, Tab 1 at 2. "Caution should be exercised in accepting symptoms accompanied only by patient-reported subjective alteration as evidence of a current or previous attack." Id. Finally, the criteria noted an attack, relapse, or exacerbation of MS is characterized by "objective findings . . . reflecting a focal or multifocal inflammatory demyelinating event in the CNS, developing acutely or subacutely, with a duration of at least 24 h[ours]." Id.

Dr. Moses opined that Petitioner's first attack of MS "with objectively measurable neurological symptoms" occurred in March 2019. Resp. Ex. A at 9. On March 7, 2019, Petitioner's primary care provider documented a right nystagmus which Dr. Moses characterized as "clear symptomology of neurological damage." Id.

Petitioner's May 2019 MRIs showed active MS lesions throughout the brain and cervical and thoracic spinal cord. Resp. Ex. A at 8. Dr. Moses noted that subsequent MRIs continued to show active lesions. Id. Dr. Moses summarized Petitioner's medical chronology from the May

2019 MRI through June 2022. Id. at 3-7. The medical records "document disease progression and worsening exam findings [and] worsening MRI changes with more lesions overall as well as new active lesions." Id. at 7. Petitioner's gait, vision, and strength all worsened. Id. Dr. Moses also noted Petitioner had "marked decrease in vision over a period of [four] months from November 2022 to March 2023." Id.

As to Loving factor three, Dr. Moses did not offer a specific opinion on whether Petitioner experienced a "significant aggravation." Dr. Moses agreed that Petitioner had been profoundly impacted by his MS, and he agreed that Petitioner's MS symptoms were permanent with Petitioner "unlikely to regain his pre-vaccination function." Resp. Ex. A at 7, 11. However, Dr. Moses attributed Petitioner's disease progression to "a natural history example of someone with highly active and relatively rapidly progressive MS." Id. at 7.

ii. Loving Factor Four/Althen Prong One

Dr. Moses opined "there are no causal connections between vaccines and the development of MS." Resp. Ex. A at 8.

Addressing the medical literature, Dr. Moses argued that "clinical, epidemiological, and pharmovigilance studies have demonstrated the safety of the great majority of vaccines administered in MS patients." Resp. Ex. A at 8 (citing Resp. Ex. A, Tab 2;[36] Resp. Ex. A, Tab 3).[37] In DeStefano et al., the authors reported on a case-controlled study using data from three large health maintenance organizations from 1995 to 1999 in patients aged 18 to 49 with MS or optic neuritis to determine whether vaccination increased the risk of developing these illnesses. Resp. Ex. A, Tab 2 at 1-2. Tetanus, influenza, hepatitis B, measles, and rubella vaccines were not associated with an increased risk of MS. Id. at 1. Nor was vaccination found to "trigger . . . clinical manifestations in those with subclinical [MS] disease." Id. at 4. Further, the only statistically significant finding was of "decreased risk associated with tetanus vaccination." Id. In Farez and Correale, the authors conducted a systematic review of publications from 1966 to 2011 and found a "decreased risk of developing MS" after vaccination for diphtheria and tetanus. Resp. Ex. A, Tab 3 at 1.

Dr. Moses explained that MS patients and vaccinations as triggers of MS exacerbations are "highly studied." Resp. Ex. A at 8. For example, a literature review conducted by Mailand and Fredrikson[38] in 2017 examined 51 studies on the role of various vaccines in developing MS and MS relapse. Resp. Ex. A, Tab 7 at 1-2. The authors identified eight studies assessing the

[36] Frank DeStefano et al., Vaccinations and Risk of Central Nervous System Demyelinating Diseases in Adults, 60 Arch. Neurol. 504 (2003).

[37] Mauricio Farez & Jorge Correale, Immunizations and Risk of Multiple Sclerosis: Systematic Review and Meta-Analysis, 258 J. Neurol. 1197 (2011).

[38] Mia Topsøe Mailand & Jette Lautrup Fredriksen, Vaccines and Multiple Sclerosis: A Systematic Review, 264 J. Neurol. 1035 (2017).

risk of developing MS after tetanus vaccination; three studies assessing the risk of MS relapse after tetanus vaccination; five studies investigating the risk of MS development after diphtheria vaccination; three studies addressing the risk of MS development after pertussis vaccination; and no studies investigating the risk of MS relapse following diphtheria or pertussis vaccination. Id. at 11. None of these studies found an increased tendency, risk, or positive association of MS with vaccination. Id. The authors noted that "results of the majority of the studies on tetanus vaccination and MS onset suggest that the vaccine might play a preventive role in developing MS." Id. at 12. However, Mailand and Fredrikson acknowledged the limitations of the identified tetanus vaccine studies such as small sample size and unequal gender distribution between cases and controls. Id. They suggested further research was needed on the question of "potentially protective role of tetanus- and diphtheria vaccinations." Id. at 12, 14.

An earlier systematic review by Hernan et al.[39] examined the association between tetanus vaccination and the risk of MS. Resp. Ex. A, Tab 8 at 1. Analyzing nine case-control studies between 1968 and 2004, the authors found the odds ratio of MS associated with history of tetanus vaccination was 0.67. Id. The authors concluded that tetanus vaccination was associated with a lower risk of MS. Id.

Another study by Grimaldi-Bensouda et al.[40] found no increased risk of CNS demyelinating disease amongst patients who received influenza, human papillomavirus, diphtheria-tetanus-pertussis-poliomyelitis-haemophilus ("DTPPHi"), and hepatitis B vaccines. Resp. Ex. A, Tab 10 at 1. The authors conducted a case-referent study which identified 564 patients with a "first lifetime sign of demyelination" and documented their exposure to common vaccines up to 24 months before the first sign of demyelination. Id. at 2, 5 tbl.2. Two referents were matched to each identified case of demyelination. Id. The odds ratios of association between DTPPHi vaccination and central demyelination was 0.38 at two months, 0.65 at six months, and 0.72 at 24 months. Id. at 5 fig.2. "No increased risk of [CNS demyelination] incidence was observed amongst vaccinated patients." Id. at 1.

Next, Dr. Moses identified two large population studies conducted in France and Germany addressing association with vaccination and MS. Resp. Ex. A at 11 (citing Resp. Ex. A, Tab 9; Resp. Ex. A, Tab 12).[41]

The French study, by Grimaldi et al., analyzed data from 106,523 MS patients in the national health claims database in France between 2007 and 2017. Resp. Ex. A, Tab 9 at 1. The authors looked at exposure to DTPPHi vaccine, influenza vaccine, and pneumococcal vaccines.

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[39] Miguel Hernan et al., Tetanus Vaccination and the Risk of Multiple Sclerosis: A Systematic Review, 67 Neurology 212 (2006).

[40] Lamiae Grimaldi-Bensouda et al., Association Between Vaccination and the Risk of Central Demyelination: Results from a Case Referent Study, 270 J. Neurol. 4678 (2023).

[41] Alexander Hapfelmeier et al., A Large Case-Control Study on Vaccination as Risk Factor for Multiple Sclerosis, 93 Neurology e908 (2019).

Id. "Among 35,265 patients with MS who had a flare-up requiring hospitalization and received at least [one] vaccine[,] . . . no association was found with severe MS flare-ups and vaccine exposure in the 60 days prior to the flare-up." Id. at 2. While the authors concluded that there was no association between vaccination and the risk of hospitalization due to MS flare-up, they recommended further studies "to confirm these results" given the number of vaccine subtypes available. Id. at 1.

In Hapfelmeier et al., the authors looked at "the ambulatory claims data of the Bavarian Association of Statutory Health Insurance Physicians covering 2005-2017 . . . and vaccinations in the [five] years before first diagnosis." Resp. Ex. A, Tab 12 at 1. The MS patients totaled 12,262 and controls included patients with Crohn disease (19,296), psoriasis (112,292), and those with no history of autoimmune diseases (79,185), for a total of 210,773 controls. Id. The research showed that vaccination was not associated with a risk of developing MS. Id.

Finally, Dr. Moses noted that while infections are known to cause relapse, "[v]accinations with inactivated vaccines do not precipitate relapse or flare-ups of MS." Resp. Ex. A at 8 (citing Resp. Ex. A, Tab 4).[42] In Gold et al., the authors acknowledged that vaccination should be avoided in patients experiencing active MS relapse and noted live attenuated vaccines are contraindicated for MS patients undergoing disease modifying therapies. Resp. Ex. A, Tab 4 at 2. The authors reported "no safety concerns" for MS patients receiving inactivated or subunit vaccines such as Tdap. Id. Dr. Moses further explained that vaccination with inactivated virus is routinely recommended for MS patients undergoing immunosuppressive therapies. Resp. Ex. A at 8 (citing Resp. Ex. A, Tab 6).[43]

Responding to Dr. Conte's report, Dr. Moses largely agreed with Dr. Conte's descriptions of MS as an autoimmune disorder of the CNS. Resp. Ex. A at 10 (citing Pet. Ex. 31 at 9-10). Dr. Moses explained that the cause of MS "is thought to be autoimmune mediated by T lymphocytes, which target the white matter of the central nervous system." Id. at 8. An ongoing inflammatory response in the CNS ultimately leads to a "[l]oss of myelin membrane . . . which often results in clinical disability." Id.

Turning to Dr. Conte's mechanistic theory, Dr. Moses disagreed with Dr. Conte's contention that antigen presentation is similar between a "foreign antigen as a natural virus and [a] foreign antigen as a vaccine." Resp. Ex. A at 10. Instead, Dr. Moses opined there are "well-known" differences between activation of the immune system following an infection with live viruses and vaccination with "an inactivated virus or containing proteins/peptides in adjuvant." Id. First, live virus can multiple and cause serious illness or death "while inactivated vaccine are non-immunogenic, unless associated with an adjuvant." Id. Next, live viruses activate the innate

[42] Ralf Gold et al., Vaccination in Multiple Sclerosis Patients Treated with Highly Effective Disease-Modifying Drugs: An Overview with Consideration of Cladribine Tablets, 14 Ther. Adv. Neurol. Disord. 1 (2021).

[43] Jeannette S. Lechner-Scott et al., Vaccine Hesitancy in People with Multiple Sclerosis, 65 Mult. Scer. & Relat. Disord. 104102 (2022).

immune system "by engaging Toll-like receptors." Id. "This initial innate immune response encompassing granulocytes, [natural killer] cells, and cytokines will engage lymphocytes leading to the activation of the adaptive immune responses." Id. (citing Resp. Ex. A, Tab 11).[44]

As to the relationship between EBV infection and MS, Dr. Moses opined that "EBV appears to be a prerequisite for nearly everyone who develops MS." Resp. Ex. A at 10. Dr. Moses explained that there is 99.5% likelihood of EBV infection prior to developing MS and noted that in the Bjornevik et al. cohort, the "average EBV seroconversion to a clinical diagnosis of MS was [approximately seven] years." Id.; see also Pet. Ex. 38 at 4. Later in his report, Dr. Moses characterized infection as "likely to play a role over time" in MS relapse but "not as an acute event." Resp. Ex. A at 11.

Addressing Dr. Conte's reliance on Langer-Gould et al., Dr. Moses first noted that an association between vaccination and increased risk of CNS inflammation found by the study was not statistically significant. Resp. Ex. A at 10. He further highlighted that "these authors did not conclude that vaccines resulted in or caused these [CNS] events but instead they could have been a co-factor in the development of CNS inflammation." Id. Dr. Moses acknowledged that Langer-Gould et al. identified molecular mimicry as a possible mechanism to explain the role of vaccine and/or infection in CNS inflammation. Id. at 11. He noted, however, that the authors also identified a "spectrum of possible mechanisms including bystander activation, epitope spreading, adjuvant effect[,] and enhanced antigen presentation." Id.

iii. Loving Factor Five/Althen Prong Two and Loving Factor Six/Althen Prong Three

Dr. Moses opined that the Tdap vaccination did not trigger or worsen Petitioner's MS. Resp. Ex. A at 11. Dr. Moses disagreed with assertation that "if it were not for the vaccination, [Petitioner] would not be in the position he is now." Id. Instead, Dr. Moses opined that Petitioner's clinical course was consistent with untreated and "highly active and relatively rapidly progressive MS." Id.

As discussed above, Dr. Moses reviewed Petitioner's clinical course. At Petitioner's first medical encounter after vaccination on May 16, 2018, Petitioner had "vague complaints of dizziness and imbalance" that Petitioner attributed to his April 2018 Tdap vaccination. Resp. Ex. A at 9. "These symptoms did not correspond to objective abnormalities" on examination. Id. However, Dr. Moses acknowledged that symptoms of MS can "include weakness affecting gait, bladder and bowel control, vision, incoordination, cognition deficits[,] and mood lability." Id.

Petitioner did not seek medical care again until January 2019. Resp. Ex. A at 9. Visits on January 6, 2019 and March 2, 2019 had normal neurological examinations and did not document nystagmus. Id. at 2, 9. Petitioner had a normal head CT scan at the March 2 visit. Id. at 2. Dr. Moses noted that head CTs are not used to diagnosis MS. Id.

[44] Danyang Li & Minghua Wu, Pattern Recognition Receptions in Health and Disease, 6 Signal Transduct. & Target Ther. 291 (2021).

Petitioner's first objective neurological symptom of MS—rightward nystagmus—was not documented until March 7, 2019, ten months after vaccination. Resp. Ex. A at 9. Dr. Moses opined that the first "clear symptomatology of neurologic damage, was only observed 10 months post-vaccination, too late for having any possible association." Id.

On May 6, 2018, Petitioner had a brain MRI that documented "extensive supratentorial lesions, both enhancing and non-enhancing [with gadolinium contrast], that were suspicious for possible end stage MS." Resp. Ex. A at 3 (citing Pet. Ex. 3 at 204). Dr. Moses noted that many of these lesions were described as "active: enhancing with gadolinium" and opined that Petitioner's MRI was "consistent with an active inflammatory CNS process." Id.

Next, Dr. Moses explained that active MS lesions resolve within four to six weeks. Resp. Ex. A at 12. Accordingly, the active MS lesions present on the May 2019 MRI (over a year from vaccination) had "nothing to do with vaccination, and more likely than not was the natural progress of his untreated MS." Id.

Additionally, in his review of the medical records, Dr. Moses noted various appointments between March 2019 and 2022 where Petitioner left against medical advice, refused disease modifying treatment, or rejected the diagnosis of MS. Resp. Ex. A at 2-7. Dr. Moses attributed Petitioner's significant clinical decline to his reluctance to accept treatment for MS. Id. at 7.

Addressing temporal association, Dr. Moses acknowledged that Petitioner described his initial symptoms of "imbalance and neuritis" beginning "anywhere from the time of injection to [three] days after his Tdap vaccination." Resp. Ex. A at 12-13. Dr. Moses opined that "this was not enough time" for vaccination to have caused these symptoms. Id. at 13.

Dr. Moses concluded there was "no evidence to support the claim that [Petitioner's] recurrent and ongoing MS symptoms and MRI findings resulted from his Tdap immunization." Resp. Ex. A at 12. Further, the "recurrent nature of his events, the changes in MRIs one year after immunization, and the lack of any antecedent symptoms do not support the causal role of vaccination in this case." Id.

III. DISCUSSION

A. Standard of Adjudication—Factual Issues

A petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding his 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 v. Sec'y of Health & Hum. Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

Despite the weight afforded to medical records, special masters are not bound rigidly 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) ("[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." (emphasis omitted)).

B. Standards for Adjudication—Causation

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 his 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, 991 F.2d at 1575.

"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, aff'd, 586 F. App'x 588 (Fed. Cir. 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.").

To receive compensation through the Program, Petitioner must prove either (1) that he suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that he received, or (2) that he suffered an injury that was actually caused by or significantly aggravated by a vaccination. See §§ 11(c)(1), 13(a)(1)(A); Capizzano, 440 F.3d at 1319-20. Because Petitioner does not allege he suffered a Table Injury, he must prove his Tdap vaccine significantly aggravated his injury. See Loving, 86 Fed. Cl. at 142-44.

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 his 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 Petitioner is entitled to compensation, the special master shall consider all materials 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 his 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 v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1280 (Fed. Cir. 2005) (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.

C. Standards for Adjudication—Significant Aggravation

The elements of an off-Table significant aggravation case are set forth in Loving. See Loving, 86 Fed. Cl. at 142-44; see also W.C. v. Sec'y of Health & Hum. Servs., 704 F.3d 1352, 1357 (Fed. Cir. 2013) (holding that "the Loving case provides the correct framework for evaluating off-table significant aggravation claims"). The Loving court combined the Althen test, which defines off-Table causation cases, with a test from Whitecotton. Whitecotton v. Sec'y of Health & Hum. Servs., 17 F.3d 374 (Fed. Cir. 1994), rev'd sub nom., Shalala v. Whitecotton, 514 U.S. 268 (1995) (concerning on-Table significant aggravation cases). The resultant test has six components, which are:

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

Loving, 86 Fed. Cl. at 144.

The statute defines "significant aggravation" as "any change for the worse in a pre-existing condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration in health." § 33(4).

IV. SIGNIFICANT AGGRAVATION ANALYSIS

A. Loving Factor One: What Was Petitioner's Condition Prior to Administration of the Vaccine?

The first step in the Loving test is to determine Petitioner's condition prior to the administration of his Tdap vaccine on April 25, 2018.

Petitioner's medical records contain only two visits prior to vaccination. On May 13, 2015, Petitioner was seen by dermatologist to establish care. On August 24, 2017, Petitioner sought emergency care for a sore throat and cough. Neither of these visits document MS or neurological symptoms. The lack of pre-vaccination medical records make it difficult for the undersigned to discern Petitioner's pre-vaccination condition. However, both parties' experts agree that Petitioner's MS preceded his Tdap vaccination.

Petitioner's expert, Dr. Conte, opined that lesion load in Petitioner's initial May 2019 MRI make it "more likely than not" that Petitioner had MS prior to the April 2018 vaccination. Pet. Ex. 31 at 8, 12. He also opined Petitioner's pre-vaccination MS was dormant and asymptomatic. Respondent's expert, Dr. Moses, agreed with Dr. Conte's opinion that Petitioner likely had MS prior to vaccination and Dr. Moses noted that the extensive number of lesions in May 2019 MRI support the existence of pre-vaccination silent MS lesions. Dr. Moses further noted that May 2019 MRI had characteristics of end-stage MS.

Based on the experts' opinions, the undersigned finds that Petitioner had dormant and asymptomatic MS prior to his Tdap vaccination on April 25, 2018.

B. Loving Factor Two: What Is Petitioner's Current Condition (or His Condition Following the Vaccination, If Also Pertinent)?

The second part of the Loving test is to determine the Petitioner's condition following the Tdap vaccination. Loving, 86 Fed. Cl. at 144.

In the medical records, Petitioner variably described his symptoms as beginning immediately following vaccination to three days post-vaccination. In the most contemporaneous medical record, his visit on May 16, 2018, Petitioner reported his "[symptoms] of dizziness and gait instability occurred [three] days after he was seen [for his cat bite]." Pet. Ex. 16 at 3; see also Pet. Ex. 3 at 241. But see Pet. Ex. 3 at 221 (reporting symptoms occurred "as soon as the needle entered his arm"). At the May 16, 2018 visit, Petitioner had a positive Romberg's sign and diminished pinprick sensation. Petitioner's deep tendon reflexes and strength were normal and cranial nerves were intact. The provider, PA Larson, submitted a VAERS report noting Petitioner had "complaints of dizziness, altered gait, [and] decreased sensation but all tests and examination showed no deficits." Pet. Ex. 15 at 1.

Further, Petitioner's initial declarations report that his symptoms began immediately after vaccination. In his third declaration, Petitioner retracted his earlier statements and explained that he did not have a headache, eye pressure, nor other symptoms immediately following his

vaccination. Further, he averred that his dizziness and photosynthesis did not appear until "three or more days after he received the vaccine." Pet. Ex. 41 at ¶ 12. Petitioner stated that he provided inaccurate information in his first and second declarations in an "attempt to bolster [his] case" and stated he "took liberties" in making his initial symptoms appear worse. Id. at ¶¶ 8, 11.

Due to the inconsistency between Petitioner's initial declarations and the most contemporaneous medical record as well as Petitioner's retraction of his initial declarations, the undersigned gives little weight to information provided in Petitioner's declarations. Instead, the undersigned relies on the medical records filed in this case to determine Petitioner's post-vaccination condition.

Medical records generally "warrant consideration as trustworthy evidence." Cucuras, 993 F.2d at 1528. However, greater weight is typically given to contemporaneous records. Vergara 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."). Additionally, when a petitioner's testimony is inconsistent with and contradicted by the contemporaneous medical records, it is 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, 2014 WL 2795491, at *4. This finding also extends to the lay witness affidavits and testimony. Other special masters have been faced with similar situations and found the contemporaneous medical records more persuasive than the affidavits and testimonies of lay witnesses. See, e.g., Rote v. Sec'y of Health & Hum. Servs., No. 90-036V, 1992 WL 165970, *5 (Cl. Ct. Spec. Mstr. July 1, 1992) (finding the lay witness testimony insufficient to overcome the weight of the contemporaneous medical records); Bergman v. Sec'y of Health & Hum. Servs., No. 90-1252V, 1992 WL 78671, *4 (Cl. Ct. Spec. Mstr. Mar. 31, 1992) (same); Daiza v. Sec'y of Health & Hum. Servs., No. 90-1188V, 1992 WL 59709, *4 (Cl. Ct. Spec. Mstr. Mar. 5, 1992) (same).

Petitioner's next documented medical visit was seven months later, on January 6, 2019, when Petitioner presented to the emergency room with complaints of that he was lightheaded, nauseated, and had a "cluttered mind" that he reported began seven months prior. Pet. Ex. 4 at 12. Petitioner also reported weakness, dizziness, and gradual inability to work. His neurological examination was normal. At two subsequent visits, Petitioner again complained of dizziness, nausea, confusion, blurry vision, and loss of balance. His neurological examinations were normal at both visits.

On March 7, 2019, Petitioner was seen by his primary care provider who noted horizontal nystagmus. Petitioner was seen by a neurologist, Dr. Cruz, on March 13 who noted nystagmus, ataxia, and hyperreflexia. Dr. Cruz also noted that Petitioner was "able to walk and complete all [activities of daily living]." Pet. Ex. 3 at 244. Petitioner saw another neurologist on April 11, 2019 who documented nystagmus and "prominent functional gait with intentional falls." Id. at

224. On May 4, Petitioner saw a third neurologist, Dr. Nguyen, who again noted nystagmus. Dr. Nguyen's examination showed normal strength, normal coordination, and no ataxia. However, Petitioner had decreased vibration below his knees.

Petitioner had an MRI on May 6, 2019 which revealed "extensive supratentorial lesions, both enhancing and non-enhancing, that were suspicious for possible end stage[] MS." Pet. Ex. 3 at 204. At Petitioner's next neurology visit on June 3, he was diagnosed with MS with active inflammation by Dr. Sy. On July 29, 2019, Petitioner's treating neurologist, Dr. Sy, noted Petitioner had "aggressive" MS. Id. at 12.

Petitioner's medical records show a constellation of symptoms that became more pronounced between January and May 2019. Petitioner reported that he sought care in January 2019 after the symptoms he sought treatment for caused a gradual inability to work. Petitioner's first objective neurological symptom—nystagmus—appeared March 7, 2019. At his next visit, he also had ataxia and hyperreflexia. When Petitioner finally had an MRI in May 2019 it showed active lesions and characteristics of end-stage MS.

After the May 2019 MRI and June 2019 MS diagnosis, Petitioner was seen by numerous providers for MS; however, Petitioner had not started disease modifying therapy for his MS. Both parties' experts agree that Petitioner's clinical condition declined after the May 2019 MRI. Pet. Ex. 31 at 7 ("The clinical status of [Petitioner] has continued to worsen, and he has difficulty walking along with fatigue, vision problems, urinary and bowel incontinence, and vertigo. He has had multiple falls and is unable to maintain employment."); Resp. Ex. A at 7 (noting the post-May 2019 medical records "document disease progression and worsening exam findings[] [and] worsening MRI changes with more lesions overall as well as new active lesions"). And both parties' experts agree that Petitioner's current MS symptoms are permanent with Petitioner unlikely to regain pre-vaccination function.

C. Loving Factor Three: Does Petitioner's Current Condition (or Condition After Vaccination) Constitute a "Significant Aggravation" of His Condition Prior to Vaccination?

The next factor of the Loving test is to determine whether there is a "significant aggravation" of Petitioner's condition by comparing his condition before vaccination to his condition after vaccination. The statute defines "significant aggravation" as "any change for the worse in a pre-existing condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration in health." § 33(4).

Petitioner's first visit following vaccination was on May 16, 2018. He reported symptoms of dizziness and gait instability that occurred three days after vaccination. Examination revealed a positive Romberg's sign and diminished pinprick sensation on the left side of his face. Neither of the parties' experts opined that these two findings (positive Romberg's sign and diminished pinprick sensation on the left side of his face) established a "change for the worse . . . which result[ed] in markedly greater disability, pain, or illness accompanied by [a] substantial deterioration in health" so as to constitute a significant aggravation. § 33(4).

Instead, based on the facts and circumstances here and using the diagnostic definition of MS provided by Dr. Moses, Petitioner did not have a significant aggravation of his MS until 2019. Eight months after vaccination, Petitioner presented to the emergency room with complaints of weakness, dizziness and gradual inability to work. Petitioner saw numerous providers between January 2019 and June 2019. Petitioner's condition deteriorated over this time. On March 13, 2019, neurologist Dr. Cruz noted Petitioner could walk and perform activities of daily living. An MRI in May 2019 showed "extensive supratentorial lesions, both enhancing and non-enhancing, . . . suspicious for possible end stage[] MS." Pet. Ex. 3 at 204. After the May 2019 MRI, Dr. Sy opined Petitioner had experienced "progressive decline in function" and noted he required a cane to get around. Id. at 192. At the July 29, 2019 visit, Dr. Sy concluded Petitioner had aggressive disease, that he was no longer able to work due to his poor vision, and that he was "unlikely to recover all of his function." Id. at 12.

D. Loving Factor Four/Althen Prong One: Medical Theory of Causation

The fourth Loving factor has its origins in Althen prong one, and Petitioner must set forth a medical theory explaining how the received vaccine could have caused the sustained injury. Andreu, 569 F.3d at 1379; 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 at 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 undersigned finds Petitioner failed to provide preponderant evidence of a sound and reliable theory to explain how the Tdap vaccine can significantly aggravate MS. There are several reasons for this finding.

First, Petitioner's expert, Dr. Conte, put forward a theory of molecular mimicry as a mechanism to explain how the Tdap vaccine can significantly aggravate MS. In support of this theory, Dr. Conte explained that foreign antigen can induce autoimmunity through molecular mimicry as shown with EBV and MS. He provided medical literature discussing molecular mimicry in the context of EBV and MS. See, e.g., Pet. Exs. 36-39. Dr. Conte then analogized "the foreign antigen as a natural virus [e.g., EBV] and the foreign antigen as a vaccine." Pet. Ex. 31 at 11. He opined that autoimmunity could "presumably" be induced by a "vaccine-antigen" through the process of molecular mimicry, "but at much lower rates given that there is no opportunity for the vaccine to change its structure on its own as a virus can." Id.

While Dr. Conte acknowledged that an inactivated vaccine would behave differently than a live virus, he did not provide a sufficient explanation of how, or why, the Tdap vaccine could act like EBV to significantly aggravate MS. As Respondent's expert, Dr. Moses, explained, the immune response to a live virus is not analogous to the immune response to vaccination.

While 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. v. Sec'y of Health & Hum. Servs., No. 16-811V, 2021 WL 2708941, at *31 (Fed. Cl. Spec. Mstr. May 20, 2021) ("[T]hough 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, when evaluating whether petitioners have carried their burden of proof, special masters consistently reject "conclusory expert statements that are not themselves backed up with reliable scientific support." Kreizenbeck v. Sec'y of Health & Hum. Servs., No. 08-209V, 2018 WL 3679843, at *31 (Fed. Cl. Spec. Mstr. June 22, 2018), mot. for rev. denied, 141 Fed. Cl. 138, aff'd, 945 F.3d 1362 (Fed. Cir. 2020). The undersigned will not rely on "opinion evidence that is connected to existing data only by the ipse dixit of the expert." Prokopeas v. Sec'y of Health & Hum. Servs., No. 04-1717V, 2019 WL 2509626, at *19 (Fed. Cl. Spec. Mstr. May 24, 2019) (quoting Moberly, 592 F.3d at 1315).

Second, there are other Program cases where special masters have denied entitlement when asked to determine whether Tdap can cause or significantly aggravate MS. See Hunt v. Sec'y of Health & Hum. Servs., No. 12-232V, 2015 WL 1263356, at *16-18 (Fed. Cl. Spec. Mstr. Feb. 23, 2015) (finding Tdap, varicella, and meningococcal vaccines did not significantly aggravate the vaccinee's MS); Samuels v. Sec'y of Health & Hum. Servs., No. 17-071V, 2020 WL 2954953, at *1 (Fed. Cl. May 1, 2020) (finding the petitioner failed to establish a Tdap vaccine caused her MS); Pek v. Sec'y of Health & Hum. Servs., No. 16-0736V, 2020 WL 1062959, at *16-17 (Fed. Cl. Spec. Mstr. Jan. 31, 2020) (finding the petitioner failed to establish a Tdap or influenza vaccine caused her MS). The undersigned generally agrees with the reasoning in these cases.

There have also been cases decided by special masters in favor of petitioners on the issue of whether a Tdap vaccination can significantly aggravate MS where molecular mimicry was posited as the causal theory; however, these cases involved different facts and expert opinion evidence. See, e.g., Doles v. Sec'y of Health & Hum. Servs., No. 17-642V, 2021 WL 750416 (Fed. Cl. Spec. Mstr. Feb. 1, 2021), affirmed and reinstated by, No. 2023-2404, 2025 WL

1177875 (Fed. Cir. Apr. 23, 2025); Rothstein v. Sec'y of Health & Hum. Servs., No. 14-778V, 2023 WL 9186600 (Fed. Cl. Spec. Mstr. Dec. 15, 2023). In Doles, the special master found in favor of the petitioner on Althen prong one after determining the petitioner provided a "reasonable expert discussion of the mechanism of vaccine-affected inflammation leading to autoimmune CNS demyelination coupled with" the Langer-Gould et al. study. Doles, 2025 WL 1177875, at *18.

Here, like in Doles, Petitioner has provided Langer-Gould et al. in support of his significant aggravation claim. Unlike Doles, however, Petitioner has not provided sufficient expert discussion of the mechanism involved in his case. Instead, Petitioner's expert Dr. Conte merely noted that molecular mimicry could "presumably" work in the context of this case. Additionally, in Langer-Gould et al., the 11 patients with MS had their first CNS symptoms within 30 days of vaccination. In the present case, Petitioner did not have an objective manifestation of neurological symptoms until March 7, 2019, ten months after vaccination. Accordingly, Langer-Gould et al. provides little support for the present case.

Further, Doles is not binding on the undersigned, particularly given the facts of this case in which there was no objective manifestation of neurological impairment for ten months following vaccination. Cf. Doles, 2021 WL 750416, at *20 (noting the petitioner had an attack of CNS demyelination 42 days after her Tdap vaccination). Moreover, rulings and decisions by other special masters are not binding on the undersigned. See Boatmon, 941 F.3d at 1358; Hanlon v. Sec'y of Health & Hum. Servs., 40 Fed. Cl. 625, 630 (1998), aff'd, 191 F.3d 1344 (Fed. Cir. 1999).

In summary, Petitioner has failed to offer a sound and reliable medical theory in support of his claim. Thus, the undersigned finds Petitioner has failed to provide preponderant evidence with respect to the Loving factor four and Althen prong one.

E. Loving Factor Five/Althen Prong Two: Logical Sequence of Cause and Effect

Under Loving factor five and 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.

Regarding the fifth Loving factor/second Althen prong, the undersigned finds that Petitioner has failed to show by preponderant evidence that the Tdap vaccination significantly aggravated his MS.

First, Petitioner's post-vaccination clinical course was not consistent with significant aggravation. Petitioner's provider noted "all tests and examination showed no deficits" in a VAERS report submitted the same day as Petitioner's May 16, 2018 visit. And Respondent's expert, Dr. Moses, opined that Petitioner's complaints of dizziness and imbalance did not correspond to objective abnormalities on examination.

Next, after Petitioner's initial visit on May 16, 2018, Petitioner did not receive medical attention for seven months. While Petitioner saw providers in January and February 2019, his first objective neurological symptom—nystagmus—was not documented until March 7, 2019. Dr. Moses explained that the "first neurological event constitutes the first attack of the disease, in a patient later diagnosed with MS." Resp. Ex. A at 8 (citing Resp. Ex. A, Tab 1). According to the 2017 McDonald criteria, an attack, relapse, or exacerbation of MS is characterized by "objective findings . . . reflecting a focal or multifocal inflammatory demyelinating event in the CNS, developing acutely or subacutely, with a duration of at least 24 h[ours]." Resp. Ex. A, Tab 1 at 2. Here, Petitioner's first objective neurological finding occurred ten months after vaccination.

Moreover, while Petitioner's initial brain MRI showed extensive enhancing and non-enhancing supratentorial lesions, indicating an active inflammatory CNS process, this MRI was taken more than one-year post-vaccination. As Dr. Moses explained, active or enhancing lesions, typically resolve within four to six weeks. Accordingly, the undersigned cannot attribute the active lesions seen on MRI in May 2019 to Petitioner's April 2018 vaccination.

Petitioner's expert, Dr. Conte, opined that the large number of lesions present "[j]ust one year after vaccination" supports the casual role of vaccination. Pet. Ex. 31 at 12. However, while both experts note that there was large number of lesions present in the May 2019 MRI, both experts also acknowledge that MS lesions may be silent (or asymptomatic). Here both experts opined that most likely Petitioner had silent lesions prior to his vaccination. Accordingly, the undersigned finds that lesion load present in the May 2019 MRI does not provide evidence that Petitioner's vaccination on April 25, 2018 caused a significant aggravation of his MS.

For the above reasons, the undersigned finds that Petitioner's clinical course does not provide preponderant evidence of a logical sequence of cause and effect.

Regarding Petitioner's treating physicians, Petitioner's treating neurologist Dr. Sy expressed an opinion on causation. On July 29, 2019, Dr. Sy wrote "Various vaccinations are known to be associated with triggering MS relapses. When he received the vaccine, he was not

on disease modifying therapy, so he was at even more risk. Most likely, the tetanus shot in April 2018 was related to worsening of MS which caused deterioration in his functioning." Pet. Ex. 3 at 12. Dr. Sy's note attributing Petitioner's worsening to his vaccination appears to be based on Petitioner' history of present illness where Petitioner reported that his symptoms deteriorated after the Tdap vaccination. Dr. Sy first saw Petitioner on June 3, 2019. Thus, he did not have personal knowledge of Petitioner's history, including knowledge of the gap in time between vaccination and the first objective symptom of Petitioner's MS.

While Petitioner was seen by other treating neurologists and specialists who noted that Petitioner attributed his symptoms to the April 25, 2018 Tdap vaccination, no other treating provider appears to have provided an opinion on causation. Further, Dr. Sy continued to follow Petitioner from July 2019 through 2022 and did not opine on the etiology of Petitioner's MS in subsequent assessments. Instead, he noted that Petitioner "suspect[ed] symptoms started" after vaccination or noted that Petitioner "stated" symptoms started after vaccination. See Pet. Ex. 20 at 224; Pet. Ex. 23 at 149, 170, 303, 308.

Generally, treating physician statements are typically "favored" 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.'" Capizzano, 440 F.3d at 1326 (quoting Althen, 418 F.3d at 1280). However, no treating physician's views bind the special master, per se; rather, their views are carefully considered and evaluated. § 13(b)(1); Snyder, 88 Fed. Cl. at 746 n.67. "As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases." Welch v. Sec'y of Health & Hum. Servs., No. 18-494V, 2019 WL 3494360, at *8 (Fed. Cl. Spec. Mstr. July 2, 2019).

While Dr. Sy does initially endorse the casual role the Tdap vaccination in his assessment of Petitioner, he does not appear to reiterate this opinion over time. Later records from Dr. Sy only note that Petitioner suspected or stated that the April 2018 vaccination was associated with his MS symptoms. None of Petitioner's other treating neurologists endorsed the casual role of vaccination. Further, Dr. Sy's opinion does not appear to be supported by a complete knowledge of Petitioner's clinical history.

Treating physicians' "recitations of petitioner's medical history as he related it to them" do not reflect "the independent diagnostic conclusions drawn by the physicians and are therefore, of little evidentiary value." Bailey v. Sec'y of Health & Hum. Servs., No. 06-464V, 2008 WL 482359, at *7 (Fed. Cl. Spec. Mstr. Feb. 12, 2008) (citing Ryman v. Sec'y of Health & Hum. Servs., 65 Fed. Cl. 35, 41 (2005) ("[Vaccine] . . . case law expresses a preference for contemporary medical history, not subjective recounting.")). Further, physician opinions that merely reflect a petitioner's recounted medical history or that are based on incomplete medical records cannot establish causation. See, e.g., La Londe ex rel. M. L. v. Sec'y of Health & Hum. Servs., 110 Fed. Cl. 184, 206, 206 n.37 (2013), aff'd, 746 F.3d 1334 (Fed. Cir. 2014).

Accordingly, the undersigned finds that Petitioner's treating physicians did not provide preponderant evidence of vaccine causation.

For these reasons, the undersigned finds that Petitioner has failed to provide preponderant evidence of a logical sequence of cause and effect to satisfy his burden under Loving factor five/Althen prong two.

F. Loving Factor Six/Althen Prong Three: Proximate Temporal Relationship

The last element in the six-part Loving test has origins in Althen prong three. As stated in Loving, this element is "a showing of a proximate temporal relationship between vaccination and the significant aggravation." 86 Fed. Cl. at 144. Althen prong three requires Petitioner to establish a "proximate temporal relationship" between the vaccination and the injury alleged. Althen, 418 F.3d at 1281. A proximate temporal relationship has been equated to mean a "medically acceptable temporal relationship." Id. Petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disease'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 coincide with the theory of how the relevant vaccine can cause the injury alleged (under Althen prong one). Id.; Koehn v. Sec'y of Health & Hum. Servs., 773 F.3d 1239, 1243 (Fed. Cir. 2014); Shapiro, 101 Fed. Cl. at 542.

Based on the case law cited above, this factor/prong consists of two parts. Petitioner must first establish the time frame within which it is medically acceptable to infer causation. And secondly, he must show that the onset of the worsening or aggravation of his illness occurred during this time frame.

Relying on Langer-Gould et al., Dr. Conte opined that an onset period of less than 30 days after vaccination was temporally appropriate. Respondent's expert, Dr. Moses, opined that an onset of three days or less was "not enough time" for vaccination to cause symptoms of imbalance or neuritis described by Petitioner. Resp. Ex. A at 13.

Regarding onset, the undersigned finds that the initial manifestation of significant aggravation of Petitioner's MS occurred in March 2019 when objective neurological symptoms were first documented by his treating provider.

As discussed above, Petitioner first presented to health care provider on May 16, 2018, less than 30 days after his Tdap. At that visit, Petitioner reported dizziness and gait instability that he stated began three days after vaccination. Petitioner's neurological examination showed normal strength, normal deep tendon reflexes, and intact cranial nerves. While Petitioner had a positive Romberg's sign and diminished pinprick sensation on the left side of his face, the VAERS report submitted by his provider that same day noted "all tests and examination showed no deficits." Pet. Ex. 15 at 1. Dr. Moses opined that Petitioner's reported symptoms at this visit did not correspond to objective abnormalities on examination. And Dr. Conte did not opine that the positive Romberg's sign or diminished sensation constituted objective neurological symptoms.

Instead, Petitioner's first objective neurological symptom of MS (nystagmus) was documented in March 2019, ten months after vaccination. Relying on the 2017 McDonald

criteria, Dr. Moses explained that the "first neurological event constitutes the first attack of the disease[] in a patient later diagnosed with MS." Resp. Ex. A at 8. The 2017 McDonald criteria note that an attack, relapse, or exacerbation of MS is characterized by "objective findings . . . reflecting a focal or multifocal inflammatory demyelinating event in the CNS." Resp. Ex. A, Tab 1 at 2. Dr. Moses opined that nystagmus was Petitioner's first attack of MS with "objectively measurable neurological symptom." Resp. Ex. A at 9. An MRI taken May 6, 2019 (over a year after vaccination) showed active lesions consistent with MS. As active MS lesions resolve within four to six weeks, the undersigned cannot attribute the active lesions to his April 25, 2018 vaccination.

Although Dr. Conte opined that Petitioner's MS became "symptomatic very shortly after vaccination," he did not explain what symptoms constituted the onset of Petitioner's significant aggravation of MS nor did he provide medical literature establishing that the subjective symptoms reported at Petitioner's May 16, 2018 visit are associated with an attack or relapse of MS. See Pet. Ex. 31 at 12. Dr. Conte opined that Petitioner's MS occurred within the 30 day window consistent with Langer-Gould et al., but he did not provide persuasive evidence that Petitioner had symptoms consistent with MS within that time. Further, there is no MRI imaging to support an attack or relapse of MS in the thirty day period following vaccination.

Because the undersigned finds that Petitioner did not have a significant aggravation or relapse of his MS symptoms in the 30 days after vaccination, the undersigned finds that Petitioner has failed to provide preponderant evidence satisfying Loving factor six/Althen prong three. He has failed to show that he suffered a significant aggravation of his MS within the temporal period appropriate given the proffered theory of molecular mimicry.

Finally, even if Petitioner had demonstrated that he experienced a significant aggravation within 30 days of vaccination, he would still not have satisfied his burden of proof in this claim. Because Loving factor six/Althen prong three coincides with Loving factor four/Althen prong one, Petitioner's inability to meet his burden demonstrating how the Tdap vaccine can significantly aggravate MS effectively precludes him from being able to meet his burden under the third Althen prong/fourth Loving factor. Thus, because the undersigned found that Petitioner did not offer a sound and reliable theory of causation, he cannot demonstrate that his condition arose in a medically acceptable timeframe pursuant to that theory.

V. CONCLUSION

The undersigned extends her sympathy to Petitioner for the pain and suffering and disability that he has experienced due to his illness. The undersigned's 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 his Tdap vaccination significantly aggravated his MS. 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. [45]

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master

[45] Due to the sensitive nature of Petitioner's medical and psychiatric history, Petitioner is encouraged to seek redaction of his names to his initials in accordance with Vaccine Rule 18(c).