In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 16-1676V

Filed: October 23, 2023

DAVID GOODWIN,	*
Petitioner,	*
v.	*
SECRETARY OF HEALTH AND HUMAN SERVICES,	*
Respondent.	*

Maximillian J. Muller, Muller Brazil, LLP, Dresher, PA, for Petitioner
Catherine E. Stolar, U.S. Department of Justice, Washington, DC, for Respondent

DECISION ON ENTITLEMENT[1]

Oler, Special Master:

On December 21, 2016, David Goodwin ("Petitioner" or "Mr. Goodwin") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq*.[2] (the "Vaccine Act" or "Program"). The petition alleges that Mr. Goodwin developed Transverse Myelitis ("TM") as a result of the tetanus, diphtheria, acellular pertussis ("Tdap") vaccine he received on January 7, 2015. Pet. at 1, ECF No. 1.

[1] Because this Decision contains a reasoned explanation for the action in this case, it must be made publicly accessible and will be posted 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, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

Upon review of the evidence in this case, I find that Petitioner developed his condition before he received the Tdap vaccine, and further, that Petitioner, more likely than not, did not have transverse myelitis. The petition is accordingly dismissed.

I. Procedural History

Mr. Goodwin filed his petition on December 21, 2016. Pet. at 1. He filed medical records in support of his petition on that same day (Exs. 1-5) and on January 27, 2017 (Ex. 6). Petitioner filed a Statement of Completion on January 27, 2017. ECF No. 8. Respondent filed his Rule 4(c) Report on June 13, 2017 indicating that the "case is not appropriate for compensation under the terms of the Vaccine Act." Resp't's Rep. at 1, ECF No. 18.

After that, the parties filed a series of expert reports, each offering opinions from a neurologist and an immunologist. Petitioner relied upon the opinions of Dr. Akbari and Dr. Nahm while Respondent submitted reports from Dr. Donofrio and Dr. Tompkins. Exs. 7, 10, 15; Exs. A, C, D, F.

I referred the case to ADR on December 16, 2019. ECF No. 41. ADR was unsuccessful, and the case was returned to my docket on June 26, 2020. ECF No. 49.

On August 28, 2020, Petitioner requested that I schedule his case for an entitlement hearing. ECF No. 50. The parties filed pre-hearing briefs on June 30, July 14 and 22, 2021. ECF Nos. 63, 71, 72. I held an entitlement hearing via Zoom on July 28 and 29, 2021. Petitioner testified, and also presented testimony from Dr. Omid Akbari and Dr. Frederick Nahm. Dr. Peter Donofrio and Dr. Mike Tompkins testified on behalf of the Respondent.

After the hearing, Petitioner filed a supplemental expert report from Dr. Akbari (Ex. 71) and Respondent filed a responsive report from Dr. Tompkins (Ex. O).The parties then submitted post-hearing briefs. ECF Nos. 90, 96, 97. This matter is now ripe for adjudication.

II. Medical Records

A. Relevant Pre-Vaccination History

Petitioner was 48-years old and in relatively good health prior to the January 7, 2015 Tdap vaccination. *See* Ex. 1 at 1.

On January 7, 2015, Petitioner presented to Dr. David Gee for a routine medical exam. Ex. 1 at 9-12. Dr. Gee's history ("HPI") for Petitioner's ongoing issue included the following:

> ringing in [his] ears for many years after taking amoxicillin. [A]lso would like to discuss pain in left flank area. … Has had a little issue with the knee with cycling than running. Is seeing the orthopedist for this soon. Other issue has had a superficial burning sensation on the left side of the back and then radiated anteriorly in the midabdomen. Keeps him from sleeping. Not severe; low grade…. Present

> now for three weeks… No trauma or pulling noted of the area. No fall or trauma reported.

Id. at 9. Petitioner received a Tdap vaccine during his visit with Dr. Gee on January 7, 2015. *Id.* at 11. Regarding his back pain, Dr. Gee noted that Petitioner will do some lab work and then get an abdominal US (ultrasound) if not clearing. *Id.*

B. Post-Vaccination History

On January 19, 2015, Petitioner returned to Dr. Gee's office but was seen by Laura Poly, P.A. Ex. 1 at 7-8. Petitioner reported that he felt feverish after receiving the Tdap vaccine on January 7, 2015 and when he checked his temperature it was 101ºF. *Id.* at 7. Petitioner also reported having a tingling feeling in his hands and feet, and was experiencing fatigue and could work only four hours a day. *Id.* PA Poly assessed Petitioner as having paresthesia and indicated that it was "likely a side effect of vaccinations and expect full resolution over time." *Id.* at 7-8.

Petitioner followed up with Dr. Gee on January 20, 2015. Ex. 1 at 5-6. The HPI section indicated, "possible reaction to Tdap… no issues at injection site." *Id.* at 5. Petitioner's recorded symptoms were systemic symptoms of fatigue and myalgias, mild GI change with looser stools, upper extremity symptoms of paresthesias had mostly resolved, lower extremity numbness and tingling had persisted. *Id.* Specifically about his lower extremity sensations, Petitioner reported "both a numb and prickly sensation" in the right leg and "numbness" in the left; in the past 24 hours there have been progressive weakness in the right left and "a sense of it being more club like." *Id.* Dr. Gee remarked in the record, "not clear on etiology but some likely post viral or post vaccine neuritis." *Id.* at 6. Petitioner was prescribed a Medrol dose pack. *Id.*

On January 27, 2015, Petitioner presented to the St. Luke's Meridian Medical Center Emergency Department. Ex. 3 at 1-3. Petitioner's chief of complaint was "allergic reaction(s)" and "having neuro changes in BL (bilateral) legs." *Id.* at 1. Petitioner's self-reported history is as follows:

> The patient reports he got a DTAP shot on January 7th from his PCP. The patient states he was feverish and weak for 5 days after the shot. The patient then began to feel his bilateral toes go numb, followed by his bilateral feet. The patient consulted his PCP who prescribed him steroids. The patient felt no difference with the steroids. The numbness has spread up his leg. His left leg is currently numb up to his thigh. The patient states the numbness is "spotty" and he has areas in between the numbness that have full sensation. The patient states his right leg numbness is worse. He explains that the numbness is causing him weakness which causes difficulty walking. The numbness causes him to be appositionally unaware of where he is walking. Today he had difficulty going up and down the stairs. The patient states he has to rest often during the day. He reports his right side, right arm, and right facial area around the lips will begin to tingle if he exerts himself too much. The patient's wife states the left leg seems to be a few days behind the right leg in terms of spreading numbness. The patient's PCP wants him to see a neurologist.

Id. at 1-2. Petitioner had MRIs done for his cervical spine, which was largely normal, and thoracic spine, which identified an "abnormal T2 hyperintensity in the central thoracic spinal cord extending from the level of T7 to… T10. Abnormal patchy enhancement within the spinal cord at the level of T8 and T9." *Id*. at 7. The differential considerations included multiple sclerosis ("MS"), transverse myelitis, acute disseminated encephalomyelitis ("ADEM"), viral myelitis, and neuromyelitis optica ("NMO"). *Id*. at 7. Dr. Sergei Kashirny, a neurologist, was consulted for Petitioner's neurological issues and noted "presentation and clinical evaluation and radiological finding indicate [a]n acute myelitis. Etiology of this presentation is unclear. Differential diagnosis includes idiopathic myelitis, multiple sclerosis and neuromyelitis optica." Ex. 5 at 21.

Petitioner was subsequently transferred to the St. Luke's Regional Medical Center in Boise, Idaho where he was admitted for treatment for "acute myelitis." Ex. 3 at 11. Petitioner was started on Solu-Medrol and experienced "significant improvement" on January 28, 2015. *Id*. at 16. On January 29, 2015, Petitioner was discharged from the hospital with a diagnosis of: 1) acute myelitis of unknown etiology (question post vaccine, question multiple sclerosis, question neuromyelitis optic); 2) elevated blood glucose, likely secondary to stress; 3) and hypertension at presentation. Ex. 3 at 15. Petitioner reported a return to baseline with some tingling and numbness in his right foot. *Id*. at 16. Petitioner was to follow up in two weeks if his symptoms did not worsen. *Id*. at 17.

On February 12, 2015, Petitioner visited Dr. Kashirny for a follow-up. Ex. 2 at 6-7. Dr. Kashirny's notes for Petitioner's history of present illness reads: "had tdap vaccination and later developed mild flulike symptoms that led to development of low extremity numbness.… The patient received 3 days of IV Solu Medrol and reported initial improvement of his numbness… in the last 2 days he noticed increased [] numbness mostly in right leg compared to left leg." *Id*. Under "Plan," Dr. Kashirny noted that the etiology of Petitioner's idiopathic TM was unclear. *Id*. at 7. Dr. Kashirny noted that "possibly postvaccine inflammation is not completely excluded." *Id*. Dr. Kashirny ordered another MRI due to the fact that Petitioner's symptoms increased in intensity. *Id*. Other differential diagnoses included neoplasm and viral myelitis. *Id*.

Petitioner's follow-up MRI, performed on February 16, 2015, demonstrated an "interval decrease in the T2 hyperintensity within the thoracic spinal cord extending from the level of T7 to the level of T10." Ex. 2 at 14-15. There was no evidence of a new T2 hyperintensity. *Id*. at 15. Diagnostic considerations were still the same and included: MS, TM, ADEM, viral myelitis, and NMO. *Id*.

On July 24, 2015, Petitioner underwent a thoracic spine MRI. Ex. 2 at 10-11. This scan showed "[i]nterval resolution of previously seen cord signal abnormalities compatible with resolved transverse myelitis," and "[s]mall left paramedian disc ridge complex T4-5 unchanged." *Id*. at 11.

On July 28, 2015, Petitioner consulted with Dr. James Whiteside, a neurologist, at the St. Luke's Health Neurology Clinic. Ex. 5 at 11-13. These records note that Petitioner improved with steroids "but has had some recurrent symptoms recently." *Id*. at 11. The history further notes that "earlier this month he experienced some four limb tingling.… Transverse myelitis was interestingly diagnosed 20 days after the DTAP vaccination." *Id*. Dr. Whiteside recommended a

cervical spine MRI to look for recurrent myelitis and a visually evoked potentials for NMO. *Id.* at 13.

Petitioner had a visual evoked potential exam for "possible optic neuritis" with Dr. Kashirny on July 31, 2015 which was normal. Ex. 5 at 19.

On August 3, 2015, Petitioner had a cervical spine MRI that was normal and had "[n]o right eccentric transverse myelitis." Ex. 5 at 29-30.

On September 28, 2015, Petitioner followed up with Dr. Whiteside. Ex. 5 at 8-9. Petitioner reported intermittent numbness in his hands that wakes him from sleep at night. *Id.* at 8. Dr. Whiteside assessed Petitioner with resolved TM and informed Petitioner he believed his hand numbness was unrelated to his transverse myelitis and may have carpal tunnel syndrome. *Id.* at 9. Dr. Whiteside recommended bilateral wrist splints to be worn while sleeping. *Id.*

On February 4, 2016, Petitioner presented to St. Luke's Regional Medical Center Emergency Department in Boise with the following history of present illness:

> [E]valuation for upper back pain that began suddenly 4 days ago. The patient has [a] history of transverse myelitis which was first diagnosed 13 months ago. Since then he's intermittently experienced numbness in his hands… this discomfort has been constant, waxing and waning, better with movement, and described as dull. He states the discomfort is identical to when he had transverse myelitis a year ago but now the pain is located higher up his back between the shoulder blades…. Other associated symptoms include diarrhea. Symptoms are moderate in severity.

Ex. 3 at 141. Petitioner was given IV heparin and saline, and was discharged with a prescription of azithromycin. *Id.* at 143, 145. Petitioner underwent cervical and thoracic spine MRIs on February 5, 2016 which was largely normal with "stable mild degenerative changes." *Id.* at 150-152.

On March 1, 2016, Petitioner had a follow-up appointment with Dr. Whiteside. Ex. 5 at 4-5. Dr. Whiteside recorded Petitioner "developed recurrent interscapular pain in the setting of influenza earlier this month," and Petitioner's back pain "moves up and down his spine, and is associated with tenderness in the spinous processes." *Id.* at 4. Dr. Whiteside noted that Petitioner's recent MRI was normal and that there was no evidence of his TM recurring. *Id.* at 5.

On March 21, 2016, Petitioner returned to his PCP, Dr. Gee, for an annual physical. Ex. 12 at 13-15. Petitioner reported that he was "doing well" but still dealing with symptoms from his reaction to the Tdap vaccine he received last year and continues to have intermittent back pain and paresthesias and numbness in all four extremities. *Id.* at 13. Dr. Gee noted that Petitioner also stated "still in the process of working out the etiology of the sensory changes. Seeing [Dr. Whiteside] locally and then pending consult at U of Utah." *Id.* Dr. Gee's assessment of Petitioner's ongoing issues were hyperglycemia and myelitis. *Id.* at 14.

On July 19, 2016, Petitioner presented to Dr. Stacey Clardy, a neurologist, at the University of Utah Health Center Neurology Clinic for "idiopathic longitudinally extensive thoracic transverse myelitis." Ex. 4 at 6-9. Petitioner provided a history of his symptoms which included: tingling and weakness in his legs five days after Tdap vaccination, pain in the subscapular region in March 2015, severe back pain in June 2015, right eye pain in October 2015, which became intermittent pain in both eyes in January 2016, urinary frequency in the past 6 months, and the worsening of his symptoms in the setting of influenza A in February 2016. *Id.* at 6. Dr. Clardy recommended some additional testing but noted "[e]tiology post-infectious TM vs autoimmune" and added a differential of a vascular etiology during "dural AV fistula given chronic course, but seems less likely." *Id.* at 8-9. Dr. Clardy referred Petitioner to Dr. Judith Warner, a neuro-ophthalmologist. *Id.* at 13.

Petitioner was seen by Dr. Warner on September 27, 2016, at the University of Utah Moran Eye Center. Ex. 4 at 14-21. The HPI documented Petitioner's right eye pain from October 2015 as a "Dull ache from 3 to 5/10 in severity, faint initially, rubbing helps. … This pain lasted for a few days. These happen once a month for a week at a time, corresponds to the tingling and back pain." *Id.* at 15. Under the "Impression" section of the record, Dr. Warner observed square wave jerks, which "generally indicates cerebellar/brainstem dysfunction or can occur with age." *Id.* at 19. Dr. Warner's impression included: idiopathic transverse myelitis, square wave jerks "generally indicates cerebellar/brainstem dysfunction," right eye pain "could be due occasional dry eye syndrome or headaches/occipital spasm, and congenital cataracts." *Id.* at 19, 21. No follow up was booked with Dr. Warner. *Id.* at 21.

On December 15, 2016, Petitioner presented to Dr. Gee with digestive issues that started around a year prior. Ex. 12 at 11-12. Petitioner was assessed as having "right upper quadrant abdominal pain." *Id.* at 11.

Petitioner was seen by Dr. Gee on March 8, 2017 for liver pain. Ex. 12 at 9-10. Petitioner reported heartburn, right flank pain, irregular stools, and bloating. *Id.* at 9. Petitioner had discontinued use of gabapentin in November (2016) but still experienced reflux and occasional diarrhea. *Id.* Petitioner's lab work returned relatively normal. *Id.* at 9-10.

On April 20, 2018, Petitioner visited Dr. Gee's office but was seen by Michele Miles, P.A. Ex. 12 at 7-8. Petitioner complained of hip and back pain after a long mountain bike ride three weeks prior. *Id.* at 7. Petitioner stated that the pain was in his low back but radiated into the left buttock and thigh and the pain seems to have "settled" in the left hip, which he fractured years ago. *Id.* He was recommended physical therapy and home exercise after bike rides and a hip x-ray. *Id.*

On June 12, 2018, Petitioner returned to Dr. Gee for an annual physical. Ex. 12 at 4-6. Petitioner had no real issues addressed during this visit.

No other medical records relevant to my adjudication of this case were submitted.

III. Petitioner's Affidavit and Testimony

A. Petitioner's Affidavit

Petitioner signed his affidavit on April 27, 2018. Ex. 9 at 3. Petitioner averred that he changed jobs in December 2014 and his health insurance changed effective January 1, 2015. *Id.* at 1. Petitioner had no active PCP prior to 2015 so he selected Dr. Gee for a "base-line physical." *Id.* In presenting his prior medical history, Petitioner mentioned "a few incidental scrapes and some mild mid-back pain tied to a skiing injury more than 20 years earlier," that would manifest as pain or burning when he was out of shape. *Id.* Petitioner averred that no new symptoms prompted his visit with Dr. Gee and that it was a routine physical. *Id.*

Petitioner averred that he began to experience symptoms three to four days after this visit, which included pain at the injection site, fever, as well as tingling and numbness "further down than anything I had experienced to that point." Ex. 9 at 2.

Petitioner further averred that since developing his condition, he has "cyclically experienced numbness, tingling, and back pain that is very distinct and persistently painful, occurring every 3-5 weeks and lasting for about 4 weeks." Ex. 9 at 2. In terms of the location of the pain, Petitioner stated that "the tightness and pain move[] up and down my spine, but generally is around T-1-3 or sometimes in the mid C or, more rarely lower in the T-area." *Id.* Petitioner stated that the pain is different from the pain he experienced prior to January of 2015. *Id.*

Because of this pain, Petitioner averred that he cannot consistently work an eight-hour work day and that air travel is particularly difficult, due to the long sedentary flights. Ex. 9 at 2.

Petitioner reported that his influenza and strep throat infection in February 2016 brought the symptoms to their worst since January 2015 and have since stabilized but have not improved much since. Ex. 9 at 3. Petitioner also recounted that Dr. Clardy had told him that she did not believe his symptoms would subside and that he should expect it to be a part of his life. *Id.*

B. Petitioner's Testimony

Petitioner testified that he initially went to see a doctor because he had new insurance and thought he should get a physical. Tr. at 9. Petitioner explained that because he was seeing a new doctor, he gave him a history of past issues to establish a baseline. *Id.* Regarding pain in his left flank, Petitioner testified that he told Dr. Gee it was the result of a skiing accident, and it was a chronic issue since 1998. *Id.* at 10. Petitioner testified he received stitches after the accident, as he had hit his head with his ski, but had otherwise not received additional treatment. *Id.* at 11.

Petitioner testified about his doctor's visit on January 19, 2015. Tr. at 12. Petitioner reported that he felt feverish about two to three days after receiving the vaccine and felt numb and weak in his lower extremities, mostly in his right leg, but also sometimes in his left. *Id.* He was primarily concerned about the tingling sensation because he knew the fever and soreness were a common vaccine reaction. *Id.* at 12-13.

Petitioner returned to Dr. Gee the following day, on January 20, 2015, because his symptoms were getting worse and he had an upcoming business trip. Tr. at 15. Petitioner recalled "club-like" symptoms in his legs, testifying he felt that he couldn't control them. *Id.* He ended up

going to his business trip in Phoenix but was "unable to stay vertical" and would return to his hotel room to lay down to regain feeling in his legs. *Id.* at 17. Upon return from this business trip, Petitioner had difficulty climbing the stairs in his home and went to the ER. *Id.*

Upon admission to his local ER, Petitioner was sent to get an MRI immediately and was transferred via ambulance to St. Luke's Boise, which was a larger hospital with more capabilities. Tr. at 18-19. The neurologist, Dr. Kashirny informed Petitioner that his spinal tap results were negative, placed Petitioner on intravenous steroids, and told him that he had transverse myelitis. *Id.* at 20.

Petitioner was discharged on January 29, 2015 and remembered feeling "very good." Tr. at 20-21. Petitioner testified he felt that the tingling and numbness hadn't resolved but was "repressed" and that he could move around for a period of time. *Id.* at 21.

Petitioner testified that his next hospitalization was in February when he was sick with flu symptoms and a sore though and the "symptoms of [] transverse myelitis seemed to have come back more severely than usual." Tr. at 25. Tests for strep and influenza were positive but his MRIs were negative for TM. *Id.* at 26.

Petitioner explained that he sought a consultation with Dr. Stacey Clardy because one of the board members at the association he works for was an executive at the Mayo Clinic and recommended going to a research hospital for a follow-up. Tr. at 27. Petitioner described his symptoms during this time as pretty severe, and his back pain and leg tingling was worse when he was sick. *Id.* at 28. Mr. Goodwin stated that he would know when he was getting sick because his back pain would flare up more than usual. *Id.* at 29. Regarding his consultation with Dr. Clardy, Petitioner recalled that she told him that he would likely never fully recover from his condition. *Id.* at 29. Dr. Clardy indicated she could not rule out the vaccine based on his history. *Id*. at 29-30.

Petitioner testified that prior to the Tdap vaccine, he was a very active person, engaging in activities such as mountain biking, hiking, skiing, and backpacking. Tr. at 36. After receiving the vaccine, Petitioner's back pain and numbness prevent him from maintaining the same level of activity. *Id.* at 38. Petitioner explained that his current symptoms are an itching, pressure-like pain in his mid-back, followed by tingling in his legs. *Id.* at 37. His symptoms are exacerbated by extended hours sitting or standing, strenuous exercise, or heat; under these conditions, his legs will go numb. *Id.* at 38.

Petitioner testified about his back injury roughly 20 years ago. Tr. at 40. Petitioner stated he had a skiing injury that required stitches on his head. *Id.* at 40-41. When questioned about the left flank pain documented during the initial January 7, 2015 appointment with Dr. Gee, Petitioner testified that he did not recall actively experiencing the left flank pain at the time of the appointment. *Id.* at 41-46. Petitioner also physically indicated that his left flank pain was located approximately at the bottom of his rib cage. *Id.* at 46.

IV. Expert Opinions and Qualifications

A. Petitioner's Expert: Dr. Frederick Nahm

1. Qualifications

Dr. Frederick Nahm received a B.S in Philosophy and Neuroscience from the University of Michigan Ann Arbor and a M.S. and Ph.D. in neuroscience from the University of California San Diego. Ex. 11 (hereinafter "Nahm CV") at 1. Dr. Nahm received his medical degree from the University of Michigan. *Id.* Dr. Nahm is board certified in neurology and electrodiagnostic medicine. *Id.* at 3. He is the author of 12 papers in the fields of neurology and neurophysiology. Tr. at 63. Dr. Nahm is a consulting physician at Greenwich Hospital, and sees around 4,000 patients per year. *Id.* at 100, 122. He has treated 40-50 patients with TM since 2004. *Id.* at 99. I recognized Dr. Nahm as an expert in neurology. Tr. at 64.

2. Expert Report and Testimony

a. Expert Report

Dr. Nahm authored one expert report. Ex. 10 (hereinafter "Nahm Rep."). In his report, he opined that the Tdap vaccine caused Petitioner to develop TM. *Id.* at 1.

Dr. Nahm opined that Petitioner's left flank and radiating abdominal pain that he was experiencing on the day of vaccination was caused by a thoracic disc prolapse, which was visible in the initial thoracic MRI. Nahm Rep. at 5. Regarding Petitioner's diagnosis, Dr. Nahm criticized Dr. Donofrio's overreliance on the American Academy of Neurology's proposed criteria for transverse myelitis. *Id.* at 6; Transverse Myelitis Consortium Working Group, *Proposed diagnostic criteria and nosology of acute transverse myelitis*, 59 NEUROLOGY 499-505 (2002); (filed as Ex. A1) (hereinafter "AAN Criteria"). He emphasized that the AAN criteria are a framework and have not been validated. *Id.* Dr. Nahm disputed Dr. Donofrio's use of the AAN criteria as exclusionary for Petitioner's TM diagnosis based on the interval between onset of Petitioner's symptoms and maximal deficit. *Id.* Dr. Nahm agreed that Petitioner's upper extremity and ophthalmological symptoms could not be explained by the TM diagnosis but believed that existence of other symptoms or another condition does not nullify Petitioner's TM diagnosis. *Id.* at 7.

Dr. Nahm identified Petitioner's systemic reaction to the Tdap vaccine, which included fever, chills, loose stools, and myalgia, a few days after his vaccination as the onset of his TM. Nahm Rep. at 7. Petitioner's subsequent development of lower extremity weakness and radiological findings of an inflammatory thoracic cord lesion, and CSF evidence for high protein levels is consistent with a TM diagnosis. *Id.* Petitioner tested negative for NMO and MS, the only other possible neurological injuries he could have suffered. *Id.* Dr. Nahm opined that with a high degree of medical certainty and a preponderance of evidence, the Tdap vaccine caused Petitioner's injury. *Id.* at 8.

b. Testimony

Dr. Nahm defined transverse myelitis as an inflammatory condition of any part of the spinal cord (cervical, thoracic, or lumbar). Tr. at 66. Dr. Nahm stated that Petitioner met the AAN inclusionary criteria for TM. *Id.* at 69. Regarding the AAN criteria for a "clearly defined sensory

level," Dr. Nahm opined that Petitioner was not adequately tested, therefore he did not meet the criteria but believed it not to be exclusionary. *Id.* at 70. Dr. Nahm further opined that Petitioner did not meet any of the AAN exclusionary criteria. *Id.* at 73.

Dr. Nahm described how he diagnoses a patient with TM; he generally begins with the patient's history. Tr. at 74. He then testified that he would obtain other confirmatory tests such as spinal fluid (CSF), MRIs, and other blood tests. *Id.* When faced with a hypothetical patient who met all the inclusionary and exclusionary criteria except for one, Dr. Nahm testified that the AAN criteria only served as a guide and he would not use the criteria to diagnose a patient. *Id.* at 74-75. Dr. Nahm indicated that all three of Petitioner's neurologists diagnosed him with TM and he was unaware of any other potential diagnoses. *Id.* at 75.

Regarding Petitioner's preexisting back and flank pain that he described during his January 7, 2015 annual physical, Dr. Nahm testified that this pain was most likely caused by a disc bulge. Tr. at 82. Dr. Nahm discussed Petitioner's thoracic MRI to support his theory. *Id.* at 78-80; *see also* Ex. 3 at 7. He stated the MRI showed a central bulge effacing the covering of the spinal cord at the T4 region. Tr. at 79. Dr. Nahm also opined that a disc bulge can cause back pain without compression. *Id.* at 80; *see also* Ex. 1 at 9.

Dr. Nahm noted that Petitioner's prior left flank pain was inconsistent with a typical progression of TM. Tr. at 89-90. He claimed that the five-day onset of Petitioner's symptoms following his Tdap vaccine fits within the appropriate temporal window. *Id.* at 94. Moreover, Dr. Nahm claimed that Petitioner did not have any prior medical history or non-vaccine factors that could have caused TM. *Id.*

Dr. Nahm critiqued Dr. Donofrio's theory that Petitioner's upper extremity symptoms disqualified a diagnosis of TM. Tr. at 91. He stated that neither he nor the other treating physicians were clear where the upper extremity symptoms came from, but the other symptoms seemed unrelated to Petitioner's TM based on the location of his cord abnormalities. *Id.* at 91-92. Dr. Nahm claimed that the existence of other symptoms does not exclude Petitioner's TM diagnosis. *Id.* at 91.

Beyond the upper extremity pain, Dr. Nahm testified that Petitioner's ongoing symptoms such as exercise intolerance, numbness and tingling in the lower extremities, and gastrointestinal issues were consistent with TM. Tr. at 93. Dr. Nahm testified that the cyclical symptoms that Petitioner continues to experience are a common pattern depending on fatigue, diet, illnesses, or lack of sleep. *Id.*

Dr. Nahm conceded that Petitioner's disc bulge in the T4-5 region correlated to the nipple region on a dermatome chart, and not the mid-abdomen. Tr. at 116. Regarding Petitioner's other neurological symptoms, Dr. Nahm testified that tinnitus, right-sided face numbness, numbness in the hands, eye pain, and upper extremity pain were not consistent with TM. *Id.* at 102-03. Dr. Nahm agreed that TM is monophasic; TM generally exhibits as a monophasic process with a nadir three to four weeks after onset, but can be followed by a long and protracted ebbing and flowing of residual symptoms. *Id.* at 122. Dr. Nahm elaborated that Petitioner's TM was monophasic because there was a certain level of weakness that he did not experience again. *Id.* at 109.

B. Petitioner's Expert: Dr. Omid Akbari

1. Qualifications

Dr. Akbari received a B.S. and M.S. in medical and general microbiology from the University College London, and a Ph.D. in cellular and molecular immunology from the National Institute for Medical Research in London, England. Ex. 16 (hereinafter "Akbari CV") at 1. He is currently a tenured professor of immunology at the Keck School of Medicine at the University of Southern California, and an adjunct professor of pediatrics at the David Geffen School of Medicine at the University of California Los Angeles. *Id.* at 2. Dr. Akbari is actively involved in researching the role immune tolerance plays in triggering autoimmune disease and has specifically studied immune regulation/dysregulation after influenza infection and vaccination. *Id.* Dr. Akbari received the Henning Lowenstein Research Award in allergy and immunology in 2005. *Id.* at 1. Dr. Akbari participates as a reviewer on a number of publications including Nature Immunology, Nature Medicine, and PLoS one. *Id.* at 5. As of December 2020, Dr. Akbari had published 95 peer-reviewed papers. *Id.* at 9-16. I recognized Dr. Akbari as an expert in immunology. Tr. at 130.

2. Expert Reports and Testimony

Dr. Akbari authored three expert reports in this case and provided testimony at the entitlement hearing. Exs. 7, 15, 71.

a. First Report

In his first expert report, Dr. Akbari opined that the Tdap vaccine Petitioner received on January 7, 2015 caused him to suffer "neurological [injuries] including transverse myelitis." Ex. 7 (hereinafter "First Akbari Report") at 1. Dr. Akbari posited that molecular mimicry was the mechanism that induced Petitioner's TM. Dr. Akbari first provided a broad overview of the immune system but focused his opinion on T helper cells. *Id.* at 3-7, 5. A study (not filed in this case) identified Th17 cells, which secrete interleukin-17 ("IL-17"), as a molecule that induces inflammation. *Id.* at 5. Patients with GBS and CIDP "have increased levels of Th17 cells, which are known to cause inflammation in patients with MS, in their peripheral blood and CSF." *Id.* Dr. Akbari correlated this study involving GBS/CIDP to the case at hand by summarizing, "[i]n both acute myelitis and demyelination disease, research indicates that this balance is being disrupted leaving the host susceptible to an adverse autoimmune reaction upon stimulation of the immune system from infection or vaccination." *Id.*

Dr. Akbari cited to a number of studies that show that tetanus toxoid containing vaccines "are antigenically complex and capable of cross-reactivity with various biomolecules including DNA and bacterial toxins." First Akbari Rep. at 10; *see also* Inic-Kanada, et al., *Murine Monoclonal Antibody 26 Raised Against Tetanus Toxoid Cross-Reacts with b2-Glycoprotein I: Its Characteristics and Role in Molecular Mimicry*. AM J REPROD IMMUNOL. 2009;61(1):39-51. (filed as Ex. 41) (hereinafter "Inic-Kanada"). In one such study, blood samples were taken from participants one week post-vaccination and revealed the antibodies could cross-react with epitopes and self-antigens from tetanus and diphtheria toxoid. *Id.* at 11.

Dr. Akbari opined that host susceptibility to "the development of Multiple Sclerosis and Neuromyelitis is arguably one of the most important factors in the development of Multiple Sclerosis and Neuromyelitis independent of the initiating pathologic cause." First Akbari Rep. at 11. Dr. Akbari identified the Epstein Barr virus as a microbe that can induce neurological disease but added that not all people exposed to the Epstein Barr virus develop neurological injuries, therefore there was high variability in host susceptibility. *Id.* Dr. Akbari also noted that MS and neuromyelitis occur within families, which indicates there may be a genetic factor which has not been identified. *Id.* Wide genetic diversity can explain why reactions to vaccines are so rare. *Id.* Dr. Akbari concluded that the Tdap vaccine cause Petitioner's TM. *Id.* at 12.

b. Second Report

In his second expert report, Dr. Akbari responded to Dr. Tompkins' first expert report (Ex. D). Ex. 15 ("Second Akbari Rep."). Dr. Akbari explained the importance of regulatory T cells in maintaining order in the immune system. *Id.* at 2. He opined that Dr. Tompkins takes a narrow view of the regulatory role of Treg cells in the immune system, stating that this is an evolving area of research. *Id.* at 1-2. Dr. Akbari cited several studies to explain how disruption of immune homeostasis, specifically between pro-inflammatory T helper cells and regulatory T cells can trigger the onset of pathological disease such as TM. *Id.* at 1-3.

Dr. Akbari disagreed with Dr. Tompkins' argument that the lack of demonstrated cross-reactivity between the specific pathogens and pathogenic protein mean that the theory is either incorrect or implausible. Second Akbari Rep. at 4-5. Dr. Akbari explained that current research recognizes the ability of a single T cell to respond to various peptides, making cross-reactivity a more common occurrence. *Id.* at 4. Dr. Akbari claimed new research challenging the requirement for "significant" sequence homology for cross-reactivity to occur. *Id.* He opined that there is scientific support for molecular mimics after receipt of a vaccine. *Id.* at 4.

Dr. Akbari stated that the complex nature of the Tdap vaccine can dysregulate an immune response. Second Akbari Rep. at 6. He cited to the Sutjita paper showing the cross-reactive capabilities of antibodies derived from immunization with tetanus and diphtheria toxoids. *Id.* at 7; *see also* Sutjita et al., *Polyspecific human and murine antibodies to diphtheria and tetanus toxoids and phospholipids*. CLIN EXP IMMUNOL. 1988;73(2):191-7 (filed as Ex. 42) (hereinafter "Sutjita"). He also argued that the aluminum adjuvant in tetanus vaccines can induce acute and chronic inflammatory disorder through secretion of IL-1β and IL-18 from dendritic cells. *Id.*

Dr. Akbari reiterated his opinion that the Tdap vaccine induces a subset of T helper cells called Th17 cells, which are involved in the pathogenesis of autoimmune diseases, including TM. *Id.* at 7. However, he clarified that this area of immunology requires additional research. *Id.*

Dr. Akbari presented the Agmon-Levin and Moro papers as proof that the Tdap vaccine can cause TM. Second Akbari Rep. at 9; *see also* Agmon-Levin et al., *Transverse myelitis and vaccines: a multi-analysis*. LUPUS 2009;18(13):1198-204. (filed as Ex. 62) (hereinafter "Agmon-Levin"); Moro et al., *Safety Surveillance of Diphtheria and Tetanus Toxoids and Acellular Pertussis (DTaP) Vaccines*. PEDIATRICS 2018;142(1) (filed as Ex. 63) (hereinafter "Moro"). Dr. Akbari was not persuaded by the Baxter study, presented by Dr. Tompkins, which analyzed nearly

64 million vaccine doses and found only 7 TM cases. *Id.* at 9; *see also* Baxter et al., *Acute Demyelinating Events Following Vaccines: A Case-Centered Analysis.* CLIN INFECT DIS. 2016;63(11):1456-62 (filed as Ex. C2) (hereinafter "Baxter"). Dr. Akbari instead argued that the study showed that ADEM (acute disseminated encephalomyelitis) did have an association with the Tdap vaccine. *Id.* at 9. Dr. Akbari criticized the Baxter study as lacking focus and sensitivity and therefore opined that the findings did not overcome the credible case reports of the Tdap vaccine causing TM from the Agmon-Levin and Moro papers. *Id.* at 9-10.

c. Testimony

Dr. Akbari testified that the Tdap vaccine Petitioner received on January 7, 2015 caused his TM through molecular mimicry. Tr. at 131. Dr. Akbari relied on a PowerPoint (filed as Ex. 70) during his testimony. Dr. Akbari began by explaining how the Tdap vaccine interacts with the immune system. *Id.* at 132-35. He first explained how the tetanus toxin binds to the gangliosides in the nervous system. *Id.* at 133. He then described how the innate immune system triggers the production of cytokines such as IL-1 and IL-6, and T-cells. *Id.* at 135. He further testified that the IL-1 and IL-6 cytokines play a role in creating flu-like symptoms post-vaccination. *Id.* at 136.

Dr. Akbari then detailed the different medical literature he relied upon, including the Inic-Kanada, Sutjita, and Volk articles. Tr. at 137-38. He cited the different factors that lead to autoimmunity following a Tdap vaccine, such as toxins binding to gangliosides, the recruitment of proinflammatory cells, and cross-reactivity. *Id.* at 138.

Dr. Akbari opined that Petitioner's TM was a result of molecular mimicry. Tr. at 143. In support of his molecular mimicry theory, Dr. Akbari cited the Kohm article providing evidence for sequence homology and cross-reactivity which can cause pathologies. *Id.* at 148 (citing Ex. 30, Kohm et al., *Mimicking the way to autoimmunity: an evolving theory of sequence and structural homology.* TRENDS MICROBIOL. 2003;11(3):101-5). Dr. Akbari also described the relationship between individuals with Campylobacter Jejune and demyelinating GBS to further provide an example of molecular mimicry in vaccine-induced demyelinating disease. *Id.*

Dr. Akbari testified about the role of regulatory T-cells in controlling a dysregulated immune response because of their anti-inflammatory properties. Tr. at 150. He claimed that the impairment of regulatory T-cells is another causal mechanism in demyelinating diseases. *Id.* He opined that an imbalance between anti-inflammatory regulatory T-cells and pro-inflammatory T-effector cells can also lead to autoimmune disease. *Id.* at 151-52. In support of this theory, Dr. Akbari cited numerous articles in which an imbalance between regulatory T-cells and T-effector cells existed in different autoimmune or demyelinating disorders. *Id.* at 161 (citing Ex. 17, Anderton et al., *Regulatory T cells in the control of inflammatory demyelinating diseases of the central nervous system.* CURR OPIN NEUROL. 2008;21(3):248-54; Ex. 18, Kleinewietfeld et al., *Regulatory T cells in autoimmune neuroinflammation.* IMMUNOL REV. 2014;259(1):231-44; Ex. 20, Gratz et al., *Cutting edge: Self-antigen controls the balance between effector and regulatory T cells in peripheral tissues.* J IMMUNOL. 2014;192(4):1351-5; Ex. 21, Wang et al., *The regulatory T cells in anti-influenza antibody response post influenza vaccination.* HUM VACCIN IMMUNOTHER. 2012;8(9):1243-9. (hereinafter "Wang"); Ex. 22, Brill et al., *Foxp3+ regulatory T cells expression in neuromyelitis optica spectrum disorders.* MULT SCLER RELAT DISORD. 2019;30:114-8).

Dr. Akbari cited the Journal of Experimental Medicine in support of his theory of causation, claiming that T-effector cells are induced by the innate immune response after vaccination, and in turn attack the body. Tr. at 153 (citing Ex. 49, Wagner et al., *Pathogenic T cell cytokines in multiple sclerosis.* J EXP MED. 2020;217(1) (hereinafter "Wagner"). Regarding TM, Dr. Akbari testified that Th17 is the main T-effector cell in demyelination. *Id.*

Regarding the role of regulatory T-cells in vaccinations, Dr. Akbari cited the Wang article in which vaccination can cause induction of pathogenic T-effector cells because of the impairment of regulatory T-cells. Tr. at 162. He posited that this article further proves that any issue with regulatory T-cells due to genetic predisposition, environmental exposure, age, or other factors can lead to demyelinating disease. *Id.*

Dr. Akbari continued to cite a number of medical articles in support of his theory of molecular mimicry causing demyelinating disease. Tr. at 154 (citing Graber; Ex. 46, Kunkl et al., *T Helper Cells: The Modulators of Inflammation in Multiple Sclerosis.* CELLS 2020;9(2); Ex. 47, Dalakas, *Future perspectives in target-specific immunotherapies of myasthenia gravis.* THER ADV NEUROL DISORD. 2015;8(6):316-27; Ex. 48, Profaci et al., *The blood-brain barrier in health and disease: Important unanswered questions.* J EXP MED. 2020;217(4); and Wagner). Specifically, he cited studies in which the cerebral spine fluid samples showed increased cytokines in patients with demyelination. *Id.* at 154-55 (citing Ex. 59, Dixit et al., *Cytokines and matrix metalloproteinases in the cerebrospinal fluid of patients with acute transverse myelitis: an outcome analysis.* INFLAMM RES. 2016;65(2):125-32).

Dr. Akbari testified that one can generally anticipate swelling, redness, fatigue, and fever immediately following the Tdap vaccine, indicating activation of the innate immune system. Tr. at 166. He stated that, if there were an imbalance between the T cells, then the innate immune cells and inflammasomes would become active five to seven days following vaccination and then rapidly decline. *Id.* Following this decline, Dr. Akbari testified that Th17 and Th1 cells would begin to attack the myelin and nervous system about ten to twelve days after vaccination, furthering the demyelinating disease. *Id.* Finally, he stated that tingling would generally begin twelve days following vaccination. *Id.* at 167. Dr. Akbari testified that Petitioner began experiencing tingling around nine days following his vaccination, which conforms with the general sequence he cited. *Id.* Dr. Akbari conceded that he did not include analysis of Petitioner's back or left flank pain prior to his vaccination when arriving at this estimate date of onset. *Id.* at 186. Dr. Akbari explained that it is possible to get a fever as soon as one day following vaccination. *Id.* at 194. However, he also agreed with Dr. Nahm that the symptoms of demyelination and adaptive immune response arise between four to 26 days after vaccination. *Id.*

Dr. Akbari summarized a number of studies he had previously cited in his first two expert reports. Regarding the Agmon-Levin article, Dr. Akbari cited the 37 reported cases of TM following vaccination between 1970 and 2009. Tr. at 172. Out of those 37 cases, Dr. Akbari confirmed that around four or five were related to tetanus toxin containing vaccines. *Id.* at 189. He further stated that the Agmon-Levin study proved a temporal causal relationship. *Id.* at 191. Dr. Akbari also cited the Moro article, discussing the reported adverse effects of the Tdap vaccine, with 25% of the adverse effects localized to the nervous system. *Id.* at 172-73. He further testified

that the Moro article shows a temporal and causal relationship between the Tdap vaccine and demyelinating disease. *Id.* at 174.

d. Third Report

Dr. Akbari filed a final expert report after the entitlement hearing. Ex. 71 (hereinafter "Third Akbari Report"). Dr. Akbari elaborated on the effects of aluminum salt, a component of the Tdap vaccine, that stimulates the innate immune system. *Id.* at 3. Dr. Akbari cited to two papers that he stated demonstrate the Tdap vaccine and adjuvants induce secretion of IL-1β, IL-6, and IL-18, which increase Th17 levels. *Id.*; *see also* Kool et al., *Alum adjuvant: some of the tricks of the oldest adjuvant.* J MED MICROBIOL. 2012;61(Pt 7):927-34 (filed as Ex. 82); da Silva et al., *Th1/Th17 polarization persists following whole-cell pertussis vaccination despite repeated acellular boosters.* J CLIN INVEST. 2018;128(9):3853-65 (filed as Ex. 83). Dr. Akbari remained steadfast in his opinion that Th17 levels are increased in patients with demyelinating diseases, like MS and TM. *Id.* at 7.

Finally, Dr. Akbari lamented that rare diseases inherently have fewer data points to rely on, and often do not get published because of lesser statistical power. *Id.* at 13-15. Dr. Akbari stated his opinion remained unchanged and that the believed that the January 7, 2015 Tdap vaccine more like than not caused Petitioner's TM. *Id.* at 16.

C. Respondent's Expert: Dr. Peter Donofrio

1. Qualifications

Dr. Donofrio received his B.S. from the University of Notre Dame and his M.D. from the Ohio State University School of Medicine. Ex. B (hereinafter "Donofrio CV") at 1. After medical school, Dr. Donofrio completed his residency in neurology from the University of Michigan Medical Center in 1981, followed by a neuromuscular fellowship in 1982. *Id.* at 2. Dr. Donofrio is board certified in internal medicine, neurology, electrodiagnostic medicine, and neuromuscular medicine. *Id.* Dr. Donofrio is currently Professor Emeritus of Neurology at Vanderbilt University School of Medicine; he retired as a full Professor in 2021. *Id.* at 2-3. He also served as the Director of the Neuromuscular Program, the Director of the EMG Laboratory, Director of the Amyotrophic Lateral Sclerosis ("ALS") Clinic, and Vice Chairman of the Compliance and Quality and Assessment at Vanderbilt University Medical Center. *Id.* Dr. Donofrio is a member of the Medical Advisory Committee of the GBS/CIDP International Foundation. *Id.* at 8. He has authored over 100 articles in the field of neurology, with a focus on neuromuscular disorders. *Id.* at 12-21. I recognized Dr. Donofrio as an expert in the field of neurology, spinal cord disease, and neuroinflammatory disease. Tr. at 208, 213.

2. Expert Reports and Testimony

Dr. Donofrio authored two expert reports and testified at the entitlement hearing. Exs. A, C.

a. First Report

In his first report, Dr. Donofrio concluded that Petitioner did not suffer from TM.[3] Ex. A (hereinafter "First Donofrio Report") at 8. Dr. Donofrio stated that Petitioner's prior symptoms of left flank pain and superficial burning sensation were the initial presentation of myelitis, which preceded the vaccination. *Id.* at 6. Dr. Donofrio further opined that any symptoms above the T7 region, such as Petitioner's hand tingling and numbness could not be attributed to TM. *Id.* Dr. Donofrio posited that Petitioner's upper extremity symptoms could be indicative of issues with the central nervous system or the cervical spinal cord. *Id.* Moreover, Dr. Donofrio pointed out that Petitioner's repeat thoracic MRI scan on February 8, 2015, showed resolution of his prior cord abnormalities. *Id.* Dr. Donofrio opined that new TM symptoms would not be expected given the resolution of cord abnormalities. *Id.*

Dr. Donofrio identified a number of symptoms that do not satisfy the criteria for acute transverse myelitis published by the Transverse Myelitis Consortium Working group, such as no clearly defined sensory level and no nadir between four hours and 21 days following onset of symptoms. First Donofrio Rep. at 7; AAN Criteria. According to Dr. Donofrio, Petitioner did not have serological testing to eliminate other connective tissue diseases, which is part of the AAN exclusionary criteria. *Id.*

b. Second Report

Dr. Donofrio's second expert report responded to Dr. Nahm's second expert report. Ex. C (hereinafter "Second Donofrio Report") at 1. Dr. Donofrio clarified that Petitioner's TM diagnosis was presumed based on parts of his clinical course, especially his hospital visit on January 20, 2015, however evaluating the clinical course in its totality presents a different clinical picture. *Id.* at 1-3. Dr. Donofrio identified the same symptoms as in his first report as not clearly part of the TM clinical course. *Id.* at 1-3. Dr. Donofrio also disagreed with Dr. Nahm's assertion that Petitioner's symptoms began four days after vaccination; Petitioner had a documented history of three weeks of left flank pain, and separately documented superficial burning sensation radiating to his mid-abdomen on the day of vaccination. *Id.* at 4-5. Dr. Donofrio summarized his opinion as 1) Petitioner had symptoms three weeks prior to vaccination; 2) his symptomology does not satisfy the AAN diagnostic criteria for idiopathic TM; 3) many connective tissue or other autoimmune disorders were not tested for; and 4) Petitioner's neurological symptoms above the T7-10 levels could not have been caused by TM. *Id.* at 5.

c. Testimony

Dr. Donofrio testified that Petitioner suffered from a myelitis unrelated to the January 7, 2015 Tdap vaccination. Tr. at 214.

Dr. Donofrio described TM as a monophasic disease, meaning it is a single illness with a distinct beginning and ending with no recurrence. Tr. at 210. He also explained that nadir is the point of the most severe symptoms or manifestation of the disease. *Id.* Dr. Donofrio testified that onset to nadir within 21 days is a significant component in a TM diagnosis. *Id.* at 211.

[3] As discussed later in this Decision, Dr. Donofrio distinguished between TM and myelitis.

Dr. Donofrio testified that he uses the AAN Criteria for idiopathic TM when diagnosing patients. Tr. at 210. He explained that the AAN Criteria were created by neurologists with expertise in spinal cord disease to aid clinicians in evaluating patients with possible idiopathic TM. *Id.* at 236, 240. Dr. Donofrio admitted that in an academic setting, he applies the AAN guidelines rather rigidly to avoid making an incorrect diagnosis. *Id.* at 273. Dr. Donofrio accepted that all three treating neurologists and Petitioner's expert agreed that Petitioner had TM but reiterated that he believes Petitioner had a myelitis and that not enough testing had been done to determine the cause of the myelitis. *Id.* at 270-71.

Dr. Donofrio provided a review of the records that he believed were most relevant in this case. Dr. Donofrio identified Petitioner's superficial burning and radiating pain in his mid-abdomen as neurological symptoms. Tr. at 215-16. Dr. Donofrio used a dermatome chart to discuss where certain areas of the body correlated to the spinal cord. *Id.* at 217. He testified that Petitioner's abdominal pain would manifest in the T7-10 level of the spinal cord and an abnormality at that range was identified on Petitioner's MRI scan. *Id.* at 218-19. Dr. Donofrio disagreed with Dr. Nahm's claim that Petitioner's disc bulge at T4-5 would manifest as mid-abdomen pain because radicular pain around T4 and T5 corresponded to the nipple area of the abdomen. *Id.* at 219. Dr. Donofrio noted that neurological symptoms can be hard to localize and can overlap in dermatomes. *Id.* at 262. However, he explained that an overlap can lead to referred pain, where pain in one region radiates to another part of the body because it shares a similar dermatome; Dr. Donofrio reiterated that he would not expect to see overlap from T4-5 to the T7-10 region. *Id.* at 280.

In discussing Petitioner's affidavit, Dr. Donofrio opined that Petitioner's superficial burning sensation was an early manifestation of myelitis and that this diagnosis is consistent with the dermatome level of the spinal cord lesion. *Id.* at 224. Dr. Donofrio added that in his experience, TM symptoms are not cyclical, as described by Petitioner in his affidavit. *Id.* at 227. He also explained that Petitioner's ability to ski, hike, and mountain bike are an important aspect of a functional assessment, which also does not support a TM diagnosis. *Id.*

Dr. Donofrio testified that the sensory levels are an important inclusionary criterion when diagnosing for TM, however, Petitioner was never tested for sensory levels, and there is no evidence concerning whether he was experiencing normal sensation in his abdomen or back. Tr. at 237-38.

Dr. Donofrio testified that Petitioner was not serologically tested for 10 to 11 illnesses that could have explained Petitioner's symptoms. Tr. at 239. Petitioner had tingling in his fingertips and mouth which are inconsistent with TM at the level of T7-T10. *Id.* at 230, 41. As a treating physician, Petitioner's symptoms would make him look to other causes for the myelitis other than TM. *Id.* Dr. Donofrio also noted that Petitioner's cervical spine and brain MRI did not show any abnormalities that would explain his upper extremity symptoms. *Id.* at 240-41. Dr. Donofrio added that Petitioner's recurring interscapular pain, back pain, and hand tingling following an influenza injection is also significant because it indicated other causes for TM, particularly NMO or MS. *Id.* at 243.

Dr. Donofrio opined that Petitioner had a number of other symptoms that could be related to a viral illness preceding his 2016 myelitis. Tr. at 232-34. Dr. Donofrio identified Petitioner's shortness of breath as a possible upper respiratory infection or pneumonia; Petitioner also had a sore throat, cough, dyspnea, neck pain, gray phlegm, and fever of 101º F. *Id.* at 232-33 (citing Ex. 3 at 141). Dr. Donofrio opined that it was notable to him that Petitioner had reported that his pain in February 2016 was similar to that which he experienced 13 months prior; Dr. Donofrio believed that his evaluation at the hospital during January 2015 could have been incomplete and could have been the cause of his TM. *Id.* at 234.

Dr. Donofrio stated that Petitioner's nadir was on approximately January 27, 2015, because he was only hospitalized once. *Id.* at 257-58. However, Dr. Donofrio still posited that Petitioner's symptoms were probably due to a viral illness, but his development of the illness is difficult to determine because of his incomplete medical history. *Id.* at 260. Dr. Donofrio testified that, despite what the recovery looks like, once a patient recovers from TM, they do not get worse again. *Id.* at 275. He claimed that 1/3 of TM patients fully recovered, 1/3 recovered with a moderate disability, and 1/3 recovered with a severe disability. *Id.* at 276. However, he stated that one would expect to see evidence of a thoracic lesion if someone was still experiencing symptoms. *Id.* He related the concepts of nadir and monophasic TM, stating that when a person reaches a nadir and begins to recover afterwards, they would not experience a worsening symptoms. *Id.*

Dr. Donofrio testified concerning the medical literature submitted by both parties on the Tdap vaccine and TM. Tr. at 243-46. He summarized that the Agmon-Levin paper as a retroactive meta-analysis. *Id.* at 244. He also testified that the study found 37 cases of TM occurring post-vaccination over 39 years, with only three of those cases relating to the Tdap vaccine or tetanus toxoid. *Id.* He criticized the study for counting cases of TM almost nine years following a patient's vaccination. *Id.* Dr. Donofrio also pointed out that the study clarified that the causality was accepted only in the case of the oral polio vaccine, not for any other vaccines. *Id.* at 246. Dr. Donofrio believed that the Baxter paper was a more persuasive epidemiological study, as it looked at 64 million vaccinations and TM and found no increased incidence of TM after any of the 64 million vaccinations, which included the Tdap vaccine and other vaccines with the tetanus toxoid. *Id*. at 246-47.

Dr. Donofrio reiterated his opinion that Petitioner did not suffer from an idiopathic TM and that his myelitis was incompletely evaluated because it did not fully assess all of the AAN Criteria with inclusionary and exclusionary criteria. Tr. at 244. Dr. Donofrio mentioned that TM caused by a separate disease can be treated, but idiopathic TM does not have a cure because the cause is unknown. *Id.* at 252. Dr. Donofrio specified that the difference between TM and myelitis due to other diseases is that myelitis is a manifestation of another illness while TM is idiopathic. *Id.* at 272. He testified that myelitis is a general term for inflammation of the spinal cord while transverse myelitis is defined as inflammation across both sides of the spinal cord. *Id.*

Dr. Donofrio also testified that for TM patients who recover but have lingering symptoms, one would be able to see evidence of a thoracic lesion on a MRI, however there was no evidence of a lesion or abnormality on Petitioner's July 2015 MRI. Tr. at 280.

D. Respondent's Expert: Dr. S. Mark Tompkins

1. Qualifications

Dr. S. Mark Tompkins received a B.S. in microbiology from the University of Illinois - Urbana and then he received a Ph.D. in Immunology from Emory University in Atlanta. Ex. E (hereinafter "Tompkins CV") at 1. Dr. Tompkins' research is focused on viral immunology, host response to infections, and vaccine development. Tr. at 289-90. Dr. Tompkins received his postdoctoral training at Northwestern University Medical School with a focus on immunological mechanisms of induction of autoimmune disease, specifically interrogating autoimmune and virally induced encephalomyelitis. Tr. at 293. He is currently a Professor and Assistant Department Head in the Department of Infectious Diseases at the University of Georgia, Athens. Tompkins CV at 2. Dr. Tompkins has also received the Charles C. Shepard Award for his collaborative work with the CDC. *Id.* at 3. Dr. Tompkins has authored approximately 90 peer-reviewed papers. Tr. at 299; *see also* Tompkins CV at 29-40. I recognized Dr. Tompkins as an expert in the field of immunology and molecular pathogenesis. Tr. at 300, 307.

2. Expert Reports and Testimony

Dr. Tompkins authored three expert reports in this case and testified at the entitlement hearing. Exs. D, F, O.

a. First Report

In his first expert report, Dr. Tompkins deferred to Dr. Donofrio regarding Petitioner's diagnosis. Ex. D ("First Tompkins Rep.") at 3. Dr. Tompkins focused his expert report on rebutting Dr. Akbari's molecular mimicry theory. *Id.*

Dr. Tompkins began by analyzing whether there is a known association between vaccinations and transverse myelitis. First Tompkins Rep. at 3. Dr. Tompkins cited to the Agmon-Levin and Baxter studies, which found only a few cases of TM after vaccination, which the authors concluded were not causative. *Id.* at 3-4. He next addressed Dr. Akbari's molecular mimicry theory. Dr. Tompkins criticized molecular mimicry as a generally unproven theory. *See id.* at 4. Dr. Tompkins also stated that the Epstein-Barr virus and MS/neuromyelitis example that Dr. Akbari provided were very different from the case at hand, in that infectious etiologies (not vaccinations) are known to be associated with autoimmune diseases. *Id.*

Specific to the Tdap vaccine, Dr. Tompkins opined there is little evidence that the tetanus toxoid can elicit a cross-reactive antibody response. First Tompkins Rep. at 5. The medical literature cited by Dr. Akbari has not been highly cited nor is the evidence robust. *Id.* Dr. Tompkins also criticized Dr. Akbari's reliance on Treg cells, noting that Dr. Akbari failed to connect how Tregs function in MS or other autoimmune diseases with Petitioner's case. *Id.* at 6. Dr. Tompkins opined that Dr. Akbari has "fail[ed] to provide a clear argument connecting the Tdap vaccination administer to [Petitioner] with eliciting antibodies that allegedly caused the TM." *Id.* at 7. Dr. Tompkins stated that the Tdap vaccine did not cause the onset of Petitioner's TM, but the left flank

pain and superficial burning that started three weeks prior more likely represented the onset of Petitioner's TM. *Id.*

b. Second Report

Dr. Tompkins' second expert report was a rebuttal to Dr. Akbari's second expert report (Ex. 15). Ex. F (hereinafter "Second Tompkins Report") at 1. Dr. Tompkins was critical of the medical literature cited by Dr. Akbari regarding vaccination disruption of peripheral tolerance in the immune system. Second Tompkins Rep. at 2. While Dr. Tompkins accepted the mechanism of peripheral tolerance and the presence of autoreactive T cells in the periphery, he concluded there was no evidence to suggest that the Tdap vaccine, in particular, disrupts peripheral tolerance in a way that elicits autoimmune disease. *Id.* at 2-3.

Dr. Tompkins disagreed with Dr. Akbari's theory that the Tdap vaccine elicits Th17 T cells, which can cause TM. Second Tompkins Rep. at 3. Dr. Tompkins cited a number of papers indicating, contrary to Dr. Akbari's theory, the components of the Tdap vaccine "do not elicit robust Th17 responses." *Id.* at 3-4; *see also* Wu et al., *Insight into Non-Pathogenic Th17 Cells in Autoimmune Diseases*, 9 FRONT. IMMUNOL. 1112 (2018) (filed as Ex. F2); Bancroft et al., *Th1 versus Th2 T cell Polarization by Whole-Cell and Acellular Childhood Pertussis Vaccines Persists Upon Re-Immunization in Adolescence and Adulthood*, 304-305 CELL. IMMUNOL. 35, 35-43 (2016) (filed as Ex. F3); van der Lee et al., *Robust Humoral and Cellular Immune Responses to Pertussis in Adults After a First Acellular Booster Vaccination*, 9 FRONT. IMMUNOL. 681 (2018) (filed as Ex. F4). Moreover, Dr. Tompkins noted that where Th17 T cells were present, they were non-pathogenic, as opposed to Dr. Akbari's assertion that they are pathogenic and can elicit an autoimmune disease. *Id.* at 4; *see also* Livingston et al., *CD4 T-Helper Cell Cytokine Phenotypes and Antibody Response Following Tetanus Toxoid Booster Immunization*, 390 J. IMMUNOL. METHODS 18, 18-29 (2013) (filed as Ex. F5).

Dr. Tompkins also reiterated his opinion that there is no evidence of molecular mimicry at play between TM and the Tdap vaccine. Second Tompkins Rep. at 4-5. Dr. Tompkins opined that the literature Dr. Akbari used in support of his theory provided weak evidence for cross-reactivity. *Id.*; *see also* Inic-Kanada. He also criticized the Sutjita paper's conclusion and opined that the antibody clones described in the paper were not the result of the tetanus toxoid boost. *Id.* at 5; *see also* Sutjita.

Dr. Tompkins cited to two studies that demonstrated Tdap booster vaccinations had almost no increase in the cytokines which Dr. Akbari claimed to be involved in the causation of TM. Second Tompkins Rep. at 5-6; *see also* Nakayama et. al., *Long-Term Regulation of Local Cytokine Production Following Immunization in Mice*, 62 MICROB. IMMUNOL. 124, 124-31 (2018) (filed as Ex. F12) (hereinafter "Nakayama"); Kooijman et. al., *Vaccine Antigens Modulate the Innate Response of Monocytes to $Al(OH)_3$*, PLOS ONE (May 29, 2018), https://doi.org/10.1371/journal.pone.0197885 (filed as Ex. F16) (hereinafter "Kooijman"). Specifically in the Kooijman paper, Tdap stimulated monocytes found increased levels of IFNγ, IL-4, and IL-10, which inhibited Th17 responses. Second Tompkins Rep. at 6. Dr. Tompkins opined that these papers contradicted Dr. Akbari's theory that the Tdap vaccine can cause a non-

specific immune response that enhances Th17 response can lead to the development of an autoimmune disease, like TM. *Id.* at 6.

Finally, Dr. Tompkins asserted that the Tdap vaccination is not associated with TM or other demyelinating diseases. Second Tompkins Rep. at 6-7. Dr. Tompkins criticized Dr. Akbari's reliance on data from the Vaccine Adverse Event Reporting System ("VAERS") because of its "passive surveillance." *Id.* at 6. Moreover, Dr. Tompkins reiterated that the Baxter paper was more persuasive than both the Agmon-Levin and Moro papers based on the methodology used to collect data from vaccinees. *Id.* Dr. Tompkins stated that the study was focused on vaccine causation and TM/ADEM and found no evidence of causation. *Id.* at 7. Dr. Tompkins was similarly not persuaded by the two case studies cited by Dr. Akbari as their presentations were different to that of Petitioner's. *Id.* at 7.

c. Testimony

Dr. Tompkins testified that the Tdap vaccine did not cause Petitioner's TM. Tr. at 311. Dr. Tompkins also relied on a PowerPoint presentation during his testimony. *Id.* at 312; *see also* ECF No. 76-1. Dr. Tompkins opined that the literature cited by Dr. Akbari did not support a link between the Tdap vaccine and TM. Tr. at 313. Dr. Tompkins analyzed Dr. Akbari's reliance of the Agmon-Levin paper, summarizing that the study found four cases of TM associated with a tetanus-toxoid containing vaccines over 39 years. *Id.* at 313. He emphasized that all neurological injuries found in the Agmon-Levin study were merely temporal associations and rare given the low number of cases found compared to the millions of doses of the tetanus vaccines given in the 40 years of the study. *Id.* at 315-17. Dr. Tompkins opined those four cases out of millions over 40 years is not a statistically significant number, but also there was not enough data to calculate a rate due to the lack of a denominator value. *Id.* at 317. Dr. Tompkins added that the Agmon-Levin study did not clarify whether the AAN Criteria were used or not in evaluating whether a subject had TM, only that they included some criteria for inclusion and exclusion. *Id.* at 318.

Dr. Tompkins testified that VAERS cannot be used to determine whether an adverse event is caused by a vaccine or is simply coincidental because there are limitations to the system that prevent it from proving causality. Tr. at 320-21. Dr. Tompkins explained that one of those limitations is the failure of VAERS to report the number of people vaccinated in a population. *Id.* at 321.

Dr. Tompkins discussed the Vaccine Safety Datalink ("VSD") and how it differs from VAERS. Tr. at 322. He explained that VSD was developed "specifically because of the weaknesses in VAERS"; VSD is not open to the general public for reports but instead gathers data from medical charts and patient interviews from several healthcare organizations around the country. *Id.* at 322-24. Moreover, Dr. Tompkins testified that the VSD system receives data from nine million vaccinated individuals every year, creating a wide database for adverse events. *Id.*

Dr. Tompkins explained how the Moro study utilized the VAERS system to look for a signal regarding adverse effects of the Tdap vaccine. Tr. at 326. Ultimately, Dr. Tompkins stated that the study found no new adverse effects and a low frequency of neurological adverse events connected to the Tdap vaccine. *Id.*

Regarding the Baxter study, Dr. Tompkins emphasized its importance in his conclusion that there is no epidemiological evidence for an association between the Tdap vaccine and TM. Tr. at 328. He explained that the study assessed more than 63 million vaccines and the development of neurological symptoms up to 42 days after vaccination. *Id.* at 328-39. Dr. Tompkins stated that the Baxter study utilized the VSD data to conclude that there is no association between any vaccine and TM. *Id.* at 328. He also emphasized how important and rigorous the Baxter study was in the immunology field. *Id.* at 329-30. Dr. Tompkins opined that the study was not biased because it was peer-reviewed. *Id.* at 330. Dr. Tompkins stated that all TM and ADEM cases identified in the Baxter study used stringent criteria for their diagnoses. *Id.* at 387-88.

Dr. Tompkins discussed the 2012 Institute of Medicine report which reviewed the adverse events associated with vaccinations. *Id.* at 332. The meta-analysis done by the IOM did not find mechanistic or epidemiological association between the Tdap vaccine and adverse effects or autoimmune diseases. *Id.* at 333. He also emphasized that the IOM a commissioned committee of national experts and independent of the Federal Government despite being commissioned by Congress. *Id.* at 334.

In addressing Dr. Akbari's arguments, Dr. Tompkins categorized them as follows: 1) the Tdap vaccine could cause acute myelitis by the mechanism of molecular mimicry; 2) there are increased frequencies of T cells or autoantibodies in persons with autoimmune disease; 3) stimulation of the immune system by vaccination could elicit antibodies that are self-reactive; and 4) Tdap vaccines could elicit Th17 responses that could be associated with autoimmune disease. Tr. at 336. Dr. Tompkins testified that Dr. Akbari placed an emphasis on the herpes virus and its associated neuropathies. *Id.* at 343. However, Dr. Tompkins stated that the neuropathies following the herpes virus or EBV are caused by viral damage, not molecular mimicry. *Id.* Further supporting this statement, he described that the herpes viruses survive through "hid[ing] themselves inside of cells" that only produce RNA and use that RNA to modulate cellular processes, which is not a comparable mechanism to that which Dr. Akbari is proposing in this case. *Id.* at 345.

Beyond the studies that do not demonstrate any epidemiological associations between the Tdap vaccine and TM, Dr. Tompkins also rebutted Dr. Akbari's argument about autoimmune markers. Tr. at 347. Dr. Tompkins pointed out there is a "chicken and egg" issue with this argument, stating that it is unclear whether the antibodies or T-cells present in individuals with an autoimmune disease were the actual cause of onset. *Id.* Rather, he claimed that the autoimmune markers could be a product of neuroinflammation caused by a prior infection or injury. *Id.* 347-49. Dr. Tompkins concluded that Dr. Akbari's theories about autoreactive immune responses could not be established to a reasonable degree of medical probability. *Id.* at 348.

Dr. Tompkins identified the Sutjita study as the "crux" of Dr. Akbari's argument. Tr. at 354. He explained how the study followed individuals who had been vaccinated against diphtheria or tetanus and activated their peripheral blood lymphocytes, isolating seven monoclonal antibodies that are specific for tetanus or diphtheria toxoids. *Id.* at 351-53. Dr. Tompkins pointed out two issues with the conclusions of the Sutjita study. *Id.* at 354. He testified that the first issue stems from the non-specificity of activated cells, stating that the activation could be due to non-vaccine related mitogen stimulation or pathogens. *Id.* The second issue was the low affinity and the

attractiveness of the IgM antibodies produced. *Id.* at 354-55. Dr. Tompkins testified that the affinity of the IgM antibodies could explain the cross-reactivity found in the study. *Id.* at 355. Dr. Tompkins concluded that the Sutjita study does not conclusively show, to a degree of medical probability, that there is causation between the Tdap vaccine and TM. *Id.* at 357.

In further opining that the Tdap vaccine does not elicit a Th17 cell response, Dr. Tompkins cited to the Nakayama study and the Spina study. Tr. at 363-65; *see also* Spina et al., *Immune response to a Tdap booster in vertically HIV-infected adolescents.* VACCINE 2018. 36(37): 5609-5616 (filed as Ex. F13) (hereinafter "Spina"). Dr. Tompkins explained the Nakayama paper tested the cytokine levels of Tdap-immunized and boosted mice, which found no increase of IL-6 after the Tdap booster vaccination. *Id.* In the Spina study, patients with HIV were given the Tdap vaccine and found participants had notable Th1 and Th2 responses, but a transient increase in IL-17A, meaning that, while IL-17 and Th17 were present, they were still a subdominant response. *Id.* at 365.

In conclusion, Dr. Tompkins disagreed with Dr. Akbari's molecular mimicry theory and the individual steps of his theory. Tr. at 365. He testified that he found no evidence of molecular mimicry in relation to the Tdap vaccine and TM. *Id.* at 367. He also testified that an autoimmune response is not an indication of causation; just because there is an autoantibody response or self-reactive T-cell response in an individual with an autoimmune disease, that does not mean that those antibodies or T-cells caused the autoimmune disease. *Id.* at 368. Dr. Tompkins further opined that there was no evidence of disease-causing antibodies elicited by the Tdap vaccine or its components. *Id.* He stated that, while Dr. Akbari presented some literature suggesting the opposite, those papers were "deeply flawed." *Id.*

d. Third Report

Dr. Tompkins authored a third expert report in response to Dr. Akbari's post-hearing expert report (Ex. 71). Ex. O (hereinafter "Third Tompkins Report"). Dr. Tompkins repeated many of the same arguments made in his first two reports but refuted a few additional arguments made by Dr. Akbari. Dr. Tompkins refuted Dr. Akbari's arguments of bias in the literature cited, namely the Baxter paper. Third Tompkins Rep. at 7-11. Dr. Tompkins concluded that Dr. Akbari has strung together many piece-meal claims to formulate a theory of how the Tdap vaccine can cause TM, but has not provided any evidence to substantiate these claims. *Id.* at 12.

V. Applicable Law

A. Petitioner's Burden in Vaccine Program Cases

Under the Vaccine Act, when a petitioner suffers an alleged injury that is not listed in the Vaccine Injury Table, a petitioner may demonstrate that he suffered an "off-Table" injury. § 11(c)(1)(C)(ii).

In attempting to establish entitlement to a Vaccine Program award of compensation for a off-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). *Althen* requires that

petitioner establish by preponderant evidence that the vaccination she received caused her injury "by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* at 1278.

Under the first prong of *Althen*, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Proof that the proffered medical theory is reasonable, plausible, or possible does not satisfy a petitioner's burden. *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359-60 (Fed. Cir. 2019).

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). However, special masters are "entitled to require some indicia of reliability to support the assertion of the expert witness." *Boatmon*, 941 F.3d at 1360, *quoting Moberly*, 592 F.3d at 1324. Special Masters, despite their expertise, are not empowered by statute to conclusively resolve what are complex scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Hum. Servs.*, 121 Fed. Cl. 230, 245 (2015), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017); *see also Hock v. Sec'y of Health & Hum. Servs.*, No. 17-168V, 2020 U.S. Claims LEXIS 2202 at *52 (Fed. Cl. Spec. Mstr. Sept. 30, 2020).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326 ("medical 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 particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"). 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. The views of treating physicians should also be weighed against other, contrary evidence also present in the record. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Health & Hum. Servs.*, No. 06-522V, 2011

WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. App'x 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. Law Governing Analysis of Fact Evidence

The process for making factual determinations in Vaccine Program cases begins with analyzing the medical records, which are required to be filed with the petition. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 413, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records created contemporaneously with the events they describe are generally trustworthy because they "contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions," where "accuracy has an extra premium." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378 (Fed. Cir. 2021) citing *Cucuras*, 993 F.2d at 1528. This presumption is based on the linked proposition that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11-685V, 2013 WL 1880825 at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013), *claim den.*, 2020 WL 5641872 (Fed. Cl. Spec. Mstr. Aug. 26, 2020), *rev. den.*, 152 Fed. Cl. 782 (2021), *rev'd and remanded*, 34 F.4th 1350 (Fed. Cir. 2022).

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL

6117475 at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony -- especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; see also *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), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral 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) ("like 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*, 2005 WL 6117475 at *19 ("[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*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent and compelling." *Sanchez*, 2013 WL 1880825 at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808V, 1998 WL 408611 at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *LaLonde v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), aff'd, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. Analysis of Expert Testimony

Establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of her claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (*citing Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or

technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora. *Daubert* factors are employed by judges to exclude evidence that is unreliable and potentially confusing to a jury. In Vaccine Program cases, these factors are used in the weighing of the reliability of scientific evidence. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted").

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). A "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly*, 592 F.3d at 1324. Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Id.* at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations").

D. Consideration of Medical Literature

Although this decision discusses some but not all of the medical literature in detail, I reviewed and considered all of the medical records and literature submitted in this matter. *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 [s]he does not explicitly reference such evidence in h[er] decision."); *Simanski v. Sec'y of Health & Hum. Servs.*, 115 Fed. Cl. 407, 436 (2014) ("[A] Special Master is 'not required to discuss every piece of evidence or testimony in her decision.'" (citation omitted)), *aff'd*, 601 F. App'x 982 (Fed. Cir. 2015).

VI. Analysis

Because Petitioner does not allege an injury listed on the Vaccine Injury Table, his claim is classified as "off-Table." As noted above, to prevail on an "off-Table" claim, Petitioner must

prove by preponderant evidence that he suffered an injury and that this injury was caused by the vaccination at issue. *See Capizzano*, 440 F.3d at 1320.[4]

In certain cases, the appropriate first step is to determine the precise nature of a petitioner's injury before engaging in the *Althen* analysis. *Broekelschen,* 618 F.3d at 1346. An injury which predates vaccination can defeat a Vaccine Program claim entirely. *Shalala v. Whitecotton,* 514 U.S. 268, 274-75 (1995) (Vaccine Act claimant who demonstrates she experienced symptoms of injury after receipt of vaccination does not succeed in her claim if the evidence indicates that she had symptoms of injury before her vaccination); *Locane v. Sec'y of Health & Hum. Servs.,* 99 Fed. Cl. 715, 727 (2011), *aff'd*, 685 F.3d 1375 (Fed. Cir. 2012) (finding that petitioner's Crohn's disease began prior to her vaccinations and therefore vaccine causation could not be established).

A. Petitioner Has Not Carried His Burden of Proof

1. Acute Transverse Myelitis

Transverse means "acting, lying, or being across."[5] Myelitis simply refers to inflammation of the spinal cord.[6] Accordingly, transverse myelitis is a "myelitis in which the functional effect of the lesions spans the width of the entire cord at a given level."[7] Transverse myelitis is a heterogeneous group of inflammatory disorders of the spinal cord "resulting in motor, sensory, and autonomic dysfunction." AAN Criteria at 500; Frohman at 564.

TM can have different underlying causes; as a result, it can present as "a multi-focal central nervous system (CNS) disease (e.g. multiple sclerosis), a result of direct injury to the spinal cord (e.g. radiation, spinal cord infarct), as part of a systemic (e.g. malignancy) or autoimmune disease (i.e. systemic lupus erythematosus), or as an isolated entity." Agmon-Levin at 1198.

The drafters of the AAN Criteria comment on the importance of distinguishing idiopathic TM from TM that is caused by underlying disease. "Many systemic inflammatory disorders (SLE, Behçet disease, Sjögren syndrome, and so on) are associated with vasculitides that can result in ATM. As these conditions occur along a similar pathophysiologic spectrum and most have established treatment regimens, ATM associated with these disorders must be distinguished from

[4] I note that Petitioner has alleged his Tdap vaccine caused him to develop TM; he did not advance a significant aggravation claim. Because it is not pled, I have not analyzed whether Petitioner's Tdap vaccine resulted in the significant aggravation of his condition. However, many of the same points that prevent Petitioner from prevailing in a causation-in-fact analysis also undermine a significant aggravation claim. Accordingly, Petitioner's failure to allege significant aggravation does not impact my ultimate determination in his case.

[5] www.merriam-webster.com/dictionary/transverse (last accessed September 19, 2023).

[6] www.dorlandsonline.com/dorland/definition?id=32680&searchterm=myelitis (last accessed September 19, 2023).

[7] www.dorlandsonline.com/dorland/definition?id=91212&searchterm=transverse+myelitis (last accessed September 19, 2023).

idiopathic ATM." AAN Criteria at 501. *See also*, Tr. at 272 (Dr. Donofrio discussing myelitis due to another disorder versus idiopathic TM).

2. *Althen* Prong One

In the context of the Program, "to establish causation, the standard of proof is preponderance of evidence, not scientific certainty." *Langland v. Sec'y of Health & Hum. Serv.*, 109 Fed. Cl. 421, 441 (2013). Petitioner's burden under *Althen*'s first prong is to provide a medical theory causally connecting the vaccination and the injury. *Id.* This theory must be sound and reliable. *Boatmon*, 941 F.3d at 1359.

While Dr. Akbari has articulated a theory describing how the Tdap vaccine can cause TM, I need not reach that question. My factual findings, discussed in the next section, that the onset of myelitis predated Petitioner's vaccination, and further, that Petitioner, more likely than not, does not suffer from TM, make analysis of his causal theory unnecessary. Accordingly, in my analysis of *Althen* prongs two and three, I have assumed, but have not decided that Petitioner has established a medical theory causally linking the Tdap vaccine to TM.

3. *Althen* Prong Two

Under *Althen's* second prong, a petitioner must "prove a logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Althen*, 418 F.3d at 1278. The sequence of cause and effect must be "'logical' and legally probable, not medically or scientifically certain." *Id.* A petitioner is not required to show "epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." *Id.* (omitting internal citations). *Capizzano*, 440 F.3d at 1325. Instead, circumstantial evidence and reliable medical opinions may be sufficient to satisfy the second *Althen* prong. *Isaac v. Sec'y of Health & Hum. Servs.*, No. 08-601V, 2012 U.S. Claims LEXIS 1023 at *75 (Fed. Cl. Spec. Mstr. July 30, 2012), *aff'd* 108 Fed. Cl. 743 (Fed. Cl. 2013).

a. *Factual Determination: The Onset of Petitioner's Condition*

On the day of vaccination, Petitioner presented to Dr. Gee with "a superficial burning sensation on the left side of the back and then radiating anteriorly in the mid abdomen," along with left flank pain. Ex. 1 at 7-9. Petitioner indicated that this burning and radiating sensation and left flank pain began three weeks prior and that the pain prevented him from sleeping. *Id.* at 9. The record further notes "No fall or trauma reported." *Id.* Under "Plan" the medical record indicates, "will check labs as noted and then to get abdominal US if not clearing." *Id.* at 11.

Dr. Donofrio opined that this burning and pain that radiated to the mid abdomen likely represented the initial presentation of Petitioner's condition. First Donofrio Rep. at 8; Tr. at 224. In his supplemental report, Dr. Donofrio opined that "petitioner's presentation on January 7, 2015,

prior to the Tdap vaccination, was consistent with transverse myelitis."[8] Second Donofrio Rep. at 1.

The medical literature supports Dr. Donofrio's position. Frohman & Wingerchuk describe that neuropathic pain in transverse myelitis may occur and can be radicular (radiating) with a sensation of burning. Frohman & Wingerchuk, *Transverse Myelitis,* 363 N ENGL J MED 6, 564-72, 65 (2010) (filed as Ex. A2) (hereinafter "Frohman & Wingerchuk"). Frohman & Wingerchuk also state that "[p]ain is common during and after an attack of myelitis…" Frohman & Wingerchuk at 570.

During the hearing, Petitioner presented two arguments that the symptoms reported at the January 7, 2015 appointment did not constitute the onset on his myelitis. First, Petitioner attempted to differentiate the pain he described at this appointment from the pain associated with his myelitis. He testified that he attributed the pain he described at the January 7, 2015 appointment to a skiing accident in 1998. Tr. at 10. However, this medical record from January 7, 2015 did not document that the left flank pain was a result of Petitioner's skiing accident many years before. Instead, the record indicated that the pain had been present for three weeks and that there was "no trauma reported". Ex. 1 at 9.

In order to overcome the presumption that contemporaneous written medical records are accurate, testimony must be "consistent, clear, cogent, and compelling." *Blutstein*, 1998 WL 408611, at *5. Because of this presumption, "special masters in this Program have traditionally declined to credit later testimony over contemporaneous records." *Sturdivant v. Sec'y of Health & Hum. Servs.,* No. 07-788V, 2016 WL 552529, at *15 (Fed. Cl. Spec. Mstr. Jan. 21, 2016). *See, e.g., Stevens v. Sec'y of Health & Hum. Servs*., No. 90–221V, 1990 WL 608693, at *3 (Fed. Cl. Spec. Mstr. Dec. 21, 1990); *see also Vergara v. Sec'y of Health & Hum. Servs*., No. 08–882V, 2014 WL 2795491, at *4 (Fed. Cl. Spec. Mstr. Jul. 17, 2014) ("Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recorded in later medical histories, affidavits, or trial testimony."); *See also, Cucuras*, 993 F.2d at 1528 (noting that "the Supreme Court counsels that oral testimony in conflict with contemporaneous documentary evidence deserves little weight").

Dr. Nahm presented Petitioner's second argument that the pain described at the January 7, 2015 medical appointment did not constitute the onset of Petitioner's myelitis by attributing Petitioner's symptoms to a prolapse or bulge in Petitioner's thoracic spine. Dr. Nahm initially opined that Petitioner's symptoms were caused by a thoracic disc "prolapse" at T4 seen on Petitioner's MRI of the thoracic spine. Nahm Rep. at 5. In his expert report, Dr. Nahm opined that this disc "prolapse" accounted for Petitioner's left flank pain and burning sensation that he reported to Dr. Gee on January 7, 2015. *Id.* During the entitlement hearing, Dr. Nahm conceded that Petitioner did not have a disc prolapse, but instead had a disc bulge.[9] Tr. at 113.

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[8] Dr. Donofrio later testified that he used the term "myelitis" and "transverse myelitis" interchangeably. Tr. at 254-55.

[9] Dr. Nahm testified that in a prolapse (or a herniation) "the material inside the disc seeps out and can sometimes compress on a spinal cord or impinge on a spinal cord." Tr. at 113.

For the reasons discussed below, I find that Petitioner's disc bulge at T4 does not account for his burning sensation and pain that radiated to his mid abdomen, and instead, that the burning sensation and pain, more likely than not represented the onset of his myelitis. I base this finding on two main pieces of evidence: Petitioner's three thoracic MRIs, and the relationship between the specific location of his pain and the location of the disc bulge.

i. Petitioner's Thoracic MRIs

The three thoracic MRI scans taken within several months of vaccination did not show spinal cord compression or narrowing. Ex. 3 at 7; Ex. 2 at 14; Ex. 2 at 10. According to Dr. Donofrio, these signs would almost certainly have been present in order for burning and radiating pain to have been caused by a disc bulge. Tr. at 223.

Petitioner's first thoracic MRI, performed on January 27, 2015, showed an abnormal T2 hyperintensity extending from T7-10. Ex. 3 at 7. In relation to the disc bulge, the MRI noted: "T4-5: Left central disc bulge effaces the ventral thecal sac and abuts the ventral surface of the adjacent thoracic spinal cord. No significant central spinal canal narrowing or neural foraminal narrowing." *Id.* In describing these findings, Dr. Donofrio testified:

> the spinal cord is not narrowed and so there's plenty of room for the spinal cord to function. The neural foramina is where the nerve roots come out before they go to the chest or abdominal region. So since there's no significant pathology there, you would not expect that to cause any pain at all…

Tr. at 222.

Petitioner had a follow-up MRI on February 16, 2015. This MRI showed that the T2 hyperintensity at T7-10 had decreased, and with respect to T4-5: "Left central disc bulge effaces the ventral thecal sac and abuts the ventral surface of the adjacent thoracic spinal cord. No significant central spinal canal narrowing or neural foraminal narrowing." Ex. 2 at 14. Like the previous scan, this MRI did not show spinal cord compression or foraminal narrowing. Second Donofrio Rep. at 2.

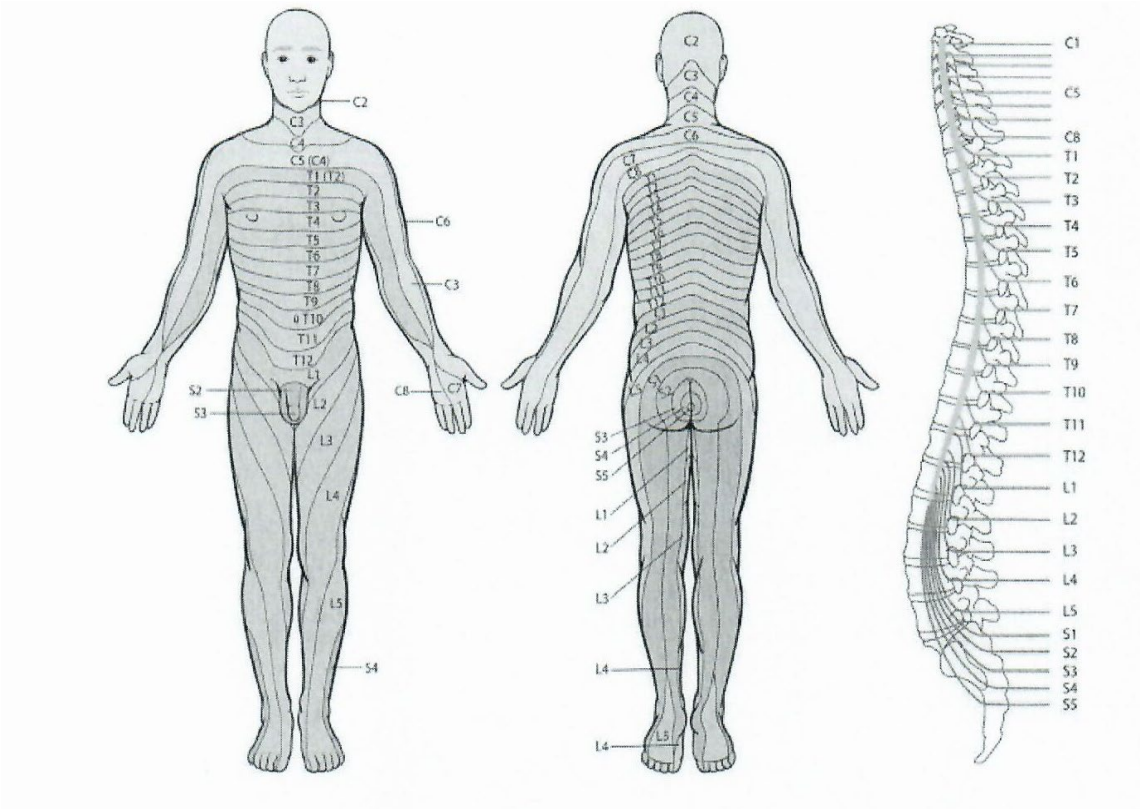
A third thoracic MRI was performed on July 24, 2015. Dr. Donofrio opined that it "showed complete resolution of the previously seen spinal cord abnormality compatible with resolved transverse myelitis." Second Donofrio Rep. at 2; Ex. 2 at 10. As with the other two MRIs, this scan did not demonstrate spinal cord compression or foraminal narrowing. Second Donofrio Rep. at 2. In fact, the examiner concluded that the T4-5 disc protrusion was "small" and "unchanged". Ex. 2 at 11. During the time of this third MRI, Petitioner was not experiencing symptoms of numbness and tingling, which also suggests that an unchanged disc bulge did not cause his initial symptoms. Dr. Donofrio stated, "[o]n reviewing the medical records, many of Petitioner's complaints are present after 7-24-15 when the thoracic MRI showed complete resolution of the spinal cord abnormalities at T7-10. Thus none of Petitioner's complaints after that date should be ascribed to TM." Second Donofrio Rep. at 3.

Dr. Donofrio persuasively testified that in order for Petitioner to have experienced symptoms as a result of this disc bulge, the bulge should have been severe enough to cause compression of the spinal cord. He stated that a disc bulge is extremely common in patients above the age of 45 or 50 and is part of degeneration that occurs with aging. Tr. at 223-34. Dr. Donofrio further testified that a small bulge usually does not cause any neurological symptoms. *Id.* at 224.

Dr. Nahm testified that a disc bulge can cause back pain, and further that it does not have to cause compression to result in back pain. Tr. at 80. Dr. Nahm did appear to concede that in order to cause pain, a disc bulge would normally result in compression (although his testimony is not entirely clear on this point). *Id.* Ultimately, I am persuaded by Dr. Donofrio's clear and unequivocal testimony that a disc bulge that causes neither spinal cord compression nor foraminal narrowing is unlikely to have resulted in the symptoms that Petitioner experienced.

ii. Dermatomes

The dermatome chart depicts the "sensation given off by each branch of the roots of the body." Tr. at 216-17. Dr. Donofrio discussed the dermatome chart (filed within Dr. Nahm's expert report) at the entitlement hearing.



Nahm Rep. at 6. This chart demonstrates that a disc bulge at T4 would result in pain which radiated

to the nipple region.[10] Tr. at 219. Petitioner's cord abnormality was at T7-10. Thus, the pain associated with his T7-10 abnormality would manifest within several inches of the umbilicus (the mid abdomen). Tr. at 217. When I asked Petitioner to indicate specifically where he felt the pain he described at his January 7, 2015 medical appointment, he pointed to his mid-back area. This testimony is consistent with the medical record from January 7, 2015. Ex. 1 at 9 (noting pain "radiating anteriorly in the mid abdomen"). Accordingly, I find that the specific location of Petitioner's pain provides strong evidence that his disc bulge did not cause his pain in the mid-abdomen. Further, the specific location of his pain also provides evidence in support of the fact that Petitioner's cord abnormality at T7-10 was the cause of his pain that he reported to Dr. Gee on the day of vaccination.

Aside from opining that the disc bulge at T4 caused Petitioner's pain in the mid-abdomen, Dr. Nahm did not offer any other alternate explanation for what caused Petitioner's symptoms of pain, numbness, and tingling that he reported to Dr. Gee on January 7, 2015. Petitioner testified that he had experienced similar pain that he thought was from a skiing accident in 1998. While I do not discount Petitioner's testimony, I note that there is no objective evidence (for example, imaging) of a separate injury that would cause pain and burning at this precise location.

Ultimately, I am preponderantly convinced that the symptoms Petitioner reported on January 7, 2015, to include burning and pain that radiated to his mid-abdomen, represented the onset of his myelitis. He reported to Dr. Gee that these symptoms had been present for three weeks. Thus, I find that the onset of Petitioner's condition began on approximately December 17, 2014, three weeks before his vaccination. A petitioner cannot succeed on a claim of causation-in-fact where the alleged condition preexisted the vaccination. *See W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1354–55 (Fed. Cir. 2013) (affirming the special master's denial of compensation on claim of causation-in-fact because "[i]f a petitioner has a disorder before being vaccinated, the vaccine logically cannot have caused the disorder"). Although the onset issue is dispositive of Petitioner's claim, I will further analyze the question of diagnosis.

b. *There is not Preponderant Evidence that Petitioner Suffers from TM*[11]

As a threshold matter, a petitioner must establish he suffers from the condition for which he seeks compensation. *Broekelschen,* 618 F.3d at 1346. "The function of a special master is not to 'diagnose' vaccine-related injuries, but instead to determine 'based on the record as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [petitioner]'s injury.'" *Andreu v. Sec'y of Health & Hum. Servs*., 569 F.3d 1367, 1382 (Fed. Cir. 2009) (quoting *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994)). "Although the Vaccine Act does not require absolute precision, it does require the petitioner to establish an injury – the Act specifically creates a claim for compensation for

[10] Dr. Nahm conceded that the dermatome for T4 is around the nipple and the dermatome for T10-T11 is around the belly button. Tr. at 116-17. He testified, however, that people do not always experience pain in accordance with the dermatome chart. *Id.* at 117.

[11] While Petitioner did have inflammation of the spinal cord that spanned the width of the cord at T7-10, I conclude that the evidence does not support he has the condition of acute transverse myelitis, as defined by the AAN Criteria.

'vaccine-related injury or death.'" *Stillwell v. Sec'y of Health & Hum. Servs*., 118 Fed. Cl. 47, 56 (2014) (quoting 42.U.S.C. § 300aa-11(c)). Accordingly, the Federal Circuit has concluded that it is "appropriate for the special master to first determine what injury, if any, [is] supported by the evidence presented in the record" before applying a causation analysis pursuant to *Althen v. Secretary of Health & Human Services, 418 F.3d 1274 (Fed. Cir. 2005). Lombardi v. Sec'y of Health & Hum. Servs*., 656 F.3d 1343, 1351-53 (Fed. Cir. 2011).

An important question to be addressed is whether Petitioner's medical history supports a finding that he suffered from TM. For the reasons discussed below, I find that it does not.

i. The AAN Working Group Criteria are the Appropriate Diagnostic Criteria for Acute TM, although Failure to Meet these Criteria does not per se Preclude a TM Diagnosis

Dr. Donofrio testified at the entitlement hearing that the criteria used to diagnose TM are published in the proposed diagnostic criteria for acute transverse myelitis by the Transverse Myelitis Consortium Working Group of the American Academy of Neurology. Tr. at 236-37.

Dr. Nahm opined that the AAN Criteria have not been prospectively validated and because of that, represent no more than a useful framework.[12] Nahm Rep. at 6. I asked Dr. Nahm at the hearing whether there were other diagnostic criteria I should consider in evaluating the evidence with respect to a TM diagnosis. He responded that he was not aware of other criteria that should be applied. Tr. at 123-24. Dr. Donofrio noted that "in the 18 years that has transpired since the publication of the 2002 AAN proposed criteria, no other criteria or guidelines have been proposed to supplant the 2002 criteria." Second Donofrio Rep. at 3.

Dr. Nahm did not criticize the AAN Criteria at the entitlement hearing, but instead testified that clinicians do not rigidly apply the criteria when diagnosing acute TM. Tr. at 74-75. Dr. Donofrio agreed. *Id.* at 273-75.

Based on the above, I am convinced that the AAN Criteria are the appropriate diagnostic criteria for TM. While the failure to meet all of the criteria may not automatically preclude a TM diagnosis, I note that Petitioner has not presented any alternative criteria that I should use in their place.

ii. Petitioner does not Meet the AAN Criteria for a Diagnosis of Acute TM

[12] In addition to this criticism, Dr. Nahm noted "the authors of these proposed criteria wrote that… 'the exclusion of cases based on the interval between symptom onset and maximal deficit is arbitrary…" Nahm Rep. at 7 (*citing* AAN Working Group at 501). However, the entirety of the Working Group's sentence reads: "Likewise, although the exclusion of cases based on the interval between symptom onset and maximal deficit is arbitrary, this criterion is felt to be valid based on the authors' clinical experience and review of the literature." *Id.*

The AAN Working Group lists the following inclusion criteria that support an acute TM diagnosis:

- Development of sensory, motor, or autonomic dysfunction attributable to the spinal cord
- Bilateral signs and/or symptoms (though not necessarily symmetric)
- Clearly defined sensory level
- Exclusion of extra-axial compressive etiology by neuroimaging (MRI or myelography; CT of spine not adequate)
- Inflammation within the spinal cord demonstrated by CSF pleocytosis or elevated IgG index or gadolinium enhancement. If none of the inflammatory criteria is met at symptom onset, repeat MRI and lumbar puncture evaluation between 2 and 7 d following symptom onset meet criteria
- Progression to nadir between 4 h and 21 d following the onset of symptoms (if patient awakens with symptoms, symptoms must become more pronounced from point of awakening)

AAN Criteria at 500. With respect to the progression of symptoms from onset to nadir, the drafters commented as follows:

> [A]lthough the exclusion of cases based on the interval between symptom onset and maximal deficit is arbitrary, this criterion is felt to be valid based on the authors' clinical experience and review of the literature. We remain committed to distinguishing ATM from a rapidly evolving vascular myelopathy (< 4-hour progression), a slowly progressive or stuttering hereditary myelopathy, spinal cord tumor, myelopathy due to a dural arteriovenous fistulas, and a chronic progressive form of MS (all longer than 21 days of progression).

Id.

The AAN Working Group also lists the following exclusion criteria with respect to an acute TM diagnosis:

- History of previous radiation to the spine within the last 10 y
- Clear arterial distribution clinical deficit consistent with thrombosis of the anterior spinal artery
- Abnormal flow voids on the surface of the spinal cord c/w AVM
- Serologic or clinical evidence of connective tissue disease (sarcoidosis, Behcet's disease, Sjögren's syndrome, SLE, mixed connective tissue disorder, etc.)
- CNS manifestations of syphilis, Lyme disease, HIV, HTLV-1, *Mycoplasma*, other viral infection (e.g. HSV-1, HSV-2, VZV, EBV, CMV, HHV-6, enteroviruses)
- Brain MRI abnormalities suggestive of MS
- History of clinically apparent optic neuritis

AAN Criteria at 500.

Dr. Donofrio testified that the exclusion criteria are "equally important" as the inclusion criteria. Tr. at 237. He further noted that "what was not done in this case is he wasn't evaluated for about 10 or 11 illnesses here that, if present, would have explained the transverse myelitis." *Id.* at 239.

Dr. Donofrio opined that Petitioner met all of the inclusion criteria except for two: he did not display a clearly defined sensory level (because it was not tested) and his illness did not reach nadir between 4 hours and 21 days after symptom onset. Tr. at 237-38. Dr. Donofrio defined nadir as "the timing of the most severe manifestation of the disease." *Id.* at 210.

Dr. Nahm testified that Petitioner met all of the AAN diagnostic criteria with the caveat that no one tested Petitioner for sensory level.[13] Tr. at 68-76.

With respect to a progression to nadir between four hours and 21 days following onset of symptoms, Dr. Nahm testified that Petitioner met this criterion. In arriving at this determination, Dr. Nahm opined that Petitioner experienced onset of symptoms five days after Tdap vaccine, or on January 12, 2015, and that the nadir of his illness occurred on January 27, 2015. Tr. at 72. This represents an interval of 15 days.

Dr. Donofrio did agree that the nadir of Petitioner's condition took place on January 27 or 28, 2015. Tr. at 238. However, he disagreed with Dr. Nahm concerning the onset of Petitioner's illness, and instead opined that Petitioner began to experience symptoms of his myelitis on approximately December 17, 2014, 41 days prior to nadir. *Id.*

Both experts agree that Petitioner reached nadir on January 27, 2015. These opinions are supported by the medical record, which documents that "[o]n the evening of 01/28/2015, the patient began experiencing significant improvement." Ex. 3 at 16. Accordingly, I find that a preponderance of the evidence supports that Petitioner reached the nadir of his myelitis on approximately January 27, 2015.

Earlier in this decision, I found that Petitioner's symptoms of left flank pain and the burning sensation that radiated anteriorly to his mid-abdomen constituted the onset of his condition. Based on this finding, Petitioner's onset of symptoms to nadir took place over the course of 41 days, from December 17, 2014 (three weeks prior to his January 7, 2015 medical appointment with Dr. Gee) to January 27, 2015. This represents a period of time that is substantially longer than the progression of symptoms defined in the AAN Criteria. In fact, Dr. Nahm testified at the entitlement hearing that 3-4 weeks of back and flank pain followed by burning in the extremities is not a typical progression of TM. In his words, "It's like wildfire … it goes fast." Tr. at 89-90. I find that Petitioner did not meet the AAN criterion which requires a progression to nadir of between four hours and 21 days following onset of symptoms. Dr. Donofrio testified that this longer progression of symptoms establishes that acute TM is not Petitioner's correct diagnosis. I agree with Dr. Donofrio's assessment.

[13] Because both experts ultimately agreed that no one tested Petitioner for a sensory level, and that this omission does not prevent Petitioner from receiving a TM diagnosis, I have not analyzed this issue.

Other special masters have found that a lengthy period of time between onset of symptoms and nadir suggests that a Petitioner does not have vaccine-induced TM. *Pearson v. Sec'y of Health & Hum. Servs.*, No. 16-09V, 2019 WL 3852633, at *15 (Fed. Cl. Spec. Mstr. July 31, 2019) (noting that "most TM sufferers advance from onset of symptoms to maximum deficit within weeks, days, or even hours."); *Murray v. Sec'y of Health & Hum. Servs.*, No. 19-1976, 2022 WL 17853378, at *9 (Fed. Cl. Spec. Mstr. November 30, 2022) (finding a six month plus progression of TM from onset to nadir is not consistent with TM).

Ultimately, although the fact that Petitioner's presentation did not meet the AAN Criteria is not dispositive of the question of diagnosis, it is one point which suggests that preponderant evidence does not support TM as his correct diagnosis.

iii. Other Factors Suggest that Petitioner does not have Vaccination-Induced TM

Both experts in this case agree that TM is a monophasic illness. Tr. at 104 (Dr. Nahm agreeing that TM by definition is monophasic); Tr. at 210 (Dr. Donofrio testifying "Transverse myelitis, by definition, is monophasic."). Frohman & Wingerchuk support this point; they state: "The postinfectious, postvaccination, and idiopathic forms of transverse myelitis are usually monophasic syndromes, whereas multiple sclerosis and neuromyelitis optica–spectrum disorders are relapsing diseases that are associated with a high risk of future attacks of transverse myelitis and other neurologic events." Frohman & Wingerchuk at 567. Monophasic is defined as "exhibiting only one phase or variation."[14] According to Dr. Donofrio, in the context of TM, this means that when a person reaches a nadir and they begin to make a recovery, they do not experience a subsequent worsening of their symptoms. Tr. at 210.

Dr. Nahm testified that Petitioner's disease course was monophasic for the first three to four weeks of his illness. Tr. at 122. Then he experienced an ebbing and flowing of his condition over a long period of time. *Id.* This description provided by Dr. Nahm does not describe a monophasic illness as there is more than one phase or variation of the disease.

Petitioner also argues that because disease prognosis in TM is "highly variable", this supports Petitioner's clinical picture as being consistent with TM. Petitioner cites to the AAN Criteria, which describe that approximately one third of patients make a complete recovery, while one third are left with moderate disability, and one third with severe disability. Tr. at 91; referencing AAN Criteria at 499. Petitioner contends, therefore, that his "course and ongoing symptoms were consistent with the course of the disease as described in the literature." Petr's Post Hearing Brief at 13. Petitioner has misapprehended this issue. The fact that a percentage of patients with TM do not make a complete recovery does not suggest that their disease course is something other than monophasic. *See* Tr. at 275-76.

[14] https://www.dorlandsonline.com/dorland/definition?id=32043 (last accessed July 29, 2021).

Petitioner experienced several phases of worsening and remittance. He developed his initial symptoms of lower extremity numbness, tingling, and weakness which reached nadir on approximately January 27, 2015. Then he improved such that his discharge summary from St Luke's noted that "On the evening of 01/28/2015, the patient began experiencing significant improvement." Ex. 3 at 16. By January 29, 2015, Petitioner described himself as almost back to normal. *Id.* Then on approximately February 10, 2015, Petitioner began to experience increased numbness in the right leg. Ex. 2 at 6. On July 28, 2015, Petitioner told Dr. Whiteside that he had "some recurrent symptoms recently" which included tingling in all four limbs. Ex. 5 at 11. He developed worsening of symptoms in early 2016, which began to improve in February 2016 and have since stabilized. Ex. 9 at 2. Petitioner described his symptoms as cyclical in nature, "occurring every 3-5 weeks and lasting for about 4 weeks." *Id.*

The fact that Petitioner's illness was not monophasic provides additional evidence that he did not suffer from vaccine induced TM.

Additionally, Petitioner repeatedly reported experiencing upper extremity symptoms during the course of his illness.[15] Both experts agreed that pain, tingling, or numbness occurring in the upper extremities or face cannot be attributed to Petitioner's T7-10 lesion. *See* Tr. at 230 (Dr. Donofrio testifying that "if you're going to imply that the vaccination caused transverse myelitis from T7 through T10, then it would still not explain those symptoms in the hands and in the lips."); Tr. at 125 (Dr. Nahm describing Petitioner's upper extremity symptoms as puzzling). Dr. Donofrio opined that an attempt should be made to diagnose Petitioner with one illness that encompasses his signs and symptoms above T7-10. He stated, "In the field of medicine, the term Occam's razor is used for a concept that clinicians should try to explain a patient's presentation by one disease or disorder rather than using several diseases to explain all patient's complaints." Second Donofrio Rep. at 3. Dr. Donofrio persuasively testified at the entitlement hearing that Petitioner's numbness and tingling in his upper extremities suggests that he likely has a condition other than TM. Tr. at 241.

Dr. Nahm opined that the presence of Petitioner's upper extremity symptoms does not mean he did not also have TM. In other words, Dr. Nahm's opinion is that Petitioner's correct diagnosis is TM and something else. Tr. at 91-93. He did not indicate what Petitioner's other condition might be.

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[15] *See e.g.*, Ex. 5 at 11 (On July 28, 2015, Petitioner told Dr. Whiteside that he had "some recurrent symptoms recently" which included tingling in all four limbs. This description of symptoms occurred in the context of a thoracic MRI performed just four days earlier which was consistent with resolved transverse myelitis.). Ex. 4 at 15 (medical appointment on September 27, 2016 where Petitioner described experiencing episodes of right eye pain beginning in October of 2015 which corresponded with tingling and back pain); Ex. 3 at 22 (medical appointment from January 27, 2015, where Petitioner was noted to experience tingling sensation affecting the tips of his fingers and his mouth); Ex. 3 at 141 (February 4, 2016 medical visit which documents that Petitioner's upper back pain began suddenly four days ago and was noted by Petitioner to be "identical" to when he had TM one year ago; the record further describes that Petitioner has intermittently experienced numbness in his hands).

While it is certainly possible that Petitioner has myelitis and another disorder, I do not find this explanation to be either likely or persuasive. Petitioner consistently associated facial and/or upper extremity numbness with his lower extremity symptoms. *See e.g.*, Ex. 1 at 7-8 (At his initial presentation to Dr. Gee on January 19, 2015, Petitioner described tingling in his hands and feet); Ex. 3 at 2 (On January 27, 2015, Petitioner described numbness in his legs, along with tingling in his right arm and the right side of his face around his lips if he exerts himself too much); Ex. 5 at 11 (Petitioner described tingling in all four limbs in July of 2015); Ex. 3 at 141, 143 (On February 4, 2016, Petitioner reported upper back pain "identical to when he had transverse myelitis a year ago" accompanied by tingling on the right side of his face and both hands); Ex. 12 at 13 (On March 21, 2016, Petitioner reported that he was still experiencing numbness and parethesias in all four extremities); Ex. 4 at 15 (On September 27, 2016, Petitioner linked eye pain to tingling and back pain). A finding that Petitioner suffered from two separate disorders would mean that both distinct conditions began and flared around the same time. While this is possible, it is not more likely than not. The fact that Petitioner's upper extremity symptoms must have been caused by something other than his cord abnormality at T7-10 is not dispositive on the issue of whether TM is his correct diagnosis. However, it is some evidence that I have considered in arriving at my determination that Petitioner has not provided preponderant evidence that vaccine-induced TM is his correct diagnosis.

iv. Petitioner's Treating Physicians

In weighing evidence, special masters are expected to consider the views of treating doctors. *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006). The views of treating doctors about the appropriate diagnosis are often persuasive because the doctors have direct experience with the patient whom they are diagnosing. *See McCulloch v. Sec'y of Health & Hum. Servs.*, No. 09-293V, 2015 WL 3640610, at *20 (Fed. Cl. Spec. Mstr. May 22, 2015).

Although several of Petitioner's treating physicians diagnosed him with TM, the Court is not obliged to adopt the same view. *See* 42 U.S.C. §§ 300aa-13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted").

I note that none of Petitioner's treating doctors, with the exception of Dr. Gee, were aware that Petitioner experienced left flank pain along with a superficial burning sensation on the left side of his back that radiated anteriorly to his mid-abdomen three weeks before his Tdap vaccination. *See* Ex. 1 at 7-9. It is unclear whether these doctors would have found this to be the onset of Petitioner's condition, and if they did, whether they would have still ascribed this diagnosis to Petitioner's condition, given the length of time between onset of his illness and nadir (41 days).

Furthermore, the upper extremity symptoms Petitioner experienced after several of his treating doctors diagnosed him with TM call these diagnoses into question.

Ultimately, I have considered the views of Petitioner's treating physicians in arriving at my conclusion that there is not preponderant evidence that Petitioner suffered from TM. I find it significant that Petitioner's treating neurologists did not know of his left flank pain and superficial burning sensation on the left side of his back that radiated anteriorly to his mid-abdomen which occurred three weeks before his Tdap vaccination. Further, the treating physicians who initially diagnosed TM did not know Petitioner's symptoms would recur in a region completely unrelated to his initial presentation. A treating physician's opinion on vaccine causation is only as strong as its underlying basis. *See Perreira v. Sec'y of Health & Hum. Servs.*, 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994).

For the reasons articulated above, I find that Petitioner has failed to preponderantly demonstrate that his Tdap vaccination "did cause" any of his medical problems and has thus not established the second prong of *Althen*.

1. *Althen* Prong Three

The timing prong contains two parts. First, a petitioner must establish the "timeframe for which it is medically acceptable to infer causation" and second, he must demonstrate that the onset of the disease occurred in this period. *Shapiro v. Sec'y of Health & Hum. Servs.,* 101 Fed. Cl. 532, 542-43 (2011), *recons. denied after remand on other grounds*, 105 Fed. Cl. 353 (2012), *aff'd without op.,* 503 F. App'x 952 (Fed. Cir. 2013).

Petitioner may well have established that five days after vaccination is a medically acceptable timeframe to infer that the vaccine caused his condition. However, because I have found that Petitioner began to develop symptoms of myelitis three weeks before vaccination, Petitioner cannot demonstrate that the onset of his disease occurred in a timeframe for which it is medical acceptable to infer causation. Petitioner has not established the third *Althen* prong.

VII. Conclusion

Upon careful evaluation of all the evidence submitted in this matter, including the medical records, the affidavits and testimony, as well as the experts' opinions and medical literature, I conclude that Petitioner has not shown by preponderant evidence that he is entitled to compensation under the Vaccine Act. **His petition is therefore DISMISSED. The clerk shall enter judgment accordingly.**[16]

IT IS SO ORDERED.

s/ Katherine E. Oler
Katherine E. Oler
Special Master

[16] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by each filing (either jointly or separately) a notice renouncing their right to seek review.