# In the United States Court of Federal Claims
**OFFICE OF SPECIAL MASTERS**
**No. 22-136V**

| | | |
|---|---|---|
| JORDANNA ROSS, | * | Chief Special Master Corcoran |
| Petitioner, | * | Filed: November 14, 2025 |
| v. | * | |
| SECRETARY OF HEALTH AND HUMAN SERVICES, | * | |
| Respondent. | * | |

*Christopher J. Webb,* Black McLaren Jones Ryland & Griffee, PC, Memphis, TN, for Petitioner.

*Nina Y. Ren,* U.S. Dep't of Justice, Washington, DC, for Respondent.

## ENTITLEMENT DECISION[1]

On February 9, 2022, Jordana Ross filed a petition for compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program").[2] Petition (ECF No. 1) ("Pet."). Petitioner alleges that she experienced transverse myelitis ("TM") due to a Tetanus-diphtheria-acellular pertussis ("Tdap") vaccine she received in August 2019. Pet. at 1.

Respondent questioned the alleged TM injury as a basis for compensation, and after submission of expert reports the parties briefed their positions. *See* Petitioner's Motion for Ruling on the Record, dated Apr. 30, 2025 (ECF No. 52) ("Br."); Respondent's Opposition, dated May 6, 2025 (ECF No. 53) ("Opp."); Petitioner's Reply, dated May 20, 2025 (ECF No. 55) ("Reply"). Now, based on review of the record and parties' filings, I find that TM was not likely Petitioner's

[1] Under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public in its present form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-10–34 (2012)) (hereinafter "Vaccine Act" or "the Act"). All subsequent references to sections of the Vaccine Act shall be to the pertinent subparagraph of 42 U.S.C. § 300aa.

injury, and therefore the matter is appropriately dismissed (since Petitioner's causation theory is dependent on a showing of TM as the basis for entitlement).

## I. Factual Background

Petitioner (29 years old at the relevant time) established care with a new primary care provider ("PCP") on August 20, 2019. Ex. 23 at 30. Her medical history at the time included smoking since she was 16, although she had reduced the number of cigarettes per day over time. *Id.*; *see also* Ex. 2 at 1053 (Petitioner reported smoking ten cigarettes a day). She also had received treatment for a hypertensive disorder, experienced significant weight gain after an early miscarriage and depressive episode, and suffered from chronic lower back pain. Ex. 23 at 21, 23, 30; *see also* Ex. 2 at 105 (Petitioner referred to physical therapy for her lower back pain in October 2017); Ex. 4 at 169. Petitioner's physical exam was overall normal, although her morbid obesity resulted in an abnormal gait. Ex. 23 at 30.

At the aforementioned PCP visit on August 20, 2019, Petitioner received a Tdap vaccine. Ex. 1 at 1. There is no contemporaneous record evidence of any aberrant vaccine reaction (and no medical record evidence in the ensuing four weeks that anything unusual was occurring).

Nearly 30 days later, on September 18, 2019, Petitioner was taken by ambulance to the La Porte Hospital emergency room in La Porte, Indiana, at approximately 1:00 PM. Ex. 8 at 6. She informed ambulance personnel that she woke up *that morning* with a numb sensation around her lower back and tailbone—a feeling she did not consider unusual, but which would typically subside after changing positions. *Id.* But the sensation progressed down both legs to her feet, and although she could move her legs, she could not feel anything in either leg from the hip down. *Id.* She also later reported urinary incontinence and severe back pain. Ex. 2 at 1052.

On exam, Petitioner was found to have "[m]idline, diffuse, severe, tenderness, vertebral point tenderness at L5," and she could not complete the straight leg test or any other testing due to severe pain and leg insensitivity. Ex. 2 at 1054. She also could not feel her lower legs due to her back pain, and she did not feel any pain inflicted on her lower back, upper thighs, and below her knees to feet during the painful stimuli sensory test. *Id.* Lumbar spine MRI and lumbar puncture results were unremarkable. Ex. 4 at 166. Petitioner was diagnosed with acute lumbar back pain and incontinence, and the next day (September 19th) she was transferred to Memorial Hospital South Bend ("Memorial") for additional assessment, and to make use of better imaging equipment. Ex. 2 at 1055; Ex. 4 at 164.

At Memorial, Petitioner reported experiencing a "sudden onset [of] bilateral lower extremity weakness and numbness" on September 18, 2019. Ex. 4 at 165, 168 (noting the sudden onset of pain down her legs the day before, followed by numbness). She also specified that her numbness and weakness was worse on her left, that she "actually ha[d] some sensation on [her]

right," and that she could somewhat move her right leg, but not her left. *Id.* at 168. Dr. Mary Sutherland performed a neurologic exam and observed that Petitioner could move her right leg but not against gravity; could not move her left leg at all; lacked sensation to soft or sharp touch in her left leg (but could feel a firm and sharp touch on the thigh, with no sensation below); and was unable to feel any sensation in her feet. *Id.* at 170. Neurologist Satya Ramiah, D.O., also reached comparable conclusions. *Id.* at 173–74.

The following day (September 20, 2019), Petitioner underwent a second lumbar puncture, and it now revealed a white blood cell count of 388 with 90% neutrophils. Ex. 4 at 250. The records memorializing this test finding do not contain any interpretation of its meaning, however. Additional CT scans of the lumbar and thoracic regions were also performed while Petitioner was at Memorial, but they revealed no acute abnormalities. Ex. 3 at 100.

Ms. Ross remained hospitalized at Memorial until September 21, 2019, when she was transferred to yet another facility—the neurology department at Lutheran Hospital—in relatively stable condition. Ex. 3 at 47; Ex. 4 at 165–67, 187. There, it was again noted that her symptoms had manifested abruptly. Ex. 4 at 165 (Petitioner was "in her otherwise state of health" at time her pain manifested). She again reported that she "had gotten up in the morning [of September 18], went about her normal business, went grocery shopping, and went back home to lie down in bed. When she got up, she had severe lumbosacral back pain and could not get up because of numbness to the bilateral lower extremities. She had some urinary incontinence at that time and was unable to lift herself off the bed to clean up." Ex. 3 at 47; *see also id.* at 79 (Petitioner recalled that she felt "numb [from the] waist down and the symptoms did come within minutes"). At the time of Petitioner's admission to Lutheran Hospital, it was noted that prior CT/MRI scans of Petitioner's lumbar and thoracic spine had yielded normal results, and the transfer was in part deemed necessary "to rule out possible inflammatory spinal etiology." Ex. 4 at 166.

Dr. Sharmaine Habib conducted an exam of Petitioner at her admission on September 21st. *See generally* Ex. 3 at 46–49. Petitioner was deemed stable in her presentation, with "[n]o new weakness, numbness, or tingling." *Id.* at 47. Exam did reveal an inability "to move the right and left lower extremities," and "sensation to pressure, but not to sharp or dull stimulus." *Id.* at 48. The need for a "thoracic MRI to rule out transverse myelitis" was noted. *Id.*

Dr. Andrea Haller, a neurologist, evaluated Petitioner on September 22, 2019. Ex. 3 at 99. Dr. Haller was informed at this time that Ms. Ross had experienced some kind of upper respiratory infection three weeks before (which would mean the start of September—after vaccination but closer in time to the onset of symptoms needing emergency treatment) that had resolved. *Id.* Another history was provided comparable with what Petitioner had given to earlier treaters—no preexisting symptoms before sudden onset of pain/numbness, followed within two hours by greater pain and progressive/descending weakness/numbness/loss of sensation. Ex. 3 at 99. Her weakness

had only worsened September 18–19th. *Id.* at 99–100. And prior scanning, while incomplete, had not revealed any acute concerns. *Id.*

On exam, Ms. Ross "demonstrate[d] [trace]/5 power in the abductor and adductors," and was "otherwise plegic." Ex. 3 at 101. Petitioner "report[ed] variable and patchy sensation to pinprick in the medial left mid-thigh, [ ] some intermittent [pinprick] sensation in the upper thighs and intact sensation at the level of her pannus[, and] . . . absent sensation to [left-tibia]/vibration [bilateral lower extremities] to the level of the pannus." *Id.* And additional MRI scanning of the cervical, thoracic, and lumbar regions (performed September 22, 2019) again produced normal results. *Id.* at 102–04. Dr. Haller deemed the etiology for Ms. Ross's symptoms "not entirely clear," noting the absence of abnormalities observed on imaging, and proposed that the CSF testing results at best suggested "the possibility of a bacterial meningitis," although that testing included normal results as well. *Id.* at 102. Another lumbar puncture was recommended, but prior steroid intravenous medication was to be discontinued since imaging did not support its use. *Id.*

A follow-up lumbar spine MRI was performed on September 23, 2019, and for the first time imaging findings supported the existence of a possible neurologic issue. This MRI was deemed "concerning for [an] abnormal cord signal [that] may be secondary to [a] demyelinating process, acute transverse myelitis[,] and infarctions."[3] Ex. 3 at 83. The MRI did not show any abnormal enhancements, however, which "suggests no active lesion[s]." *Id.* at 84. Petitioner's repeat lumbar puncture (the third time such a diagnostic procedure was performed) now showed twenty-nine white blood cells with 53% monocytes, 39% lymphocytes, and 8% neutrophils. *Id.* at 82.

Petitioner's progress was noted by Dr. Branko Grinfeld on September 25, 2019. Ex. 3 at 70–73. It was again observed how acutely Petitioner's symptoms had manifested. *See id.* at 70 ("the symptoms did come within minutes"). But Petitioner remained stable, despite an inability to move her extremities. *Id.* at 71. Her assessment at this point included TM, and her leg numbness and weakness were attributed to that etiology. *Id.* at 72, 76. But despite concerns for a possibly-demyelinating condition, there was no evidence of an "active lesion," and evidence from CSF testing of pleocytosis was interpreted to be inconsistent with some demyelinating conditions, although a "post infectious [TM]" remained a possible etiology. Dr. Haller proposed a repeat lumbar spine MRI be performed—in particular, a diffusion-weighted imaging/apparent diffusion coefficient ("DWI/ADC") MRI,[4] in order to rule out a possible spinal cord infarct. *Id.* at 73, 76.

[3] "Infarct" is defined as "an area of coagulation necrosis in a tissue due to local ischemia resulting from obstruction of circulation to the area, most commonly by a thrombus or embolus." *Infarct*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=25169 (last visited Nov. 14, 2025).

[4] "Diffusion-weighted MRI" is a tool that "provides image contrast through measurement of the diffusion properties of water within tissues. Application of diffusion sensitizing gradients to the MR pulse sequence allows water molecular displacement over distances of 1–20 μm to be recognized." National Library of Medicine, https://pmc.ncbi.nlm.nih.gov/articles/PMC1693785/ (last visited Nov. 14, 2025).

And Ms. Ross at this time was prescribed intravenous steroids again, although their likely benefit was deemed "not clear" since no active spine or brain lesions had been observed. *Id.* at 76.

By September 26, 2019, Petitioner was reporting that her numbness had improved. Ex. 3 at 68. But it was noted that the DWI/ADC MRI would not be performed while Petitioner was an inpatient. *Id.* at 69. A different progress note prepared by Dr. Haller indicated that Petitioner's obesity prevented such imaging from being performed (and that assessment is confirmed elsewhere in the medical records). *Id.* at 60, 73.

Dr. Arwa Al-Bedour saw Petitioner on September 30, 2019. Ex. 3 at 59–60. Dr. Al-Bedour noted the existence of imaging evidence of "[n]onenhancing T2/STIR hyperintensity involving the distal spinal cord/conus medullaris from the level of T9–T10 to the level of L1–L2, concerning for abnormal cord signal, which may be secondary to demyelinating process, acute transverse myelitis, and infarctions." *Id.* at 59. But the intravenous steroid course Petitioner had received "for possible transverse myelitis" had resulted in no improvement—and at bottom, despite the "extensive neurologic workups" Petitioner had received, treaters had not identified an etiologic explanation for her condition. *Id.*

Ms. Ross was discharged to inpatient rehabilitation on October 4, 2019. Ex. 3 at 33, 35–36, 59. Upon discharge the differential diagnosis continued to include TM and infarction. *Id.* at 33. But it was again emphasized that Petitioner's "overall etiology [wa]s at this point still unclear and [petitioner] [] need[ed] continued follow-up with neurology as an outpatient for further management and full definition of her illness." *Id.* at 33, 36. Treatment records filed in this case for subsequent periods do not shed light on the nature of Petitioner's injury (although the history sections do often include TM in her differential diagnosis).

## II. Expert Reports

### A. Petitioner's Expert – Dr. Justin Willer

Dr. Willer, a neurologist, prepared two written reports on Petitioner's behalf. Report, dated July 4, 2024, filed as Ex. 29 (ECF No. 47-1) ("First Willer Rep."); Report, dated December 16, 2024, filed as Ex. 50 (ECF No. 49-1) ("Second Willer Rep.").

Dr. Willer received his undergraduate degree from Columbia College of Columbia University and his medical degree from the University of Health Sciences/The Chicago Medical School. Curriculum Vitae, filed as Ex. 49 (ECF No. 47-21) ("Willer CV") at 1. Beginning in 1995,

"Apparent diffusion coefficient" is known to "reflect water movement over typically 10–40 µm during 10–100 ms; this predominantly represents diffusion in the extravascular extracellular space or in local capillary blood flow. Thus, ADC can be used as an indicator of pathogenic processes, or response to therapeutic interventions." National Library of Medicine, https://pmc.ncbi.nlm.nih.gov/articles/PMC10377224/ (last visited Nov. 14, 2025).

he has held hospital appointments at University Hospital, Long Island College Hospital, Maimonides Hospital medical Center, and Kings County Medical Center. *Id.* In addition, Dr. Willer has held academic appointments as a Neuromuscular Consultant and Assistant Professor of Clinical Neurology at the State University of New York, HSC at Brooklyn. *Id.* He is licensed to practice medicine in New York, New Jersey, and Florida, and is board certified by the American Board of Psychiatry and Neurology, with added qualifications in clinical neurophysiology, and the American Board of Electrodiagnostic Medicine. *Id.* at 2.

*First Report*

Approximately one third of Dr. Willer's initial report included an overview of Petitioner's medical history, consistent with what is summarized above. First Willer Rep. at 2–9. He then provided an explanation of TM, defining it broadly as "a disparate group of acute and subacute-infectious, non-infectious and inflammatory, spinal cord syndromes." *Id.* at 10. He noted its diagnostic criteria include:

> (1) Development of motor, sensory, or autonomic dysfunction attributable to the spinal cord.
> (2) Bilateral signs and/or symptoms (symmetry is not required).
> (3) A clearly established sensory level.
> (4) Exclusion of extra-axial compressive etiology by imaging studies such as MRI.
> (5) Inflammation within the spinal cord demonstrated by CSF [cerebrospinal fluid] pleocytosis or elevated IgG index or gadolinium enhancement. If all the inflammatory criteria are lacking at symptom onset, repeat the MRI and lumbar puncture between 2 and 7 days later.
> (6) Progression from onset to nadir between 4 hours and 21 days.

*Id.;* G. Barnes et al., *Transverse Myelitis Consortium Working Group – Proposed Diagnostic Criteria and Nosology of Acute Transverse Myelitis,* 59 Neurol. 499–505 (2002), filed as Ex. 31 (ECF No. 47-3) (the "Working Group Criteria").

TM, Dr Willer contended, is known to occur post-vaccination. First Willer Rep. at 10–11. It had first been observed in the 19th century that the smallpox and rabies vaccines could be associated with "encephalomyelitis," although those kinds of vaccines are easily distinguishable from Tdap. *Id.* at 10.[5] But a more recent study looking specifically at TM had observed

[5] It has been noted in prior Program cases, however, that arguments making analogies to the rabies vaccine for purposes of bulwarking causation are unpersuasive, since that vaccine's components (derived in part from animal brain tissue) are completely distinguishable from the contents of any covered vaccine, including Tdap. *See, e.g.*, *L.C. v. Sec'y of Health & Hum. Servs.*, No. 17-722V, 2021 WL 3630315, at *11 (Fed. Cl. Spec. Mstr. July 2, 2021).

associations between it and a number of different vaccines, as reflected in case studies. *See generally* N. Agmon-Levin et al., *Transverse Myelitis and Vaccines: A Multi-Analysis,* 18 Lupus 1198 (2009), filed as Ex. 35 (ECF No. 47-7) ("Agmon-Levin") (identifying five case reports in which TM was observed to have occurred after receipt of a tetanus-containing vaccine). But Agmon-Levin had to perform a literature search over a nearly 40-year timeframe in order to mine from it those five case reports, underscoring how uncommon a post-vaccination adverse reaction it was. Agmon-Levin at 1199.

Dr. Willer also referenced several case reports in which an individual experienced TM after receipt of a tetanus toxoid-containing vaccine. *See, e.g.*, R. Riel-Romero, *Acute Transverse Myelitis in 7-Month-Old Boy After Diphtheria-Tetanus-Pertussis Immunization,* 44 Spinal Cord 688 (2006), filed as Ex. 32 (ECF No. 47-4) (describing infant who developed TM within 17 days of vaccination); E. Whittle & N. Roberton, *Transverse Myelitis After Diphtheria, Tetanus, and Polio Immunisation,* 1 Br. Med. J. 1450 (1977), fled as Ex. 33 (ECF No. 47-5) (discussing infant who developed TM within six to seven days of receipt of vaccine). At the same time, however, he acknowledged that a large-scale epidemiologic study had not observed a statistically significant relationship with any vaccine. First Willer Rep. at 11; R. Baxter et al., *Acute Demyelinating Events Following Vaccines: A Case-Centered Analysis,* 63 Clin. Infect. Dis. 1:1456 (2016), filed as Ex. 38 (ECF No. 47-10) ("Baxter"), at 1460–61 (finding no statistically-significant increased risk of TM after receipt of any of the evaluated vaccines, including Tdap).[6]

Dr. Willer opined that Petitioner's TM was likely attributable to the Tdap vaccine she had received. First Willer Rep. at 15–25. But most of this section of his report simply recapitulated his prior records summary. He mainly questioned the validity of concluding that Petitioner's TM might have been post-infectious rather than vaccine-caused, emphasizing the lack of substantiation in the record for this possibility. *See, e.g.*, *Id.* at 17, 24. Dr. Willer thus felt it speculative to offer this to explain Petitioner's TM, when it was known she had been vaccinated. *Id.* at 24–25. Otherwise, there was no other explanation provided for Petitioner's injury, and the temporal association (29 days from vaccination to onset) was in Dr. Willer's opinion consistent with how long it would take for an autoimmune, cross-reactive process instigated by vaccination and resulting in TM to occur. *Id.* at 27; F. Pidcock et al., *Acute Transverse Myelitis in Childhood*, 68 Neurol. 1474 (2007), filed as Ex. 48 (ECF No. 47-20), at 1479 (noting that in 47 instances of pediatric TM, onset occurred within 30 days of receipt of a vaccine in 28 percent of sample, although authors reached no conclusions as to causation on the basis of this finding).

[6] Dr. Willer also reviewed literature discussing relationships between a different central nervous system demyelinating condition, acute demyelinating encephalomyelitis "(ADEM"). First Willer Rep. at 11–12. In fact, while Baxter observed no TM association with Tdap vaccine, it *did* with respect to ADEM. Baxter at 1460–61. But ADEM is not at issue in this case.

*Second Report*

In his supplemental report, Dr. Willer addressed criticisms from Respondent's expert, Dr. Karen Roos. He attempted to rebut Dr. Roos's view (as discussed below) that the strength/weakness testing Petitioner underwent at different times while hospitalized in late September 2019 suggested no progression of symptoms (inconsistent with TM's usual course). Second Willer Rep. at 1–2. In response, he emphasized that (a) the September 19th testing revealed weakness, and (b) in fact Dr. Haller on September 22nd observed "trace weakness," which Dr. Willer deemed evidence of "no movement across a joint and thus shows that there was progression" in Petitioner's strength diminishment. *Id.* at 2. He also observed that Dr. Sutherland's exam memorialized an ability to move the lower right limb on September 19th—and yet by the 21st a different treater observed "no visible movement in the right limb," and hence more evidence of negative symptoms progression. *Id*. at 7.

In so contending, Dr. Willer argued that Dr. Roos had misconstrued the testing criteria employed to evaluate weakness. Second Willer Rep. at 6–8. He invoked the "medical research council scale," maintaining that it differentiated between a "trace" muscle contraction (slightly more strength than no contraction at all) and other gradations, going up on a 1-5 scale but with overlaps from one level to the next. T. Paternostro-Sluga et al., *Reliability and Validity of the Medical Research Council (MRC) Scale and a Modified Scale for Testing Muscle Strength in Patients with Radial Palsy,* 40 J. Rehabil. Med. 665 (2008), filed as Ex. 57 (ECF No. 49-8), at 666 Table II. In Dr. Willer's view, "[a] drop of a full grade on the MRC scale would be considered significant worsening and would not be considered the same [as something below it]." Second Willer Rep. at 7.

Dr. Willer also denied that the "tempo of the presentation" of Petitioner's neurologic manifestations was inconsistent with TM. Second Willer Rep. at 3. He noted that Ms. Ross's initial complaint—severe lower back pain—was not specific to an infarct, but could also be seen in TM. *Id.* For support, he cited several case reports in which TM diagnoses followed initial back pain. *See, e.g.*, G. Lee, *Acute Longitudinal Extensive Transverse Myelitis Secondary to Asymptomatic SARS-CoV-2 Infection,* 14:e244687 BMJ Case Rep. 1 (2021), filed as Ex. 54 (ECF No. 49-5) (discussing woman who sought emergency care after one day of gradual onset sharp back pain). Some of these instances followed receipt of a COVID-19 vaccine (although that kind of vaccine is distinguishable from Tdap, in both its contents and how it functions). Second Willer Rep. at 3–4.

Thereafter, Petitioner's progression toward manifestation of more classic neurologic symptoms did not reach nadir within 12 hours, as Dr. Roos contended, but instead (as reflected in strength testing) her symptoms course proceeded in downward fashion over several days. Specifically, Dr. Willer concluded that "Ms. Ross' weakness progressed from September 18, 2019

until she reached her nadir on September 21, 2019 a period of 3 days"—and hence longer than might be expected for an infarct (while wholly consistent with the timeframe ranges for TM). Second Willer Rep. at 8.

Dr. Roos had also pointed to CSF testing results as more consistent with a spinal cord infarct, but Dr. Willer maintained this constituted an incomplete evaluation of all relevant results. Second Willer Rep. at 4–6. While Dr. Roos invoked initial CSF results obtained from testing performed on September 20, 2019 (notably, the second lumbar puncture performed), the next one (performed on September 22nd) revealed elevated proteins and an IgG index, both of which would be "consistent with an autoimmune process." *Id.* at 5; B. Chen et al., *A Comparison of IgG Index and Oligoclonal Band in the Cerebrospinal Fluid for Differentiating Between RRMS and NMOSD,* 12 Brain Sci. 69:1 (2022), filed as Ex. 52 (ECF No. 49-3), at 8 (noting the utility of IgG index values in distinguishing between multiple sclerosis and neuromyelitis optica spectrum disorder).

In particular, evidence from testing of increased levels of myelin basic protein ("MBP"), a nerve component, demonstrated "the active breakdown of myelin consistent with a demyelinating lesion and not a stroke," and thus "[a]n increase in myelin basic protein confirms the presence of a demyelinating process," (although Dr. Willer relied on articles not specific to TM for this contention). Second Willer Rep. at 5; A. Sokhan et al., *Assessment of the Demyelinating Process Activity in Patients with Herpesviral Meningitis and Meningoencephalitis Based on the Level of Myelin Basic Protein (MBP) in the Cerebrospinal Fluid,* 74 Wlad Lek. 3:512 (2021), filed as Ex. 60 (ECF No. 49-11). Dr. Willer compared the levels Petitioner displayed with typical levels for an infarct, noting they would be significantly lower in the latter case. But authority offered for this proposition did not involve comparing infarcts to neuroinflammatory conditions like TM. *See, e.g.*, J. Matias-Guiu et al., *Myelin Basic Protein and Creatine Kinase BB Isoenzyme as CSF Markers of Intracranial Tumors and Stroke,* 73 Acta Neurol. Scand. 461 (1986), filed as Ex. 55 (ECF No. 49-6), at 463 (observing increased MBP levels in brain infarction patients compared to *intracranial tumors*, and attributing the difference to compression or pressure changes). IgG index increases were also uncommon in instances of an acute ischemic infarction. K. Laichinger et al., *No Evidence of Oligoclonal Bands, Intrathecal Immunoglobulin Synthesis and B Cell Recruitment in Acute Ischemic Stroke,* PLOS ONE | https://doi.org/10.1371/journal.pone.0283476 (March 31, 2023), filed as Ex. 53 (ECF No. 49-4), at 7–8 (observing a low prevalence of IgG index levels in sample of patients suffering from ischemic stroke, and concluding that when evidence of a higher IgG index is found, treaters should consider whether some underlying chronic inflammatory CNS disorder existed).

The evidence of pleocytosis, however, seen in Ms. Ross's testing was in Dr. Willer's estimation fully consistent with an inflammatory myelitis like TM. Second Willer Rep. at 5–6. In support, Dr. Willer noted how TM (albeit as a presenting symptom of other kinds of central nervous system ("CNS") demyelinating diseases, like multiple sclerosis or neuromyelitis optica

spectrum disorder) can be associated with evidence of neutrophil levels and/or pleocytosis comparable to what Petitioner's testing revealed. *Id.* at 6. Thus, Dr. Willer maintained that it was incorrect to conclude that these kinds of test results were more consistent with stroke/infarction.

Dr. Willer concluded with a second review of the Working Group Criteria referenced in his first report, identifying the specific evidence from the medical record that he felt satisfied certain of them. Second Willer Rep. at 8–9; Working Group Criteria at 500 Table 1. First, Petitioner had demonstrated "the presence of paraparesis and sensory loss" consistent with the first criterion (motor/sensory dysfunction attributable to the spinal cord), and "bilateral weakness and sensory loss" in satisfaction of the second. *Id.* at 8. The fourth ("exclusion of extra-axial compressive etiology" was also met, since Petitioner's MRI and CT imaging so confirmed. *Id.* The fifth criterion was met, based on evidence of the pleocytosis and IgG index levels consistent with spinal cord inflammation. *Id.* And progression to nadir took three days (falling within the 4 hours to 21-day timeframe). *Id.*[7] Five of the six criteria were established.

B. Respondent's Expert – Dr. Karen L. Roos

Dr. Roos prepared two written reports for Respondent, relying on her expertise as a neurologist. Report, dated Oct. 7, 2024, filed as Ex. A (ECF No. 48-1) ("First Roos Rep."); Report, dated Mar. 20, 2025, filed as Ex. C (ECF No. 50-1) ("Second Roos Rep.").

Dr. Roos is a board-certified neurologist specializing in infectious diseases and serves as the John and Nancy Nelson Professor Emerita of Neurology at the Indiana University School of Medicine, where she has taught neurology since 1985. Curriculum Vitae, filed as Ex. B (ECF No. 48-6) ("Roos CV") at 1, 2. She obtained her undergraduate degree from the University of Pittsburgh, and her medical degree from the Drexel University School of Medicine. *Id.* at 1. Thereafter, she completed her residency in Neurology and training in Electroencephalography at the University of Virginia Medical Center. *Id.* Dr. Roos has over 40 years of experience in treating patients with neurological disorders with a specialization in neurological infectious diseases. First Roos Rep. at 1. She has authored or edited eight textbooks and has published over 255 manuscripts relating to neurology. *Id.* On multiple occasions, Dr. Roos has treated and cared for patients with TM and infectious/parainfectious myelitis.

[7] In fact, Dr. Willer observed, Dr. Roos's contention that Petitioner's 12-hour progression to nadir was too fast is belied by the Working Group Criteria's own timeframe, which only envisions nadir progression sooner than *four* hours—not days—to be inconsistent with TM. Second Willer Rep. at 8. In this regard, Dr. Willer is wholly correct—although the tenor of Respondent's argument (that a relatively-fast progression is less likely in the context of TM) remains somewhat valid.

*First Report*

Dr. Roos, like Dr. Willer, included her own records summary before providing her opinion. First Roos Rep. at 1–3. But she chose to emphasize different facts from it. In particular, she highlighted evidence that Petitioner's extremity weakness and numbness had manifested quite suddenly/acutely. *Id.* at 2 (*citing* Ex. 4 at 165), 3 (*citing* Ex. 3 at 79). She noted Petitioner's preexisting issues as well, like hypertension and morbid obesity. First Roos Rep. at 2. And she observed that at the time of Petitioner's discharge by the end of September/early October 2019, Petitioner's etiology remained unclear, despite a fairly comprehensive neurologic evaluation (although TM was consistently included in the diagnostic differential). *Id.* at 3.

Based on that records review, Dr. Roos opined that Petitioner's injury was not likely TM. First Roos Report at 5. She placed great weight upon the "tempo of presentation of Petitioner's neurologic disorder," which she deemed inconsistent with TM. *Id.* at 3. The record established that Petitioner had experienced severe back pain, followed by lower extremity weakness and numbness, all in the same day—a presentation Dr. Roos deemed "classic" for a "spontaneous spinal cord infarction." *Id.* One study had observed that the majority of its spinal cord infarction subjects initially experienced severe back pain. M. Gharios et al., *Spontaneous Spinal Cord Infarction: A Systematic Review,* 6:e000754. doi:10.1136/bmjno-2024-000754 BMJ Neurol. Open 1 (2024), filed as Ex. A-1 (ECF No. 48-2) ("Gharios") (acute back pain in 70 percent of cases, followed by a "prompt debut" of neurologic deficits). And progression to nadir in more than 80 percent of cases occurred within 12 hours. Gharios at 3, 5; *see also* N. Zalewski et al., *Characteristics of Spontaneous Spinal Cord Infarction and Proposed Diagnostic Criteria,* 75 JAMA Neurol. 1:56 (2019), filed as Ex. A-2 (ECF No. 48-3) ("Zalewski"), at 61 (noting proposed criteria for diagnosing spinal cord infarct includes evidence of "rapid development of severe deficits within 12 hours").

By contrast, severe and sudden back pain as a TM presenting onset symptom was less common. First Roos Rep. at 4. More importantly, Dr. Roos maintained, progression to nadir could take far longer—up to 21 days. Working Group Criteria at 500 Table 1. And Dr. Roos distinguished the interval between literal onset and first manifestation of neurologic symptoms with the subsequent interval from neurologic symptoms to nadir. First Roos Rep. at 4.

The imaging findings, and the symptoms progression they depicted, were also significant to Dr. Roos. Ms. Ross's initial lumbar and thoracic MRIs, as well as CT scans (performed September 19–22, 2019) yielded normal/unremarkable results—inconsistent with an existing or ongoing demyelinating injury to the spinal cord. Only by September 23rd did a lumbar MRI reveal an abnormal signal that was deemed possibly to support the existence of TM (along with an infarction). Dr. Roos noted, however, that "an initial normal MRI during the acute phase has been reported in spontaneous spinal cord infarction, but T2 abnormalities are expected after several days." First Roos Rep. at 4; Gharios at 7 ("[u]p to half of T2-weighted imaging may not depict any

spinal cord lesions within the first 24 hours after symptom onset"); Zalewski at 59 (24 percent of 126 infarct patient sample had initially normal MRI); C. Alblas et al., *Acute Spinal-Cord Ischemia: Evolution o MRI Findings,* 8 J. Clin. Neurol. 218 (2012), filed as Ex. A-4 (ECF No. 48-5) ("Alblas"), at 222 ("MRI findings are usually normal in the acute phase, whereas spinal-cord edema and T2 abnormalities may be expected after 1–2 days. Gadolinium enhancement appears even later after symptom onset"). Thus, Petitioner's imaging results were more consistent with infarct. And the kind of specialized imaging that could have confirmed the infarct was never performed, although it had been contemplated by treaters.

Dr. Roos also addressed the pleocytosis (meaning evidence of white blood cells in the CSF, which is evidence of an ongoing infectious condition) findings in this case. Normally, pleocytosis is evidence of an inflammatory/infectious condition in the spinal cord/CNS, and thus would be suggestive of myelitis rather than a mechanical/ischemic injury. But Dr. Roos contended that pleocytosis and/or evidence of CNS inflammation could be seen in the context of an infarct as well (even if it was not common). First Roos Rep. at 4; Gharios at 4–5 (high protein levels in CSF testing the "most common pathologic finding" in half of sample patients), and 6 Table 5 (pleocytosis observed in CSF testing of 12 percent of 174-patient sample).

Otherwise, Dr. Willer's TM diagnosis was not reliable, in Dr. Roos's estimation. First Roos Rep. at 5. Exams conducted by two of Petitioner's treaters—Drs. Sutherland and Haller—observed no change in Petitioner's weakness from the time of her first hospital exam on September 19, 2019 to September 22nd. Rather, at both times the exam findings were roughly the same (even if both revealed significant deficits). *Id.* Thus, there was no evidence of downwardly-progressing symptoms. Ex. 3 at 101.

The other general basis for Dr. Roos's diagnostic opinion appears to arise from the medical record evidence about Petitioner's comorbidities. She noted that Ms. Ross was obese; a smoker; and was hypertensive. First Roos Rep. at 2, 3. All these factors made her at serious risk for an infarction, and far more likely to have been causal than the Tdap vaccine. Gharios at 5 Table 2 (identifying as vascular risk factors in 440 patient sample hypertension (106 patients), smoking (79 patients), and obesity (3 patients)), 7 (hypertension and smoking most common risk factors in studied cohort); Zalewski at 58 (three fourths of patient sample had a history of one or more vascular risk factors), 61 ("traditional stroke mechanisms (atherothrombosis) likely have an important role" in causing a spinal cord infarct).

*Second Report*

Dr. Roos prepared a succinct, barely two-page supplemental report responding to some of Dr. Willer's criticisms. In the main, she contested Dr. Willer's argument that she had misinterpreted the proper methodology for measuring muscle strength. Second Roos Rep. at 1. She

noted that it did not appear from the records that Petitioner's treaters had actually employed the scale methodology Dr. Willer favored, and that instead clinicians tended to "loosely" apply these kind of standards (citing a version of the scale she felt had more likely been applied). *Id.* And slight differences in how exams would be performed would "always [be] expected." *Id.* Taking this into account when looking at Petitioner's records, Dr. Roos concluded that the exams performed on different days (September 19, 2019 versus September 22, 2019) by different neurologists still yielded "exactly the same" results. Second Roos Rep. at 1. Thus, none of the downward progression that would be associated with TM was shown to exist in this case.

## III. Procedural History

The matter was initiated almost four years ago. After Respondent's initial Rule 4(c) Report contesting entitlement was filed in May 2023, I ordered Respondent to initiate expert report discovery, noting that claims the flu vaccine can cause TM are fairly common, and routinely compensated. *See* Order, dated June 14, 2023 (ECF No. 40). Respondent thereafter filed an amended Rule 4(c) Report that more pointedly questioned Petitioner's likely success in establishing entitlement. *See* Amended Rule 4(c) Report, dated Sept. 12, 2023 (ECF No. 41). I thus ordered Petitioner to obtain an expert report specific to the issues in this case other than whether the flu vaccine can cause TM. Thereafter, the expert reports mentioned above were filed (and a change in counsel also occurred). The process was completed and then I set a schedule for ruling on the record. The matter is now ripe for resolution.

## IV. Parties' Argments

*Petitioner*

Petitioner maintains that she was "correctly diagnosed with TM," and that this diagnosis is further corroborated by her other treating physicians, the medical literature, and Dr. Willer's reports. Br. at 11. The medical records "reflect symptomology that is extremely consistent with TM"—noting that "[w]ithin two days of [her] beginning to lose the ability to feel her legs, Petitioner's treating neurologists began to suspect TM or another demyelinating condition as the suspected etiology." *Id.* at 12; *see also* Ex. 4 at 11. In addition, Petitioner notes the substantial testing she underwent, and emphasizes that the results and her clinical presentation are "c[onsistent] w[ith] transverse myelitis." Br. at 13 (citing Ex. 3 at 76). And her initial post-vaccination hospitalization records also continuously reflect Petitioner's prior diagnosis of acute TM, according to Petitioner. *See, e.g.*, Ex. 4 at 122; Ex. 2 at 238, 318; Ex. 25 at 43. Thus, and because none of Petitioner's treating physicians or neurologists expressed any disagreement as it relates to Dr. Haller's proposed TM diagnosis, Petitioner contends that she has put forth preponderant evidence demonstrating that she suffered from TM. Br. at 20.

To further bulwark this contention, Petitioner relies on Dr. Willer's opinion. Br. at 17 (citing First Willer Rep. at 25). Specifically, Dr. Willer notes that Petitioner's medical records

document the presence of paraparesis and sensory loss, as well as bilateral weakness and sensory loss; MRI and CT imaging of the thoracic and lumbar spine excluded extra-axial compressive etiology; and inflammation of the spinal cord was revealed through the presence of pleocytosis and an elevated IgG index. *See* Ex. 50 at 8; Ex. 3 at 396. Additionally, there is record evidence supporting a period of progressively worsening symptoms from onset to nadir between four and twenty-one days. Thus, he maintains that Petitioner has satisfied at least five of the six criteria for a TM diagnosis, and accordingly, was properly diagnosed with TM by her treating physicians and neurologists. Br. at 20.

Petitioner disagrees with Dr. Roos's assertion that symptomology (i.e., sudden onset of severe lower back pain) is more likely attributable to a spontaneous spinal cord infarction and not TM. In so arguing, Petitioner notes that lower back pain "frequently occurs in transverse myelitis." *Id.* at 21 (referencing case reports of TM after receipt of COVID-19 vaccine or infection). Petitioner acknowledges, however, that these case reports fail to provide an overall incidence of lower back pain in patients with TM, but maintains that such studies demonstrate that individuals with TM can present with back pain in addition to other symptoms like weakness and sensory loss. Br. at 22. Furthermore, the presence of severe lower back pain does not preclude a diagnosis of TM. *Id.* at 23. Similarly, Petitioner emphasizes her elevated protein levels, IgG index, and CSF pleocytosis as further support for the diagnosis of TM, and notes that such diagnostic test results undermine Dr. Roos's proposed alternative diagnosis of spontaneous spinal cord infarction. *See generally id.* at 23–27.

Petitioner also addresses Respondent's assertion that a progression of weakness from onset to nadir in twelve hours precludes a diagnosis of TM. Such a timeframe would *still* satisfy criteria six of the TMCWG for TM. *Id.* at 27–28. As noted by Dr. Willer, "the TMCWG provides that TM can be diagnosed, among other criteria, by a "[p]eriod of progression from onset of symptoms to nadir *between 4 hours and 21 days*." *Id.* at 28 (citing Ex. 61) (emphasis in original). Prior Program cases have not only previously applied the TMCWG criteria when assessing the propriety of a TM diagnosis, but the Program has "consistently held that a progression from onset to nadir (as contemplated by criteria [six] of the TMCWG diagnostic criteria) occurs between fours hours and twenty-one (21) days in TM cases." *Id.*; *see also Murray v. Sec'y of Health & Hum. Servs.*, No. 19-1976V, 2022 WL 17853378, at *9 (Fed. Cl. Spec. Mstr. Nov. 30, 2022) (applying the TMCWG criteria); Reply at 6 (emphasizing that "[s]pecial masters consistently note that patients with TM often may not satisfy every diagnostic criteria proposed by the TMCWG"). Therefore, and although she only met five of the six TMCWG criteria, Petitioner maintains that she was "correctly diagnosed with acute TM by her treating neurologist following her Tdap vaccination, which diagnosis was corroborated by [her] other treating physicians as well as by [her] expert, Dr. Willer." Br. at 30; Reply at 7.

*Respondent*

Respondent argues that Petitioner more likely suffered from "a spontaneous spinal cord infarction." Opp. at 8. Dr. Roos opines that "[t]he tempo of the course of [Petitioner's] neurological disorder is classic for spinal cord infarction." *Id.* at 9 (citing First Roos Rep. at 5); *see also* Ex. 3 at 79 (documenting Petitioner's report that her symptoms emerged "within minutes); Ex. 4 at 165 (describing Petitioner's complaints of "sudden onset [of] bilateral lower extremity weakness and numbness"). Although Dr. Willer suggests that Petitioner's symptoms worsened to nadir over three days, Respondent maintains that he not only "misinterprets the providers' findings" but that the medical records overall preponderate in favor of Petitioner having rapidly reached nadir within hours of her initial sudden onset of symptoms. Opp. at 10.

Respondent criticizes Dr. Willer's reliance on case reports to preponderantly demonstrate that Petitioner's low back pain was more likely caused by TM and not a spinal cord infarction. Opp. at 11. Respondent acknowledges that back pain was identified as a symptom in the three case reports cited by Dr. Willer, but contends that "the mere presence of the symptom provides no information regarding 'the incidence of lower back pain in transverse myelitis.'" *Id.* (citing Ex. 50 at 3–4). Similarly, Respondent emphasizes the role in which case reports play within the Vaccine Program—stating that it is well understood that they provide only weak evidence of causation. *Id.*; *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1253–54 (Fed. Cir. 2011) (finding that single case studies "d[o] not contain any meaningful analysis about causation"). Moreover, the case reports Dr. Willer relies upon are materially different from Petitioner's circumstances. Specifically, the patients described in the case reports not only improved with steroid treatment, but exhibited "progressive" development of symptoms, whereas Petitioner showed minimal to no improvement with steroid treatment, and she had an acute onset of symptoms. Opp. at 11, 12; *see also* Ex. 56 at 2; Ex. 59 at 2; Ex. 54 at 1. Thus, it is more likely than not that Petitioner did not suffer from TM based upon the relied upon case reports.

Then there are the risk factors Petitioner possessed for an infarct. Not only are hypertension and smoking the two most common vascular risk factors for spinal cord infarctions (Petitioner having both hypertensive disorder and a lengthy smoking history), but a diagnosis of spinal cord infarct was never officially ruled out by Petitioner's treating physicians. Opp. at 13. For example, Petitioner's discharge note, on October 4, 2019, stated that her "overall etiology [wa]s at this point still unclear and [Petitioner] [] need[ed] continued follow-up with neurology as an outpatient for further management and full definition of her illness." *Id.* (citing Ex. 3 at 33). Additionally, Petitioner's assertion that her post-hospitalization records identify TM as her diagnosis, is, as standard practice, only listed as part of Petitioner's medical history, but does not mean that Petitioner's treating providers has "verified or endorsed what the patient has subjectively reported." Opp. at 14.

## V. Applicable Legal Standards

### A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly ex rel. Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[8] There is no Table claim for TM resulting from any covered vaccine.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health and Hum. Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

[8] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. App'x. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

Each *Althen* prong requires a different showing. Under *Althen* prong one, 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). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

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). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny 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*, 121 Fed. Cl. at 245 ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)).

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Cerrone v. Sec'y of Health & Hum. Servs.*, 146 F.4th 1113, 1121 (Fed. Cir. 2025) (the argument that *Althen* prong one requires only a showing of plausibility "understates the burden [a petitioner] bears under the first factor in the *Althen* formulation"); *Kalajdzic v. Sec'y of Health & Hum. Servs.*, No. 2023-1321, 2024 WL 3064398, at *2 (Fed. Cir. June 20, 2024) (arguments "for a less than preponderance standard" deemed "plainly inconsistent with our precedent" (*citing Moberly*, 592 F.3d at 1322)); *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also Howard v. Sec'y of Health & Hum. Servs.*, 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) ("[t]he standard has been preponderance for nearly four decades"), *aff'd*, 2024 WL 2873301 (Fed. Cir. June 7, 2024) (unpublished). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

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; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions

and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *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).

Medical records and statements of a treating physician, however, 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"); *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"). 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 be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. 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 F. Appx. 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 align 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. Appx. 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 rev. den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues

begins with consideration of the medical records. 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 415, 417 (Fed. Cir. 1993) (determining that 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).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs.*, 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to 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); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

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 often 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. United States 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, the Federal Circuit has also noted that there is no formal "presumption" that

records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony (provided in the form of an affidavit or declaration) 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. *La Londe 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 often requires a petitioner to present expert testimony in support of his 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). Under *Daubert*, the 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).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *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"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts 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. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs.*, No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). 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. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

Both parties filed medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all the medical literature submitted, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, No. 2015–5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

E. *Determination of Claim on Basis of Record*

I have opted to decide entitlement in this case based on written submissions and evidentiary filings, including the expert reports filed by each side. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers rather than via evidentiary hearing, where (in the exercise of their discretion) they conclude that the former means of adjudication will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The choice to do so has been affirmed on appeal. *See D'Toile v. Sec'y of Health & Human Servs.*, No. 15-85V, 2018 WL 1750619, at *2 (Fed. Cir. Apr. 12, 2018); *see also Hooker v. Sec'y of Health & Human Servs.*, No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *See Hovey v. Sec'y of Health & Human Servs.*, 38 Fed. Cl. 397, 402-03 (1997) (special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417.

## ANALYSIS

### I. Transverse Myelitis vs. Spinal Cord Infarct

Although the parties disagree as to Petitioner's proper diagnosis (as well as the emphasis that should be given to some of the relevant medical criteria in reaching that diagnosis), they offered reliable evidence that help delineate and distinguish the competing etiologic explanations in this case. TM is defined by the Working Group Criteria as a myelitis[9] attacking the spine, and

[9] "Myelitis" is defined as "1. Inflammation of the spinal cord, often part of a more specifically defined disease process. One group of diseases is named according to whether primarily white matter or gray matter is affected (leukomyelitis and poliomyelitis); another group is defined by whether there is coexistent disease of the meninges (meningomyelitis) or the brain (encephalomyelitis). In practice, the term is also used to denote noninflammatory lesions of the spinal

"characterized clinically by acutely or subacutely developing symptoms and signs of neurologic dysfunction in motor, sensory, and autonomic nerves and nerve tracts of the spinal cord. There is often a clearly defined rostral border of sensory dysfunction, and spinal MRI and lumbar puncture often show evidence of acute inflammation." Working Group Criteria at 499.

A spinal cord infarct can also involve very similar symptoms, and also presents acutely, but is distinguishable in nature and cause. Infarcts, or ischemia, reflect dead tissue often attributable to a lack of blood supply, either from blood vessel blockage or inflammation. As noted in Gharios, spinal cord infarct has "has been ascribed to the interplay between various vascular risk factors such as diabetes, hypertension and hyperlipidaemia." Gharios at 1. Zalewski adds that "[o]nset is more protracted and radiologic distinction from competing diagnoses is more difficult than with cerebral infarction. Thus, patients with a spontaneous (i.e., nonprocedural, nontraumatic) [spinal cord infarcts] often receive misdiagnoses." Zalewski at 57. Indeed, misdiagnoses of TM occur frequently. *Id.*

## II. Petitioner Did Not Likely Experience TM

As a threshold matter, a petitioner must establish she suffers from the condition for which she 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*, 569 F.3d at 1382 (quoting *Knudsen*, 35 F.3d at 549). "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 '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*, 418 F.3d at 1274. *Lombardi v. Sec'y of Health & Hum. Servs.*, 656 F.3d at 1343, 1351–53 (Fed. Cir. 2011). Resolving the issue of what diagnosis has the most record support can impact whether causation can even be established.

The overall medical record evidence in this case preponderates against a TM diagnosis. My finding is based on a weighing of all evidence, including those clinical findings and test results that support TM. Such evidence in favor of Petitioner's preferred diagnosis unquestionably exists, but the balance of proof tilts against TM. It does not tilt *dramatically*, and I cannot determine that Respondent's counter-diagnosis proposal of spinal cord infarct is the most likely diagnosis either. But the TM diagnosis *itself* was not preponderantly established, regardless of what is the most

cord. 2. Inflammation of the bone marrow." *Myelitis*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=32680&searchterm=myelitis (last visited Nov. 14, 2025).

accurate counter diagnosis—and in so concluding I give weight to the various record elements supporting an infarct as explanatory, since they greatly undermine TM.

First, Petitioner's preexisting comorbidities suggest she possessed significant risk factors for an infarct (and hence her baseline of health heightened the chances an infarct would occur). The literature filed in this case specifically recognizes hypertension and smoking as risk factors, and obesity is also included (albeit posing a lesser risk). Gharios at 2–3; Zalewski at 58. Petitioner possessed both—along with obesity significant enough to prevent her from obtaining certain imaging deemed important to evaluate her diagnostically. And she did not adequately show why the presence of these risk factors in her medical history was not worthy of evidentiary weight.

Second, and as Dr. Roos persuasively argued, Petitioner's initial presentation was generally more consistent with an infarct. A variety of medical evidence components supports this finding. In particular, I give weight to the imaging of Petitioner's cervical and lumbar spine. That imaging did not early on reveal anything concerning, even after Petitioner's initial acute back pain *and* subsequent neurologic symptoms. This is consistent with literature suggesting that the impact of an infarct will not necessarily "show up" immediately on MRI. Alblas at 222. By contrast, had Petitioner been experiencing an antibody-mediated demyelinating injury—based on a vaccine received almost *one month* before, and thus responsible for some autoimmune inflammatory process—imaging should have revealed some existing or ongoing damage, in the form of existing inflammation or enhancing lesions (meaning recently-appearing), but did not.

Then there is the acute, unexpected character of Petitioner's initial back pain. While TM and spinal cord infarcts can both present with back pain, a sudden onset of pain is somewhat more consistent with infarct. *Kouchak v. Sec'y of Health & Hum. Servs.*, No. 18-1279V, 2023 WL 6973017, at *5, 13 (Fed. Cl. Spec. Mstr. Sept. 26, 2023) (acute/sudden manifestation of symptoms more common to infarct than with TM). Indeed, the Working Group Criteria's timeframe for progression from onset to nadir is substantially *longer* than what is usually deemed to be seen with an infarct, allowing up to 21 days to nadir. Working Group Criteria at 500 Table 1. The Working Group Criteria itself notes that a more compressed timeframe from acute onset to nadir is relevant in distinguishing TM from something else, like infarct:

> patients whose symptoms reach maximal severity in 4 < hours from onset should be presumed to have an ischemic etiology. We believe this is justified because the temporal course of vascular lesions (especially arterial thrombotic events) *usually progresses to nadir very rapidly*. If these diagnostic criteria are going to be used to identify patients for prospective therapeutic trials, it will be critical to exclude patients with ischemic myelopathies for whom anti-inflammatory strategies may not be indicated.

*Id.* at 501 (emphasis added).

Petitioner's disease progression better fits this short timeframe than the longer one allowed for TM. It is certainly true that (relying on the Working Group Criteria) Petitioner's course does fit *literally* within the Working Group Criteria's timeframe, which also envisions cases in which neurologic symptoms due to myelitis unfold quickly. But this does not mean that "more likely than not" Petitioner's temporal course was TM. The record better preponderates in favor of infarct here. And as Dr. Roos established, after Petitioner's initially-acute symptoms progression, her course largely stabilized—not fully consistent with TM, but more like an infarct that had plateaued in effect, despite ongoing sequelae. The different strength testing performed on Petitioner from September 19–22, 2019, also supporting a plateau in symptoms, not the downward progression proposed by Dr. Willer (whose reading of the relevant testing criteria was overly literal, assuming a degree of specificity not likely to be applied by actual clinical treaters, while attempting to make hairline distinctions between their more informal exam determinations that were not convincing).

There is also the fact that Petitioner's treaters at best allowed for TM as a *possible* etiologic explanation, given the mix of clinical and laboratory test findings, but did not actually end up *favoring* that diagnosis over an infarction (or some other idiopathic explanation). *See, e.g.*, Ex. 3 at 33, 36. Most notably, treaters identified the need to test specifically for infarct, via DWI/ACP imaging—and literature filed in this case underscores how useful such testing could have been. Gharios at 7 ("the use of DWI in the workup of [spinal cord infarction] may assist in establishing a definite diagnosis and facilitate the elimination of other differentials"). Of course, that test was never performed, preventing me from more assuredly resolving this diagnostic question. But its absence does not render TM more likely as the explanation, and the fact the test was even deemed necessary bulwarks the strength of the infarct's explanatory basis. And Petitioner also did not show improvement from the intravenous steroid treatment she received—the success of which could have indirectly substantiated a TM diagnosis. *See, e.g.*, *Johnson v. Sec'y of Health & Hum. Servs.*, No. 18-410V, 2025 WL 1942989, at *3 (Fed. Cl. Spec. Mstr. June 17, 2025) (efficacy of steroid treatment relevant to TM diagnosis).

As noted, there are aspects of the record that *do* support TM as the proper diagnosis. Many elements of Petitioner's presentation are consistent with the elements of the Working Group Criteria's TM diagnostic test—and the timing of Petitioner's course is not *wholly* inconsistent with it either, contrary to Dr. Roos's contention. Petitioner's pleocytosis findings (while not ruling out an infarct) are also somewhat suggestive of the existence of some ongoing inflammatory process that could reflect the kind of autoimmune process associated with TM. Certainly, TM was always included as a reasonable component of Petitioner's differential, given the difficulty in putting a finger on what the real cause of Petitioner's injury was.

Nevertheless, the weight of *all evidence* on this subject, pro and con, tilts against a finding of TM as the most likely diagnosis. I of course lack the medical capacity to diagnose Petitioner myself, and do not purport to do so. Nor can I say *how likely* it is Petitioner had a spinal cord infarct, even if I find Dr. Roos to have been more persuasive on that issue. But I can, and do, find, that TM has not been shown to have sufficient preponderant support.

## III. The *Althen* Causation Test Cannot be Satisfied

The failure to establish even one of the three *Althen* prongs in the context of a causation-in-fact claim is sufficient basis for a claim's dismissal (and therefore the three prongs need not be *all* addressed in cases where a claimant clearly fails at least one). *Dobrydnev v. Sec'y of Health & Hum. Servs.*, 566 Fed. Appx. 976, 980 (Fed. Cir. 2014).

Here, Petitioner's inability to satisfy the second prong (assuming for sake of argument she could demonstrate her injury to have been TM) prevents a favorable entitlement finding. For the record does not support the conclusion that the Tdap vaccine is a likely explanation for her injury. No treaters ever so proposed. Indeed, they often observed the *absence* of a good etiologic explanation for Petitioner's presentation. *See, e.g.*, Ex. 3 at 33 (documenting 10/4/19 hospitalization discharge note which states "overall etiology [wa]s at this point still unclear …"). And I do not in this record discern an embrace of TM as the best diagnostic explanation. Instead, TM was properly included in a differential that ultimately could not pinpoint an explanation for Petitioner's symptoms, and then repeated as Petitioner's subsequent treatment continued over time.

The lack of medical record evidence of issues of any kind in the month between onset of symptoms and vaccination also weighs against a favorable "did cause" finding. The requirement that Petitioners offer evidence on the second *Althen* prong is not eliminated by a successful prong one showing, and proving a "sequence of logical cause and effect" requires more than merely pointing to the fact that the claimant suffered the alleged disease after vaccination. *Randolph v. Sec'y of Health & Hum. Servs.*, No. 15-146V, 2021 WL 5816271, at *22 (Fed. Cl. Spec. Mstr. Nov. 12, 2021) ("the Circuit has recognized that the second prong is not an afterthought, easily satisfied one the other prongs are met, but *itself* requires the same preponderant showing, and can be dispositive if not satisfied …"). It is thus analytically proper to look for some record evidence corroborating the proposed causation theory—something suggesting a disease process was likely underway, or other evidence confirming its existence.

But this record reveals nothing that would make it more likely than not the Tdap vaccine Petitioner received had initiated some kind of autoimmune process that would spark clinical symptoms within a month. There is no evidence Petitioner possessed any specific autoantibodies proposed to be causal of TM. Petitioner did not benefit from treatments specific for TM, such as the intravenous steroid course she received while hospitalized. Ex. 3 at 59, 76. She simply

developed symptoms within four weeks of vaccination—a temporal association alone that does not at all make it more likely the vaccination explains what came after.

## CONCLUSION

Vaccine Act claimants must carry their burden of proof to be entitled to damages. Petitioner has not shown by preponderant evidence that she had TM—or that even if she did, that the Tdap vaccine likely caused it. She therefore is not entitled to damages.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.[10]

**IT IS SO ORDERED.**

/s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[10] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.