In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 18-1279V

SHABNAM KOUCHAK,	*	Chief Special Master Corcoran
Petitioner,	*	Filed: September 26, 2023
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Howard S. Gold, Gold Law Firm, Wellesley, MA, for Petitioner.

Emilie Williams, U.S. Dep't of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION[1]

On August 23, 2018, Shabnam Kouchak filed a petition for compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program").[2] Petitioner alleges that she suffered transverse myelitis ("TM") as a result of receiving the influenza ("flu") vaccine on November 12, 2015. Petition (ECF No. 1) at Introduction. For the reasons stated below, I find dismissal of the claim is appropriate. The record does not preponderantly support the conclusion that Petitioner incurred TM, the alleged injury—nor has she demonstrated that the flu vaccine can cause the more likely injury, a spinal cord infarction.

[1] Under Vaccine Rule 18(b), each party has fourteen 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. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) ("Vaccine Act" or "the Act"). Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

I. Factual Background

Vaccination and Initial Symptoms

Petitioner received the flu vaccine on November 12, 2015, when she was 41 years old. Ex. 3 at 1. Sixteen days later, on November 28, 2015, she presented to the emergency department ("ED"), complaining of bilateral leg numbness and chest and abdominal pain, noting that feelings of leg weakness began several hours before arrival at the ED. Ex. 9 at 26–34. Petitioner underwent a CT scan of her head and an angiogram, the results of which were unremarkable. Upon examination, Petitioner exhibited left leg paralysis and right leg weakness, absent bilateral patellar, plantar, and Achilles' deep tendon reflexes ("DTRs") and intact arm DTRs. *Id.* She was admitted to the hospital.

On November 29, 2015, a hospital critical care specialist/pulmonologist assessed Petitioner with "new onset paraparesis" associated with paresthesias, urinary retention, and loss of reflexes in the bilateral lower extremities. Ex. 9 at 35–38. That same day, Petitioner was also evaluated by neurologist Erin Frankowicz, M.D., who noted that Petitioner had received a lumbar puncture to rule out Guillain-Barré syndrome ("GBS") "as she had a flu shot a couple weeks ago," and "admits to a recent upper respiratory type illness." *Id.* at 38–43. But the lumbar puncture produced "unremarkable" results, and did not reveal elevated protein levels in her cerebrospinal fluid ("CSF") that would confirm GBS. Ex. 9 at 38–39. Additionally, Petitioner had a normal serum multiple sclerosis panel and displayed normal levels of CSF myelin basic protein. *Id.* Petitioner further underwent an MRI of the thoracolumbar spine, the results of which did not reveal acute spinal cord signal abnormalities, although a possible hemangioma was noted at T6. *Id.* at 151. Petitioner was eventually transferred to a different hospital.

The next day (November 30, 2015), a second MRI—this time of the cervical spine and brain—revealed "pathologic T2 high signal intensity in bilateral anterior upper thoracic spinal cord, at T3 visualized T6 levels." Ex. 10 at 60–64. Several days later, on December 4, 2015, an MRI of the thoracic spine showed that the previously-seen T2 hyperintensity within the anterior spinal cord gray matter at the level of T3-T6 "demonstrates restricted diffusion consistent with spinal cord infarct." *Id.* at 151–52.

Petitioner was discharged on December 9, 2015. Records from this time noted that "[u]ltimately, her symptoms were *determined to be from a spinal cord infarct*: however, etiology was undetermined at the time of discharge." *Id.* at 38 (emphasis added), *see also* 37–43. Additionally, Petitioner's anterior spinal artery infarct was confirmed from T3-6 levels at this time. *Id.* at 38. Later that month, Petitioner followed up with neurologist Shaneela Malik, M.D., on December 30, 2015. Ex. 10 at 43–47. During this visit, Dr. Malik noted that Petitioner's MRI of the thoracic spine supported the conclusion that she had experienced an acute infarction at the T3-T6 level. *Id.* at 47. Despite an unknown etiology for the infarction, Dr. Malik added that various

testing results suggested that sarcoidosis[3] should be further investigated as a possible explanatory factor. *Id.*

Treatment in 2016

On January 3, 2016, Petitioner returned to the ED with complaints of bilateral upper extremity paresthesias for the last day. Ex. 10 at 48–50. Petitioner was admitted to the hospital, where she was later evaluated by neurologist Mirjon Bishja, M.D. *Id.* at 57. Dr. Bishja noted that Petitioner exhibited "poor effort" and weakness in the deltoids upon examination. *Id.* Petitioner underwent repeat MRIs of the brain, cervical, and thoracic spines. *Id.* at 159. Petitioner's MRI of the thoracic spine revealed "ventral lateral and left paramedian thoracic cord signal alteration which appears less prominent and expansile when compared to prior December 3, 2015 exam," but no enhancement or new lesions were seen. *Id.* Petitioner was discharged on January 9, 2016. *Id.* at 76. The records note that "no acute findings" were shown on the MRI, and there were "no findings on exam to suggest a new acute pathology." *Id.* at 76–78.

Petitioner saw neurologist Daniel Miller, M.D., for a follow-up appointment on March 15, 2016. Ex. 10 at 93–98. Dr. Miller noted "[n]o new deficits" since the November 2015 spinal cord infarct incident, and assessed Petitioner with spinal cord infarction in T3-T6 level. *Id.* at 98. Dr. Miller, however, allowed that he could not "exclude a post-vaccination transverse myelitis with diffusion-weighted imaging ("DWI") signal" as also explanatory of Petitioner's illness. *Id.*

Several months later (on July 26, 2016), Petitioner returned to Dr. Miller. Ex. 10 at 119–20. Dr. Miller's diagnosis remained the same, but he now observed on exam "significant effort dependent deficits," including the left upper extremity, "which should not be involved by the T3 spinal lesion and is likely [reflective of] conversion disorder."[4] *Id.* at 120. Dr. Miller added "chronic pain and mood disorder with conversion disorder" to his overall diagnosis, and further recommended a behavioral health evaluation. *Id.* at 120–21. Petitioner had a follow-up

[3] "Sarcoidosis" is defined as "a chronic, progressive, systemic granulomatous reticulosis of unknown etiology, characterized by hard tubercles (q.v.). It can affect almost any organ or tissue, including the skin, lungs, lymph nodes, liver, spleen, eyes, and small bones of the hands and feet. . . ." *Sarcoidosis*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=44637&searchterm=sarcoidosis (last visited Sept. 26, 2023).

[4] "Conversion Disorder" is defined as "a mental disorder characterized by conversion symptoms (loss or alteration of voluntary motor or sensory functioning suggesting physical illness, such as seizures, paralysis, dyskinesia, anesthesia, blindness, or aphonia) having no demonstrable physiologic basis and whose psychological basis is suggested by (1) exacerbation of symptoms at times of psychological stress, (2) relief from tension or inner conflicts (primary gain) provided by the symptoms, or (3) secondary gains (support, attention, avoidance of unpleasant responsibilities) provided by the symptoms. Many patients exhibit "la belle indifference," a lack of concern about the impairment caused by the symptoms; histrionic personality traits are also common. Symptoms are neither intentionally produced nor feigned and are not limited to pain or sexual dysfunction." *Conversion Disorder*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=71092&searchterm=conversion+disorder (last visited Sept. 26, 2023).

appointment with Dr. Miller on October 25, 2016, at which time he documented improvement in Petitioner's pain and mood disorder but noted that Petitioner "now felt that this was not a stroke but transverse myelitis." *Id.* at 128.

Subsequent Treatment History

On February 7, 2017, Petitioner presented to neurologist Suheb Hasan, M.D., for a second opinion regarding her "leg weakness and spasticity." Ex. 6 at 1–4. Following his examination, Dr. Hasan concluded (consistent with prior treaters) that Petitioner had experienced an infarction of the spinal cord at the T3-T6 level, but he also was unable to exclude post-vaccination TM from the differential diagnosis. *Id.* at 4. Dr. Hasan thus requested to see Petitioner's previous MRIs for further evaluation. *Id.* After reviewing these records, however, Dr. Hassan provided an addendum to his prior February record. Ex. 6 at 4–5. Dr. Hasan concluded that the abnormal signal at T3-T6 was "somewhat vascular in distribution" and the "diffusion-weighted images were positive consistent with spinal cord infarction." *Id.* at 4. Dr. Hasan thus did not ultimately find corroboration for his prior speculation that TM might be an alternative diagnostic explanation.

Nine months later, on November 30, 2017, Petitioner self-referred to the Cleveland Clinic for a second opinion from a physical medicine and rehabilitation specialist, Frederick Frost, M.D. Ex. 4 at 1–2. Petitioner reported numbness from the chest down, difficulty walking, urinary urgency, and spasms/restless legs; however, she was back at work and able to operate a vehicle. *Id.* at 2. Upon examination, Dr. Frost noted that Petitioner could rise from sitting to standing, and exhibited no weakness on manual muscle testing; however, "muscle testing was not reliable due to inconsistent voluntary effort." *Id.* at 2. Dr. Frost diagnosed Petitioner with chronic myelopathy of undetermined cause. *Id.* He noted that Petitioner had made an "excellent recovery," and that her symptoms appeared to be improving, as opposed to progressive. *Id.*

The following year, on May 2, 2018 (now nearly two and one-half years after the vaccination at issue), Petitioner presented to a new neurologist, Nancy Cao, M.D. Ex. 5 at 1–4. Dr. Cao noted that Petitioner's history "suggests that 2 weeks after her flu vaccination, she developed new onset paralysis and numbness from her waist down within 12 hours." *Id.* at 3. Upon examination, Petitioner exhibited normal muscle bulk, 4-4+ strength in the lower extremities, and some mild hyperreflexia in the lower extremities. *Id.* at 3. Dr. Cao's impression was thoracic myelopathy with residual spastic paraparesis and paresthesia below the waist. *Id.* at 4. She opined that the etiology was likely TM "suggested by history vs spinal cord stroke." *Id.* Petitioner was also diagnosed with episodic migraine headaches and anxiety. *Id.*

Petitioner has additionally submitted a treater letter from Dr. Miller, dated August 17, 2022—thus prepared not only after the case's initiation, but almost seven years from the date of vaccination. *See* Letter, filed as Ex. 14 (ECF No. 40-1) ("Miller Ltr."). In its entirety, the letter

states as follows: "To Whom It May Concern: It is my medical opinion that [Petitioner] should not receive the Flu vaccination for medical reasons. If you have any questions or concerns, please don't hesitate to call. Sincerely, Daniel Miller MD." *See* Miller Ltr.[5]

II. Parties' Expert Reports

A. Petitioner's Expert - Nancy J. Cao, M.D., Ph.D.

Dr. Cao, a neurologist and one of Petitioner's treating physicians (albeit from well after the incidents at issue), submitted two expert reports on behalf of Petitioner. *See generally* Report, dated Jan. 10, 2020, filed as Ex. 11 (ECF No. 26-1) ("Cao First Rep."); Report dated Feb. 19, 2020, filed as Ex. 12 (ECF No. 28-1) ("Cao Second Rep."). Petitioner did not file a CV for Dr. Cao.

Dr. Cao's written reports are both very brief. The first is in the form of a letter to Petitioner's primary care physician, and the second reflects her own opinion on the matter. These reports were simply attached to Dr. Cao's provider notes from visits on May 2, 2018, and February 19, 2020, respectively. Dr. Cao opined that Petitioner suffered from TM "provoked by vaccine leading to cord inflammation based on the timing and clinical history." Cao First Rep. at 1, 3; Cao Second Rep. at 1, 3, 5.

In so opining, Dr. Cao relied on her evaluation of Petitioner from their May 2018 encounter. The first report provided a brief summary of Petitioner's past medical history and course of treatment following the onset of her alleged TM symptoms. Cao First Rep. at 1. Dr. Cao noted that Petitioner exhibited thoracic myelopathy in November 2015 which affected her T3-T6 levels accompanied by residual spastic paraparesis and paresthesia below her waist. *Id.* at 3 (citing Ex. 5 at 3–4). Petitioner had received the flu vaccine approximately two weeks prior to the onset of her symptoms, causing her primary neurologist, Dr. Miller, to suspect TM provoked by the vaccine and leading to cord inflammation. *Id.* Dr. Cao agreed with Dr. Miller in his suspicion. *Id.* Dr. Cao later maintained, in her second report, that Petitioner had been diagnosed with spinal cord stroke based on a positive DWI finding, maintaining that "[Petitioner] does not have significant ischemic risk factors." Cao First Rep. at 3 (citing Ex. 5 at 3–4); Cao Second Rep. at 5 (citing Ex. 5 at 3–4).

Dr. Cao's second expert report also noted that she saw Petitioner in the office on February 19, 2020 (the same day she drafted the report), opining again that Petitioner developed "an event of transverse myelitis in 11/2015 provoked by vaccine leading to cord inflammation based on the timing and her clinical history." Cao Second Rep. at 1. She further maintained that Petitioner's third MRI from early 2016 (within six weeks of onset) showed cord signal abnormality from T3-

[5] This document is simply too conclusory to give it much evidentiary weight—and in any event, because Petitioner's proposed TM diagnosis lacks preponderant evidentiary support (but is the injury that Petitioner's causation theory wholly depends upon), this item of evidence warrants no further discussion.

T6, and that such "abnormal cord signal expanding several levels is also typical for myelitis." *Id.* Dr. Cao concluded her report with a reference to her "detailed office note" for any additional inquiries.[6] *Id.* Dr. Cao otherwise did not cite to any medical literature to bolster her opinion.

B. Respondent's Expert - Steven Messé, M.D.

Dr. Messé, a neurologist, submitted one expert report on behalf of Respondent. *See generally* Report, dated Dec. 2, 2020, filed as Ex. A (ECF No. 33-1) ("Messé Rep."). Dr. Messé opined that it was highly unlikely that Petitioner's receipt of the flu vaccine was causal of her subsequent spinal injury, but instead that it was more likely due to a stroke/infarction. Messé Rep. at 6.

Dr. Messé obtained his bachelor's degree from Yale University, followed by his medical degree at the University of Michigan School of Medicine. *See* Curriculum Vitae, filed as Ex. B (ECF No. 33-2) ("Messé CV") at 1. Thereafter, he completed his residency, followed by a fellowship at the Hospital of the University of Pennsylvania. *Id.* He is currently a Professor of Neurology in the Division of Vascular Neurology, as well as the Assistant Director of the Vascular Neurology Fellowship at the University of Pennsylvania School of Medicine. *Id.*; Messé Rep. at 1. Dr. Messé has treated thousands of patients with strokes in both an inpatient and outpatient setting and has published extensively on issues related to cerebrovascular disease. Messé CV at 7–28; Messé Rep. at 1. He is board certified in Neurology and Vascular Neurology by the American Board of Psychiatry and Neurology. Messé CV at 1; Messé Rep. at 1.

Dr. Messé began his report with a brief overview of Petitioner's medical history. Messé Rep. at 2. He then addressed Dr. Cao's comments regarding her proposed etiology for Petitioner's injury. *Id.* at 3. Dr. Messé first noted that, of Petitioner's treating physicians, only Dr. Cao had deemed TM to be Petitioner's spinal injury, with all of the rest accepting spinal infarct as the proper diagnosis. *Id.*; Ex. 6 at 1–6; Ex. 10 at 37–47, 93–98, 110–11, 151–52. Dr. Messé next discussed the articles submitted by Petitioner to support Dr. Cao's contention that Petitioner suffered from TM, noting that much of the literature she had offered consisted of case reports. *Id.*

In discussing the cause of Petitioner's spinal cord injury, Dr. Messé observed the existence of several studies that have investigated the clinical and radiographic findings pertinent to distinguishing between a spinal cord infarct and TM, and noted that it can be difficult to separate the two. Messé Rep. at 3. The main considerations are the timing and course of symptom progression, the presence of cerebrospinal fluid, and the radiographic findings. *Id.* Here, Dr. Messé maintained that Petitioner's resolution of symptoms following "lying flat in bed overnight before

[6] While Dr. Cao refers to a "detailed office note dated 02/19/2020," the note simply appears to only mirror the previously filed records submitted as Ex. 5 in this matter.

they returned and worsened later in the morning, reaching its nadir within 6-8 hours strongly favors ischemia."[7] *Id.*; *See also* F. Romi & H. Naess, *Spinal Cord Infarction in Clinical Neurology: A Review of Characteristics and Long-Term Prognosis in Comparison to Cerebral Infarction*, 72 Eur. Neurology 95, 96 (2016), filed as Ex. C (ECF No. 33-3) (finding biphasic ictus occurs in one-fifth of all spontaneous spinal cord infarctions, and noting the importance of recognizing such patients and starting stroke treatment immediately following onset of the first symptom); B. Greenberg et al., *New Onset Transverse Myelitis Diagnostic Accuracy and Patient Experiences*, 30 Multiple Sclerosis Related Disorder 42, 43 (2019), filed as Ex. M (ECF No. 33-13).

Dr. Messé then discussed several studies that analyzed the average reported timing from onset to the peak of symptoms in patients with spinal cord ischemia, as well as any relevant imaging findings. Messé Rep. at 4. One found a reported mean time from onset to height of symptoms of 7.8 ± 23 hours. *Id.* Of the studied patients, all exhibited diffusion restriction based on the MRI results, but there was no evidence indicating inflammation on the patients' spinal tap. *Id*.; K. Nedeltchev et al., *Long-Term Outcome of Acute Spinal Cord Ischemia Syndrome*, 2 Stroke 560, 562 (2004), filed as Ex. D (ECF No. 33-4) ("Nedeltchev"). Petitioner's spinal tap similarly revealed no indication of inflammation. Messé Rep. at 4.

In addition, Dr. Messé pointed to several reports finding that MRIs performed within 16 hours of the onset of symptoms—as was the case for Petitioner—can often miss the presence of a spinal cord infarct. Messé Rep. at 4; C. Alblas et al., *Acute Spinal-Cord Ischemia: Evolution of MRI Findings*, 8 J. Clinical Neurology 218, 222 (2012), filed as Ex. E (ECF No. 33-5) ("Alblas") (examining all patients by MRI within 24 hours after symptom onset and finding normal results in four out of the five patients studied). Thus, the absence of MRI confirmation from the first MRI performed on Petitioner did not rule out an infarction (which was confirmed by the second MRI she received on November 30, 2015). Dr. Messé also briefly highlighted the evidence of Petitioner's spinal lesion involving the anterior portion of her spinal cord, deeming it consistent with an occlusion of the anterior spinal artery. Messé Rep. at 4; E. Kumral et al., *spinal Ischaemic Stroke: Clinical and Radiological Findings and Short-Term Outcome*, 18 Euro. J. Neurology 232, 237 (2011), filed as Ex. F (ECF No. 33-6) ("Kumral") (finding that "chronic spinal diseases and infarcts as a result of disk lesions, mechanical factors were present in two-thirds of patients with anterior and posterior spinal artery or unilateral stroke syndrome").

Next, Dr. Messé engaged in a brief discussion of whether the flu vaccine can cause an infarction. In his view, the medical literature "strongly supports the notion that [the] influenza vaccination is *protective* against stroke as patients who receive vaccination consistently demonstrate a reduced risk of vascular events compared to patients who do not get vaccinated."

[7] "Ischemia" is defined as a "deficiency of blood in a part, usually due to functional constriction or actual obstruction of a blood vessel." *Ischemia*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=26185&searchterm=ischemia (last visited Sept. 26, 2023).

Messé Rep. at 4 (emphasis added); A. Grau et al., *Influenza Vaccination is Associated with a Reduced Risk of Stroke*, 36 Stroke 1501, 1504 (2005), filed as Ex. I (ECF No. 33-9) (finding an association between the influenza vaccination and reduced odds of stroke/TIA after adjusting for vascular risk facts, education, health-related behaviors, and other factors); A. Siriwardena et al., *Influenza and Pneumococcal Vaccination and Risk of Stroke or Transient Ischaemic Attack—Matched Case Control Study*, 32 Vaccine 1354, 1357 (2014), filed as Ex. J (ECF No. 33-10) (reporting that influenza vaccination was associated with a 24 percent reduction in the risk of stroke among the cases studied). To further support this assertion, Dr. Messé relied on what he considered to be one of the "most important and relevant studies that addresses this question" from the New England Journal of Medicine. *See* L. Smeeth et al., *Risk of Myocardial Infarction and Stroke after Acute Infection or Vaccination*, 351 New Eng. J. Med. 2611 (2004), filed as Ex. K (ECF No. 33-11) ("Smeeth"). Smeeth's authors studied 19,063 patients with a documented first stroke and who had received the influenza vaccine, finding that there was no increase in the risk of myocardial infarction or stroke in the time period following vaccination. Smeeth at 2611, 2614. By contrast, the risks of both myocardial infarction and stroke were significantly higher after a diagnosis of a respiratory tract infection. *Id.*

Dr. Messé concluded his report with a reiteration of the medical record findings favoring infarct. Messé Rep. at 5. Petitioner's receipt of the flu vaccine was unlikely to be causal of her subsequent spinal cord injuries, which instead were more likely attributable to stroke. *Id.* Dr. Messé maintained that "the early fluctuation and then rapid progression of [Petitioner's] symptoms, bland cerebrospinal fluid studies, and the distribution of the lesion on MRI including diffusion restriction with no evidence of enhancement on multiple studies" were collectively highly suggestive of a stroke etiology. *Id.* He was unable to identify what had likely triggered the stroke itself, but noted that this was not uncommon. *Id.*; R. Hart et al., *Embolic Strokes of Undetermined source: The Case for a New Clinical Construct*, 13 Lancet Neurology 429, 429 (2014), filed as Ex. L (ECF No. 33-12) (reporting that cryptogenic, or of unknown cause, ischaemic strokes make up about 25 percent of all ischaemic strokes). Otherwise, Dr. Messé emphasized the general consensus among the medical community—"that vaccinations are protective against stroke and would not have been likely to contribute to [Petitioner's] infarct." *Id.*

III. Procedural History

As noted above, the case was initiated in August 2018, and the matter was first assigned to another special master. ECF No. 1. On August 19, 2019, Respondent filed his Rule 4(c) Report, arguing that this case was not appropriate for compensation. ECF No. 21. The case was subsequently transferred to me on February 4, 2022, after most of the expert reports discussed above had been filed. In the fall of 2022, I ordered the parties to brief the claim, for resolution via ruling on the record. Petitioner's brief was filed in January 2023 (ECF No. 44) ("Mot."), and Respondent opposed it in March 2023 (ECF No. 45) ("Opp.").

IV. Parties' Respective Arguments

Petitioner's Argument

Petitioner maintains that she has demonstrated by a preponderance that she suffered from TM. Mot. at 8. Petitioner allows that her treating physicians alternated between a diagnosis of spinal infarct or TM, but emphasizes the records favoring post-vaccination TM. *Id.* at 6–7.

Petitioner further maintains that she has provided both a medical theory connecting the flu vaccine to her alleged injury and a logical sequence of cause and effect. Mot. at 8–9. In support of her contention that the flu vaccine could cause TM, Petitioner referenced several articles, adding that "the pathogenesis of transverse myelitis is mostly of an autoimmune nature, triggered by various environmental factors, including vaccination." *Id.* at 8; N. Agmon-Levin et al., *Transverse Myelitis and Vaccines: a Multi-Analysis*,18 Lupus 1198, 1199 (2009), filed as Ex. 13-I (ECF No. 31-9) ("Agmon-Levin"); R. Garg, *Acute Disseminated Encephalomyelitis*, 79 Postgraduate Med. J. 11 (2003), filed as Ex. 13-A (ECF No. 31-1) (finding that acute disseminated encephalomyelitis (ADEM) typically follows infection or vaccination). As for Petitioner's showing of a logical sequence of cause and effect, she argues that she had no prior history of numbness or weakness in her limbs, and that there is no evidence to suggest she suffered from TM prior to her vaccination. Mot. at 9. Lastly, Petitioner maintains that a timeframe of sixteen days from vaccination to the onset of her symptoms is well within what is accepted in the medical community for this type of injury. *Id.*; Ex. 12 at 1; Agmon-Levin at 1200.

Respondent's Argument

Respondent argues the claim lacks sufficient evidentiary support for a finding of entitlement. *See generally* Opp. (reiterating and incorporating his position set forth in his previously filed Rule 4(c) Report) at 2; Respondent's Rule 4(c) Report, dated Aug. 19, 2019 (ECF No. 21) ("Rep.") at 6. Petitioner's medical records not only fail to demonstrate a medical theory causally linking her vaccine to the alleged injury, but a logical sequence of cause and effect supporting the notion that the vaccine was the reason for her injury. Rep. at 7. While Petitioner's contemporaneous medical records support the conclusion that treaters had some initial suspicion of TM given her presentation, her subsequent overall disease progression and history favor a diagnosis of anterior spinal artery infarct. Rep. at 8; *see also* Ex. 10 at 98 (Dr. Miller's diagnosis of spinal cord infarction in T3-T6 level); Ex. 6 at 1–6 (Dr. Hasan's confirmation of spinal cord infarction diagnosis after a full review of Petitioner's MRIs). The only physician who fully accepted the proposed TM diagnosis was Dr. Cao, who notably did not treat Petitioner until approximately two years following her vaccination. Rep. at 8.

Respondent further maintains that Petitioner has failed to provide a report from a medical expert to bolster her claim. Rep. at 8. Instead, Petitioner has primarily relied upon statements made by one treating physician—none of which are supported by reliable or relevant medical literature. *Id.*; Respondent's Brief, dated June 23, 2023 (ECF NO. 39) ("Br.") at 7. Respondent also notes that Petitioner submitted several articles supporting the notion that she suffered TM as a result of her receipt of the flu vaccine, even though Dr. Cao did not refer to any such literature. Br. at 8.

V. Applicable Law

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 her 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 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 the contention that the flu vaccine can cause TM.

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).

[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. Appx. 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).

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*, 418 F.3d at 1278: "(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."

Each of the *Althen* prongs 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 Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) ("[h]owever, in the past we have made clear that simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." (citing *Moberly*, 592 F.3d at 1322)); *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"), *appeal docketed*, No. 23-1816 (Fed. Cir. Apr. 28, 2023). Petitioners consistently 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 denied*, 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. denied 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. denied* (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) (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 that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *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 sub nom. Rickett v. Sec'y of Health & Hum. Servs*., 468 F. Appx. 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions 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); *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*, 2005 WL 6117475, at *20. 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*, 23 Cl. Ct. at 733 (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.")).

There are, however, 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 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 Pharmaceuticals, 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 (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, 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 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)); *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 rev. denied*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. Appx. 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").

Expert opinions based on unsupported facts may be given relatively little weight. *See Dobrydnev v. Sec'y of Health & Hum. Servs.*, 556 F. Appx. 976, 992–93 (Fed. Cir. 2014) ("[a] doctor's conclusion is only as good as the facts upon which it is based") (citing *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993) ("[w]hen an expert assumes facts that are not supported by a preponderance of the evidence, a finder of fact may properly reject the expert's opinion")). Expert opinions that fail to address or are at odds with contemporaneous medical records may therefore be less persuasive than those which correspond to such records. *See Gerami v. Sec'y of Health & Hum. Servs.*, No. 12-442V, 2013 WL 5998109, at *4 (Fed. Cl. Spec. Mstr. Oct. 11, 2013), *aff'd*, 127 Fed. Cl. 299 (2014).

D. *Consideration of Medical Literature*

Both parties filed medical and scientific literature in this case, but not every filed item factors into the outcome of this decision. While I have reviewed all the medical literature submitted in this case, 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.*, 844 F.3d 1322, 1328 (Fed. Cir. 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. Appx. 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. *Determining Matter on Record Rather Than at Hearing*

I have determined to resolve this case based on written submissions and evidentiary filings, including the numerous expert reports that have been submitted, rather than hold a trial. My determination is consistent with the Vaccine Act and Rules, which not only contemplate but *encourage* special masters to decide petitions (or components of a claim) on the papers where (in the exercise of their discretion) they conclude that such a means of adjudication will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The Federal Circuit has affirmed this practice. *Kreizenbeck v. Sec'y of Health & Hum. Servs.*, 945 F.3d 1362, 1365–66 (Fed. Cir. 2020). It simply is not the case that every Vaccine Act claim need be resolved by hearing—even where the petitioner explicitly so requests.

ANALYSIS

Petitioner Has Not Preponderantly Established TM as the Likely Injury

This is a case in which determining what diagnosis finds the most record support is especially necessary. *Broekelschen*, 618 F.3d at 1346. TM has often been found in the Vaccine Program to be caused by the flu vaccine, and so Petitioner's ability to substantiate that injury would greatly aid her chances of success. *J. v. Sec'y of Health & Hum. Servs.*, 155 Fed. Cl. 20 (2021). Petitioner does not, by contrast, propose that a spinal cord infarction could be vaccine-caused. Br. at 9. In fact, that kind of claim is more often than not unsuccessful,[9] and Respondent has offered

[9] There are a number of cases in which claimants have alleged a stroke to be vaccine-caused—but more often than not, without success. *See e.g.*, *Hayward v. Sec'y of Health & Hum. Servs.*, No. 15-005V, 2018 WL 2772495, at *17 (Fed. Cl. Spec. Mstr. May 4, 2018) ("[t]he problem with this evidence is that it does not go far enough, leaving unlinked propositions in the overall causation 'chain', or overstating the findings for an otherwise-reliable item of medical/scientific literature"); *Flores v. Sec'y of Health & Human Servs.*, No. 10-489V, 2013 WL 5587390 (Fed. Cl. Spec. Mstr. Sept. 12, 2013) (denying entitlement for a spinal cord infarction following the HPV vaccine because Petitioner did not have the "critical" genetic criteria to meet the causation theory), *mot. for rev. den'd*, 115 Fed. Cl.

some items of reliable literature suggesting receipt of the flu vaccine is more likely *preventative* of infarct than causal. *See, e.g.*, Smeeth. Accordingly, she has offered no theory upon which causation could be based if TM is not found to be the evidentiarily-supported diagnostic explanation for her injury.

The medical record strongly preponderates in favor of an infarction as Petitioner's injury, rather than TM. Dr. Messé has persuasively and comprehensively supported his opinion that Petitioner suffered from a spinal cord infarction as opposed to TM, offering numerous citations to the record as to why some factors support infarct over TM. Petitioner's other treating physicians, including Drs. Malik and Miller, were all of the opinion that Petitioner suffered from a spinal cord infarction. *See* Ex. 6 at 1–6; Ex. 10 at 47, 98. Indeed, even treaters who speculated about the possibility of TM as an etiologic explanation, like Dr. Hasan, ultimately concluded that exam or other test results were inconsistent with it. Ex. 6 at 1–5.

Dr. Cao is about the only treater embracing TM as a counter-diagnosis, but her opinion is simply too conclusory, and fails to rebut record evidence supporting an infarct as explanatory. She simply reiterates Petitioner's medical history and symptoms in concluding that there exists a causal relationship between Petitioner's vaccination and TM. And although she has noted some record evidence supporting TM, she ultimately fails to demonstrate how or why it outweighs contrary evidence.

For example, Dr. Cao questioned whether the positive DWI findings relied upon by some treaters for an infarct diagnosis were "related to T2 shine through, therefore mimicking a stroke," adding that Petitioner did not exhibit any significant ischemic risk factors. Cao First Rep. at 3. She also noted that Petitioner's T-spine MRI results from January 2016 (showing cord signal abnormality from T3 to T6), maintain that such "abnormal cord signal expanding several levels is also typical for myelitis." Cao Second Rep. at 1. And it is true that at least one neurologist Petitioner saw in the first half of 2016, Dr. Miller, allowed for the possibility of TM. Ex. 10 at 98. But all of this evidence is greatly outweighed by other evidence—from both before and after early 2016—supporting an infarct. Indeed, one treater (Dr. Hasan) tested the TM hypothesis himself—but rejected it. Ex. 6 at 1–5. Dr. Cao does not explain why these determinations are in error, or why the weight of the evidence *favors* TM over an infarct.

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157 (2014), *aff'd*, 586 F. Appx. 588 (Fed. Cir. 2014); *Carrino v. Sec'y of Health & Human Servs.*, No. 08-266V, 2013 WL 3328903 (Fed. Cl. Spec. Mstr. June 6, 2013) (denying entitlement because petitioner had not set forth a reliable theory to causally connect the flu vaccine to lateral medullary syndrome); *Francis v. Sec'y of Health & Human Servs.*, No. 99-286V, 2000 WL 1517676 (Fed. Cl. Spec. Mstr. Aug. 31, 2000) (finding that petitioner had not met his burden in establishing that an encephalopathy occurred following the DRP vaccination administration precipitating a stroke); *Wilson v. Sec'y of Health & Human Servs.*, No. 90-795V, 1992 WL 118955 (Cl. Ct. May 15, 1992) (determining that there was not preponderant evidence that petitioner suffered an encephalopathy followed by a stroke and a brain injury after receiving the DTP vaccine).

Dr. Messé also corroborated his diagnostic opinion with several items of medical literature that provide medical ballast for an infarct diagnosis given the facts. *See, e.g.*, Kumral at 237; Nedeltchev at 562; P. Barreras et al., *Clinical Biomarkers Differentiate Myelitis from Vascular and other Causes of Myelopathy*, 90 Neurology e12 (2018), filed as Ex. H (ECF No. 33-8) ("Barreras") (studying 457 patients with various etiologies of myelopathy and finding that a subacute presentation is more suggestive of an inflammatory etiology whereas a hyperacute presentation is suggestive of a spinal cord ischemic stroke). Nedeltchev notes that CSF findings (which can confirm the presence of inflammation) are not particularly corroborative of infarct—and thus Petitioner's negative CFS findings do not rebut the diagnosis of infarct. Alblas establishes why Petitioner's first MRI (performed close in time to her symptoms onset) deserved less diagnostic weight than the second, which more strongly corroborated the infarct. Barreras also discussed the importance of lesion distribution on MRIs, finding that "a lesion affecting a discrete vascular distribution or a spinal cord watershed area would be highly suggestive of an ischemic stroke"—consistent with Petitioner's MRI findings. Moreover, Dr. Messé referenced several other studies that noted degenerative spine disease as a common, causal mechanism of spinal cord infarct—and the record establishes that Petitioner suffered from a central cord herniation adjoining the anterior cord at the T6 level. Messé Rep. at 4.

Because of the above, the case is properly dismissed. Although Petitioner has reasonably cited some record evidence supporting TM, ultimately that diagnosis lacks preponderant support, and Petitioner has not offered a reliable causation theory associating the flu vaccine with the more evidentiarily-supported diagnosis.

CONCLUSION

A Program entitlement award is only appropriate for claims supported by preponderant evidence. Petitioner has not made such as showing. She therefore is not entitled to compensation.

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.