In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 18-1044V
Filed: November 7, 2022

RENEE HANDJIS, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	UNPUBLISHED Dismissal; Influenza ("Flu") Vaccine; Transverse Myelitis ("TM"); Failure to Prosecute; Failure to Follow Court Orders.

Lawrence Cohan, Esq., Saltz Mongeluzzi & Bendesky, Philadelphia, PA, for petitioner.
Darryl Wishard, Esq., U.S. Dept. of Justice, Washington, DC for respondent.

DISMISSAL DECISION ON ORDER TO SHOW CAUSE[1]

Roth, Special Master:

On July 17, 2018, petitioner filed a petition for compensation in the National Vaccine Injury Compensation Program ("the Program"),[2] alleging that an influenza ("flu") vaccination caused her to develop transverse myelitis ("TM").

Following a status conference in which the deficiencies in this case were discussed, an Order to Show Cause was issued detailing those deficiencies and providing petitioner with the opportunity to respond and cure the deficiencies.

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[1] Although this Decision has been formally designated "unpublished," it will nevertheless be posted on the Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). **This means the Decision will be available to anyone with access to the internet.** However, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, 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. *Id*.

[2] The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 *et seq.* (hereinafter "Vaccine Act" or "the Act"). Hereafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

After carefully analyzing and weighing the evidence presented in this case in accordance with the applicable legal standards, I find that petitioner has failed to provide preponderant evidence that the flu vaccine she allegedly received on December 10, 2015 caused her to suffer TM. Therefore, this case must be dismissed.

I. Procedural History

On July 17, 2018, petitioner filed a Petition alleging that she received an influenza vaccine on December 10, 2015 and thereafter suffered from TM caused in fact by the vaccination. Petition at 1, ECF No. 1.

The matter was assigned to the me on July 18, 2018. Medical records were filed in support of the petition on the same date. Petitioner's Exhibits ("Pet. Ex.") 1-9, ECF Nos. 4-5.

In a status report filed on September 17, 2018, petitioner advised that she was waiting for additional records that would update her current condition and requested 60 days within which to file those records. ECF No. 8. A Scheduling Order was issued for the filing of petitioner's records by November 16, 2018 and the filing of a status report by respondent by December 31, 2018. Petitioner filed updated records and a Statement of Completion on November 15, 2018. Pet. Ex. 10-11, ECF No. 9.

After two granted Motions for extension of time, respondent filed his status report on April 26, 2019, listing additional outstanding medical records. ECF Nos. 11-12, 15. Petitioner was ordered to file the outstanding medical records and a Statement of Completion by June 25, 2019. ECF No. 16.

Petitioner filed medical records on June 25, 2019, along with a Motion for an extension of time until July 25, 2019 to complete her filing of records. The Motion was granted. Pet. Ex. 12-15, ECF Nos. 17-18.

After petitioner filed Motions for issuance of subpoena and an extension of time to file the medical records which were granted, petitioner filed medical records on August 6, 2019 and additional records and a Statement of Completion on September 23, 2019. Pet. Ex. 16-17, ECF Nos. 19-21, 23-24, 26.

Respondent filed a status report on November 22, 2019, requesting to file his Rule 4(c) Report by January 21, 2020, and the deadline was set. ECF No. 27.

Respondent filed his Rule 4(c) Report on January 21, 2020, recommending against compensation. Respondent's Rule 4(c) Report ("Resp. Rpt") at 1. After summarizing petitioner's medical history, treatment, and burden of proof for an off-table claim, respondent highlighted several issues with petitioner's claim. Resp. Rpt. at 7-9.

First, petitioner failed to file any proof of vaccination or a vaccine administration record but instead relied on an entry in a medical record that documents "influenza high dose seasonal" with a date of December 10, 2015. Resp. Rpt. at 7; Pet. Ex. 1 at 3. Respondent submitted that the source of that information was unclear, and it was unlikely that petitioner, who was 49 years old at the time, would be given a high dose flu vaccine, which is administered to those aged 65 and older.[3] Therefore, she had failed to file a vaccine administration record as required by the Act and had not established receipt of the alleged vaccination. *Id*.

Second, petitioner failed to establish that she actually suffered from the alleged injury claimed. (citations omitted). Respondent submitted that the medical records do not support petitioner's allegation that she suffers from TM. Though petitioner's local neurologist diagnosed her with TM, none of the tests performed supported that opinion. Her MRIs, CSF, and EMG/NCS were all normal. Resp. Rpt. at 8; Pet. Ex. 2 at 7, 9, 14, 17, 67, 70, 79; Pet. Ex. 4 at 44. Further, her treating neurologist later wrote he was "convinced she had an episode of transverse myelitis or something very similar to it." Resp. Rpt. at 8; Pet. Ex. 13 at 24. However, an attending physician at Tulane opined that petitioner's condition was not a "primary neurologic condition." Resp. Rpt. at 8; Pet. Ex. 4 at 50. Therefore, petitioner has not proven that she suffered from TM as alleged. Resp. Rpt. at 8.

Third, petitioner failed to show that she "suffered the residual effects or complications of [the alleged] illness, disability, injury or condition for more than 6 months after the administration of the vaccine. 42 U.S.C.§ 300aa-11(c)(1)(D)(i). Respondent added "even where a petitioner "experience[s] a difficult reaction in the days immediately following" vaccination, injuries lasting fewer than six months shall not be compensated under the Vaccine Act." (citation omitted). Respondent submits the initial course was self-limited in this case, and the symptoms petitioner later developed were unrelated. According to the medical records, petitioner received her vaccine on December 10, 2015, and returned to baseline by March 4, 2016. Resp. Rpt. at 8; Pet. Ex. 13 at 18. Respondent points to a subsequent visit on May 4, 2016 in which the neurologist wrote that he did not think her symptoms on that date were a true exacerbation of her old TM but rather "a fatigue related phenomenon superimposed on old microscopic thoracic spine injury." Resp. Rpt. at 8-9; Pet. Ex. 13 at 21. Petitioner has therefore failed to satisfy the severity requirement.

Fourth, petitioner failed to provide evidence of a persuasive medical or scientific theory that establishes that the alleged vaccine can cause the injury claimed and any suggestion that it did is mere speculation. Further, petitioner failed to show that the onset of the condition was within a medically appropriate timeframe after the alleged vaccination. In short, petitioner failed to satisfy the requirements for an off-table claim under *Althen*. Resp. Rpt. at 9

After two granted Motions for extension of time within which to file the outstanding medical records, petitioner filed a status report on June 22, 2020, which stated: "Upon review of

[3] High-dose flu vaccines are approved only for those aged 65 or older in the United States. *See* Fluzone High-Dose Seasonal Influenza Vaccine, https://www.cdc.gov/flu/prevent/qa_fluzone htm (last visited Jan.17, 2020).

the medical records and subsequent follow up with petitioner and our expert, petitioner will be withdrawing his (sic) claim." The status report further advised that there were no additional medical records to submit, and petitioner was to sign a consent form allowing the dismissal of her claim within 20 days. ECF No. 31-33. An Order issued for petitioner to file her Motion for Dismissal by July 13, 2020.

On July 13, 2020, petitioner filed a Motion for extension of time until August 13, 2020 to obtain petitioner's consent to dismiss the petition, which was granted. ECF No. 34. Another Motion requesting the same relief was filed on August 13, 2020 and granted. ECF No. 35.

On September 2, 2020, petitioner filed a Motion for extension of time for petitioner's counsel to move to withdraw as counsel. The Motion stated that respondent consented to the extension of time, but not counsel's withdrawal. ECF No. 36.

On September 3, 2020, respondent filed a Motion for an Order to Show Cause compelling petitioner to file her Motion to Dismiss. ECF No. 37. Petitioner filed a response on September 14, 2020 opposing the Motion and stating that counsel for petitioner cannot be compelled to take any action that would be detrimental to his client. A status conference was requested and scheduled. ECF. No. 38.

A status conference was held on September 17, 2020. A detailed Order summarizing the ongoing issues in this case was issued, requiring petitioner to file a status report by November 2, 2020. ECF No. 39.

In a status report filed on November 2, 2020, petitioner's counsel quoted emails received from petitioner and requested that the Court issue an Order to Show Cause. ECF No. 40

An Order to Show Cause was issued on November 3, 2020 requiring petitioner to show cause as to why her claim should not be dismissed by November 17, 2020. *See* ECF No. 41. After filing a Motion for extension of time within which to file a response, which was granted, petitioner filed an article on "Transverse Myelitis and Vaccines" as Pet. Ex. 18, an exhibit list, and a response to the Order to Show Cause on December 24, 2020. ECF Nos. 42-45.

The matter is now ripe for adjudication.

II. Factual Summary

A. Medical History Prior to Vaccination

Petitioner has a past medical history of anemia, gallstones[4], fatigue, and abdominal pain. Pet. Ex. 1 at 7.

[4] An ultrasound on July 17, 2015 confirmed gallstones. Pet. Ex. 1 at 17.

At a visit to the Family Health Center of Natchez (hereinafter "Family Health") on August 3, 2015, petitioner reported fatigue, hair loss, cold intolerance, gynecological issues, bloating, cramping, and a 17-pound weight loss in the past six months. Examination was normal. Pet. Ex. 1 at 7-8.

On September 4, 2015, petitioner underwent a laparoscopic cholecystectomy with intraoperative cholangiogram for cholelithiasis.[5] *See generally* Pet. Ex. 9, Pet. Ex. 14.

B. Date of Vaccination

In her petition, petitioner asserts having received an influenza vaccination at Family Medical Health Center of Merit Health on December 10, 2015 and references Pet. Ex. 1 at 4 as support. Petition at 1. There is no mention of a vaccine in Pet. Ex. 1 at page 4. However, there is a reference made to a "high dose seasonal" flu vaccine at a December 14, 2015 office visit with a date of December 10, 2015 in Pet. Ex. 1 at page 3 listed under "Reviewed Vaccines". Pet. Ex. 1 at 3; Pet. Ex. 13 at 1. The record does not include information of manufacturer, route or site of administration, lot number, expiration date, date on VIS (vaccine information sheet), VIS given, or vaccinator. Pet. Ex. 1 at 3. The origin of the information contained in the record is unknown and there is no record for a December 10, 2015 visit.

Petitioner did not file an affidavit in this case.

C. Medical History After Vaccination

On December 14, 2015, petitioner presented to Family Health with complaints of fatigue, muscle aches, weakness and tremors in both legs and loss of balance. Pet. Ex. 1 at 4.[6] The record documents her report of waking at 4 am feeling nauseous and weak. She went to the porch for air and noticed that her legs were very weak "and started to jerk all over." She grabbed a pole to steady herself out of fear she was going to faint. Her son helped her inside and noticed that her left pupil was dilated. She had trouble with her vision. She has been weak since. "She states for the last few months is (sic) been having more headaches that are more frequent and also more sinus problems, with rhinorrhea and nasal congestion." *Id.* She was well-appearing on examination and ambulating normally. She had normal muscle strength and tone with no contractures or bony abnormalities. There was normal movement in all extremities without cyanosis or edema. *Id.* at 5-6. The assessment on that day was fatigue, generalized worsening headache, rhinitis, and muscle pain. *Id.* at 6. Blood work and a CT scan of the head were ordered. Petitioner was instructed to go to the emergency room if her symptoms returned. *Id.* at 6. There was no mention of a flu vaccine.

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[5] Cholelithiasis is the presence or formation of gallstones. *Cholelithiasis*, DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 344 (33rd ed. 2019) [hereinafter "DORLAND'S"].
[6] This record is also filed as Pet. Ex. 8.

Petitioner underwent a non-contrast CT of the brain on December 15, 2015 for headaches. The results were normal/negative. Pet. Ex. 1 at 16.

Records from Natchez Neurology Clinic (hereinafter "Natchez Neurology") reference a December 31, 2015 visit, but no record for that date was filed. Later records include complaints of muscle weakness, visual impairment, increased frequency of urination, numbness of lower and upper limbs, and ataxic gait. *See* Pet. Ex. 2 at 52, 57, 62. A December 10, 2015 high-dose flu vaccine is listed in the record under past vaccines but there is no reference to the flu vaccine during any visits or in the assessments following examination. *Id.* at 23, 27, 30, 34, 38, 42, 46, 51, 57, 62.

Petitioner presented for a brain MRI with and without contrast on January 7, 2016, due to "[b]ilateral lower extremity tremors and numbness, vertigo, weakness, nausea and vomiting." The MRI revealed no abnormality. The impression was "[n]egative MRI brain without/with gadolinium." Pet. Ex. 1 at 11-12; Pet. Ex. 2 at 3-4, 70-71.

Petitioner presented to Dr. Ricalde at Natchez Neurology on January 8, 2016. She had numbness in a "quadriparetic fashion" with some reflex asymmetry in the lower extremities, persistent sensory loss, and weakness. CPK and B12 were normal. MRI of the brain and ANA testing was negative/normal. An EMG/NCS study was ordered with the expectation that "by now after the onset December 14th be (sic) able to detect a demyelinating or subtle axonal process." It was noted that CSF testing may be necessary to detect neuropathic process. Pet. Ex. 2 at 60. "Since last seen [petitioner] has had her MRI-we have both reviewed it it shows no CNS demyelinating illness-it is actually quite pristine nonetheless this is not (sic) completely rule out a demyelinating illness." Pet. Ex. 13 at 2. Her vision had improved, but she still had some paresthesia and epicritic type sensations in the right greater than the left leg and foot. Fingers still had numbness and fatigue. Blood work was all normal and lupus had been ruled out. *Id.*

EMG/NCS testing was performed on January 11, 2016. Pet. Ex. 2 at 67. The results were normal with "no evidence of a neuropathy - axonal or demyelinating and no evidence of a myelopathy." *Id.* CSF testing was performed on January 12, 2016, with normal results: zero white and red blood cells, glucose of 48, protein of 36, negative Lyme antibodies, negative AchR binding antibodies, nonreactive VDRL, and zero oligoclonal bands. *Id.* at 7, 9, 14, 17, 79. An MRI of the cervical spine performed on January 14, 2016, showed "[m]inimal cervical spondylosis with no HNP [herniation] or stenosis identified." Pet. Ex. 1 at 13-14; Pet. Ex. 2 at 5-6, 65-66, 72-73.

Petitioner returned to Dr. Ricalde on January 20, 2016 with continued complaints of numbness, ataxia, and weakness which precluded her return to work as a nurse because her employment required only full-time employment. Physical and occupational therapies were ordered. No contraindication to driving was noted. It was noted that "[t]he MRI of cervical spine has been reviewed…radiologists report it is unremarkable there is no evidence of intrinsic increase in cord – there is no neuromyelitis optica and there is no severe transverse myelitis . . . Her oligoclonal bands are negative – her CSF protein was completely normal . . . there are 0 white blood cells indicating without doubt – no CNS infectious process." Pet. Ex. 2 at 49; Pet. Ex. 13 at 9. Dr. Ricalde wrote "the only explanation . . . is a monophasic transverse myelitis." *Id.*

Petitioner presented for an eye exam on January 22, 2016. She had no complaints of ocular symptoms, no headaches, double vision, floaters, light flashes, or blurry or uncomfortable vision. Pet. Ex. 7 at 10. The impression was good/acceptable contact lens comfort and vision and eye health, myopia, astigmatism, and presbyopia. *Id*. at 11.

Petitioner attended six physical therapy sessions between January 29, 2016 and February 25, 2016 for ataxic gait and diagnosis of transverse myelitis. Pet. Ex. 15.

At a February 5, 2016 visit, Dr. Ricalde wrote, "[petitioner] is rapidly/larger rhythmically improving now this is very encouraging and suggest (sic) a significant healing from the transverse myelopathy syndrome I anticipate practical full recovery. We will still continue with PT and continue to justify current leave until symptoms are at the point of patient being able to return to full duty. And we anticipate this hopefully within the next month." Pet. Ex. 2 at 44.

Petitioner returned to Dr. Ricalde on February 19, 2016 with continued improvement in stability and sensation in the lower extremities. She still had some dyspraxia[7] of the ring and pinky fingers on the right hand and her feet were cold on and off. She was exercising, using a treadmill and bike, doing squats, and walking. Her bowel function was near normal and bladder function was improving. Pet. Ex. 13 at 15. Her "transverse myelopathy syndrome" was improving and anticipated to continue improving, with a return to work in two weeks. *Id*. at 16.

Petitioner returned to Dr. Ricalde on March 5, 2016 reporting ringing in her ear and anxiety, but no other issues. Pet. Ex. 13 at 18. Dr. Ricalde wrote, "transverse myelopathy syndrome" has "returned to– baseline there is no indication that at present she cannot return to duty. She is being cleared to do so." *Id*.; Pet. Ex. 2 at 36.

Two months later, on May 4, 2016, petitioner presented to Dr. Ricalde with complaints of numbness, weakness, and headache. Pet. Ex. 2 at 32; Pet. Ex. 13 at 19. She reported she had been back to work since March 7 which was hectic due to an office move. She was exhausted but still walking an hour a day 4-5 times a week. She reported recent heaviness with walking, numbness in her lateral calves, some occipital soreness, and distal forearm twitching, but she was "overall better". Pet. Ex. 13 at 20. Blood work was ordered in case a course of Solu-Medrol with a prednisone taper was necessary for two weeks. "I do not think this is true exacerbation of the old transverse myelitis but I think it is a fatigue related phenomenon superimposed on old microscopic thoracic spine injury." Pet. Ex. 2 at 32; Pet. Ex. 13 at 21.

On May 19, 2016, petitioner returned to Dr. Ricalde for her blood work results and again reported fatigue. Pet. Ex. 2 at 28. The record for this date does not contain an assessment or blood work results. *Id*.

There are no medical records of any medical visits for the next six months. On November 22, 2016, petitioner presented to Dr. Ricalde with a complaint of "bad tinnits (sic), feel stronger, fatigue". She was noted as "doing very well." Pet. Ex. 13 at 22-24. Dr. Ricalde wrote, "I am convinced she had an episode of transverse myelitis or something very similar to it – incomplete

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[7] Dyspraxia is the partial loss of ability to perform coordinated acts. *Dyspraxia*, DORLAND'S 576.

a year ago." Pet. Ex. 2 at 25; Pet. Ex. 13 at 24. She was bothered by tinnitus (ringing in the ears) and concerned about some difficulty with anomic aphasia/decrease in immediate recall. *Id*. Her exam was relatively benign. *Id*.

There are no records of any medical visits for the next nine months. On August 29, 2017, petitioner presented as a new patient to Living Well Family Clinic for wellness check. *See generally* Pet. Ex. 3. A list of "Chronic Diagnoses" included but was not limited to vitamin deficiencies, migraine, gastro-esophageal reflux, acute transverse myelitis followed by a "Comment: Nov 2015-March 2016", cramps and spasms, urinary incontinence, muscle weakness, visual disturbances, hearing loss, amnesia, expressive language disorder, fatigue, and tinnitus. Pet. Ex. 3 at 5. She reported that she did not feel well that day and was disoriented. *Id*. at 8. She returned the next day, August 30, 2017 for a woman's checkup. *Id*. at 11. She reported a history of transverse myelitis diagnosed in 2016, "[e]pisodes started 12/2015 with muscle spasms/weakness/Testing and treatments went on through 12-2015/3-2017." *Id*. Her last brain MRI was over a year ago. She reported that she was having episodes of muscle weakness more often, decreased hearing, muscle spasms, headaches, and memory/recall problems. She described spacing out, blanking out, eye blinking, vision changes, blurry, sensitive to light, eyes feeling weak, and recent episodes of incontinence and expressive aphasia. *Id*. Her insurance would be running out the next day, so an urgent visit to neurology based on her symptoms was necessary. *Id*. at 13; *see also* Pet. Ex. 5 at 12-14.

Petitioner presented to Dr. Ricalde on August 30, 2017 reporting headache, alteration in alertness, severe spasms in her legs, and incontinence starting six weeks ago. Pet. Ex. 13 at 26. She reported awakening at 4 am two weeks ago with "completely new jerking of the muscles in the legs with standing and also some stiffness that was associated in the arms and the legs this is also associated with some blurring of the right eye and perhaps some diplopia." *Id*. at 27. The Assessment and Plan included muscle weakness, numbness of upper and lower limbs, tinnitus, intermittent paraparesis, incontinence, nystagmus, and unilateral hearing loss. Pet. Ex. 13 at 28-29; Pet. Ex. 2 at 21. In all capital letters, Dr. Ricalde wrote, "THIS IS ALMOST CLASSICALLY—SYMPTOMATICALLY AND PHYSIOLOGICALLY MS. I WILL REPEAT AN MRI BRAIN WITH AT (sic) RIVERPARK. Pet. Ex. 2 at 21; Pet. Ex. 13 at 29.

On September 3, 2017, petitioner presented to the emergency room ("ER") at Tulane reporting lower extremity weakness, leg spasms, hand and foot numbness with an 8-month history of intermittent episodes of "legs locking up", fatigue, and tingling and numbness in different areas of her body.[8] Pet. Ex. 4 at 13. She reported increased stressors at home and a history of transverse myelitis and Meniere's disease. She reported difficulty in finding words, changes in vision and hearing, dizziness, lightheadedness, a recent episode of bladder incontinence, and hot and cold flashes. She reported similar symptoms in 2015 when she was diagnosed with transverse myelitis. *Id*. at 15. She reported that she drove herself three hours to the Tulane ER because she decided it was time to get looked at. She awoke with numbness in her hands that morning, was fired from her job the week before, was a single mom of two children, and feels heavy all over. She reported her prior transverse myelitis was treated with exercise, not medication. A review of systems for

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[8] This would place onset of those symptoms in February 2017.

the foregoing complaints was negative. *Id*. at 30. She reported a daughter with a seizure disorder, a grandmother with epilepsy, and an uncle with ALS. *Id*. at 30-31. She was admitted.

An MRI of the brain and spine were negative for structural abnormality or acute process which could cause her symptoms, and all labs were normal. Pet. Ex. 4 at 13. Neurological examination revealed "giveway weakness and normal reflexes."[9] She was noted to be focused on "her previously incorrect diagnosis" and being out of work with the last event for three months. *Id*. at 43. She became angry when she was told that the MRIs of the brain, C-spine, T-spine, and L-spine were normal and could not explain her symptoms. She demanded specific names of neurological processes that could be consistent with lower extremity weakness and normal MRI studies. She reported that, while walking with a friend, she was alerted to the fact that she did not lift her legs well. She became angry, denied having stress in her life, then became tearful about her home situation and that there were no government funds to deal with situations like hers. When therapy was recommended, she said it takes too long. Pet. Ex. 4 at 44, 50. The neurologist wrote, "This is not a primary neurological condition…" *Id*. at 50. Petitioner declared she did not want any further interaction with the Tulane Neurology Team and would seek care elsewhere. She reportedly walked out of the hospital on her own at discharge without any difficulty. *Id*. at 44.

Petitioner returned to Living Well Family Clinic on November 10, 2017 to discuss her test results from Tulane. She reported driving herself to Tulane when she "woke up about 2 months ago with complete numbness to bilateral hands and legs/Couldn't walk/Headaches were still going on/severe spasms to legs moreso (sic) than arms." She planned to see a neurologist in New Orleans on November 22, 2017. She reported a history of transverse myelitis diagnosed in 2016. She wanted to discuss Lexapro which she had started taking two months ago and noticed a difference. She reported headaches and fatigue, ringing in her ears, problems urinating, chronic joint and muscle pain, spasms, numbness and tingling in her toes and fingers, and heaviness in her legs when walking. She had memory loss and intermittent aphasia with anxiety and depression. Pet. Ex. 5 at 6. Examination was normal and she was administered a vitamin B12 injection. Pet. Ex. 5 at 7.

Petitioner presented to the LSU Healthcare Network for evaluation of possible MS on November 22, 2017. She reported on "12/2015 she had an episode; she had a flushot (sic) with unusual reaction followed by extreme fatigue. She then had severe nausea, impaired balance and weakness of the legs. Prior to this she could walk several miles after this she could not walk upstairs." Pet. Ex. 6 at 1.[10] All testing was normal. She required prolonged rehabilitation and continued to have hearing loss. On "8/2017 she started noticing increased fatigue, decreased hearing." She couldn't see out of her right eye and "things were blurry . . . her vision fluctuated and now has returned to baseline. She feels pressure behind her eyes with headache in the back of her head. It took about 6 weeks for her eye to improve. She went to Tulane because she woke up with complete numbness on the hands and weakness on the legs." *Id*. She noted increased urinary urgency and has leg spasms sometimes 10 times a day. *Id*. Examination and testing were

[9] There is no formal definition for "giveway" or "giveaway" weakness; it is often used by physicians to describe patients who are not fully cooperating during examination but may also be attributed to pain. *See Davis v. Sec'y of Health & Human Servs.*, No. 14-978V, 2022 WL 1654743 n.73 (Fed. Cl. Spec. Mstr. Apr. 27, 2022).

[10] This record is also filed as Pet. Ex. 10 and Pet. Ex. 12.

normal/negative. The record documents a "[p]uzzling case. Bilateral lower extremity weakness with preserved reflexes developing after flu shot with normal MRI's of brain and spine. Improved since initial attack but still with persistent weakness." *Id*. at 3. In a discussion with petitioner, it was explained that the diagnosis was unclear but very unlikely to be MS. It was unlikely she would have subsequent events. "Discussed transverse myelitis. Reassured her that she does not have ALS." *Id*.

Petitioner returned to Dr. Lovera at LSU Healthcare Network on February 1, 2018 for impaired balance and weakness of her bilateral lower extremities. She complained of low back pain radiating into her left leg. On examination, her deep tendon reflexes were "hyper-reflexic" at the knees and symmetrical at the ankles. Strength was normal except for slight weakness of the left great toe extension. NCS testing performed on the lower extremities was normal. EMG testing of the bilateral lower extremities revealed significant chronic denervation involving the left L5 myotome. Pet. Ex. 6 at 4; Pet. Ex. 12 at 9. The impression was significant chronic L5 radiculopathy. *Id*.

Petitioner presented for an eye examination on April 18, 2018 complaining of blurry vision. She reported no disorders or current medical treatment except for a pinched nerve followed by a neurologist. Pet. Ex. 7 at 4. Following a comprehensive eye exam, petitioner was noted to have corneal neovascularization of the left eye and suspected bilateral glaucoma. *Id*. at 5. A May 3, 2018 visit confirmed primary open angle glaucoma. *Id*. at 1.

Petitioner returned for eye examination on June 12, 2018. She reported that her left eye always seemed hazy. Pet. Ex. 11 at 20. She returned on November 9, 2018 for a recheck secondary to glaucoma and was noted to be responding to topical medication. *Id*. at 29-31.

Petitioner's last medical record filed was for a follow-up eye examination on May 16, 2019. Pet. Ex. 16.

D. Transverse Myelitis

Transverse myelitis ("TM") is a rare clinical syndrome in which an immune-mediated process causes neural injury to the spinal cord, resulting in varying degrees of weakness, sensory alterations, and autonomic dysfunction. Pet. Ex. 18 at 1.[11]

The Transverse Myelitis Consortium Working Group's proposed diagnostic criteria for TM includes bilateral sensory, motor, or autonomic dysfunction attributable to the spinal cord, a clearly defined sensory level, and peaking of symptoms within 4 hours and 21 days. Pet. Ex. 18 at 1.

The pathogenesis of TM is believed to be autoimmune in nature and involves a breakdown of the blood-brain barrier resulting in cerebrospinal fluid ("CSF") pleocytosis within a focal area

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[11] N. Agmon-Levin et al., *Transverse myelitis and vaccines: a multi-analysis*, 18 LUPUS 1198 (2009), filed as "Pet. Ex. 18."

of the spinal cord. Pet. Ex. 18 at 1. Thus, where TM exists, there is observed evidence of an inflamed spinal cord, pleocytosis in the CSF, and elevated IgG index or gadolinium enhancement by MRI. *Id*. at 1-2.

TM may present as a multi-focal central nervous system disease such as multiple sclerosis, as a result of direct injury to the spine such as radiation or spinal cord infarct, as a part of a systemic issue such as malignancy, as an autoimmune disease such as lupus, or as an isolated entity. Pet. Ex. 18 at 1.

The cause of most autoimmune processes is multi-factorial, including genetic, immunological, hormonal, and environmental factors. Infectious illnesses play a key role, and up to 40% of TM cases are associated with a preceding infectious illness, mostly within a month of TM onset, and often with preceding infections of respiratory, gastrointestinal, or flu-like illness. Pet. Ex. 18 at 2. In most cases, TM begins after the infection resolves and no infectious agent has been isolated in the nervous system. *Id*. "Thus, TM appears not to be a direct infectious process, but rather an autoimmune response triggered by the infectious antigens." *Id*. Several cases of TM have been reported after vaccination and in children within one month of symptom onset. *Id*.

Transverse myelopathy, as opposed to transverse myelitis, refers to various functional disturbances or pathologic changes that extend across the spinal cord.[12] Myelopathy is a general term that refers to dysfunction of the spinal cord caused by one of many diseases, including transverse myelitis. *See Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1342 (Fed. Cir. 2010).

III. Standard for Adjudication

The Vaccine Act provides petitioners with two avenues to receive compensation for their injuries resulting from vaccines or their administration. First, a petitioner may demonstrate that he or she suffered a "Table" injury — i.e., an injury listed on the Vaccine Injury Table that occurred within the timeframe provided within the Table. 42 U.S.C. § 300aa-11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); *see* 42 U.S.C. § 300aa-13(a)(1)(B). Alternatively, where the claimed injury is not listed in the Vaccine Table or does not fit squarely within the Table parameters, a petitioner may bring an "off-Table" claim. 42 U.S.C. § 300aa-11(c)(1)(C)(ii). An "off-Table" claim requires that the petitioner "prove by a preponderance of the evidence that the vaccine at issue caused the injury." *Capizzano*, 440 F.3d at 1320; *see* 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(II). Initially, a petitioner must provide evidence that he or she suffered, or continues to suffer, from a definitive injury. *Broekelschen.*, 618 F.3d at 1346 (Fed. Cir. 2010). A petitioner need not show that the vaccination was the sole cause or even the predominant cause of the alleged injury; showing that the vaccination was a "substantial factor" and a "but for" cause of the injury is sufficient for recovery. *See Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006); *Shyface v.*

[12] *Transverse myelopathy*, DORLAND'S 1203.

Sec'y of Health & Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999). Additionally, the Vaccine Act requires petitioners to show by preponderant evidence that the "residual effects or complications" of the alleged vaccine-related injury lasted longer than six months. 42 U.S.C. § 300aa-11(c)(1)(D)(i).

IV. Analysis

Because petitioner does not allege an injury listed on the Vaccine Injury Table, her claim is classified as "off-table." As noted above, to prevail on an "off-table" claim, petitioner must show by preponderant evidence that she suffered an injury, and that the alleged injury was caused by the vaccination at issue. *Capizzano*, 440 F.3d at 1320. There are four key areas at issue in this case that affect entitlement: (1) the lack of proof of vaccination, (2) the lack of a definitive diagnosis, (3) petitioner's ability to demonstrate her injuries and/or related sequalae lasted the requisite six months, and (4) her failure to satisfy the *Althen* requirements.

A. Proof of Vaccination

The only references to a flu vaccine on December 10, 2015 is a medical record entry of "influenza, high dose seasonal" with a date of "12/10/15." *See* Pet. Ex. 2 at 23, 27, 30, 34, 38, 42, 46, 51, 57, 62. There was no record filed of any medical visit on December 10, 2015 or vaccine record.

The first reference to "influenza, high dose seasonal" vaccine on "12/10/15" is contained in a record of petitioner's visit to her primary care physician on December 14, 2015, when she complained of weakness. The amount, route, site, lot number, manufacturer, expiration date, date on VIS, VIS given, or administrator of the vaccine was not included. Pet. Ex. 1 at 3. All other references to a December 10, 2015 flu vaccine was provided by petitioner when reporting her history to providers.

In her response to the Order to Show Cause, petitioner submitted that she attempted to obtain proof of vaccination "through every means possible, but it was found that such a form does not exist." She did not recall signing any document for the vaccine, only being told she was due for the flu vaccine and verbally consenting to receiving it on that date. Petitioner's Response to the Order to Show Cause (hereinafter "Pet. Response") at 10-11. Petitioner did not file an affidavit in this case and did not provide any details of what her attempts to obtain proof of vaccination included.

Petitioner's claim that she received a high dose flu vaccine creates further questions regarding her alleged vaccination. Petitioner was 49 years old on December 10, 2015, and the high dose flu vaccine is only approved/licensed in the United States for those ages 65 and older.[13] Therefore, it is unlikely that she would have been given a high dose flu vaccine.

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[13] Centers for Disease Control, *supra* note 3.

As set forth in the Vaccine Act, petitioners are required to file an affidavit and "vaccination records associated with the vaccine allegedly causing injury," 42 U.S.C. §300aa-11(c)(1)-(2) or "an identification of any records of the type described in paragraph (1) or (2) which are unavailable to the petitioner and the reasons for their unavailability." 42 U.S.C §300aa-11(c)(3).

Here, petitioner did not provide a vaccination record or an affidavit detailing her receipt of the alleged vaccination or her efforts to secure documentation to prove receipt of the flu vaccination. She relied on a single entry in the medical record, four days after her alleged receipt of the vaccination, which does not include any information associated with the vaccine or the source of the information for the record and which appears repetitively thereafter as part of an electronic medical record. Pet. Ex. 1 at 3. Further, the record documents a high dose flu vaccine with no explanation as to why it would be given to a 49-year-old.

There is no corroborating evidence submitted in this case from any physician, nurse, or other medical professional that an influenza vaccination was administered to petitioner on December 10, 2015.

Due to the absence of contemporaneous medical records or any persuasive documentation, petitioner has failed to meet the preponderance of the evidence standard required to show administration of a vaccine on December 10, 2015. *See Lamberti v. Sec'y of Dep't of Health & Human Servs.*, No. 99-507V, 2007 WL 1772058 at *7 (Fed. Cl. May 31, 2007); *Groht v. Sec'y of the Dep't of Health & Human Servs.*, No. 00-287V, 2006 WL 3342222 at *2 (Fed. Cl. Spec. Mstr. Oct. 30, 2006); §300aa–11(b)(1)(A).

B. Defined and Recognized Injury

An initial step of an off-table claim is to "determine what injury, if any, was supported by the evidence presented in the record." *Lombardi v. Sec'y of Health & Human Servs.*, 656 F.3d 1343, 1353 (Fed. Cir. 2011). The Vaccine Act "places the burden on the petitioner to make a showing of at least one defined and recognized injury," and "[i]n the absence of a showing of the very existence of any specific injury[,] . . . the question of causation is not reached." *Id.*; *Broekelschen*, 618 F.3d at 1346 (explaining that a vaccine-related injury "has to be more than just a symptom or manifestation of an unknown injury."); *Stillwell v. Sec'y of Health & Human Servs.*, 118 Fed. Cl. 47, 56 (2014) ("[I]f the special master finds, as a preliminary matter, that petitioner has failed to substantiate the alleged injury, the special master need not apply the *Althen* test for causality."). Thus, petitioner has the burden to demonstrate the medically recognized injury from which she suffers. *Broekelschen*, 618 F.3d at 1348; *see also Lasnetski v. Sec'y of Health and Human Servs.*, 128 Fed. Cl. 242 (2016), *aff'd*, 696 F. App'x 497 (Fed. Cir. 2017).

When determining whether petitioner has adequately proven a demonstrable injury, special masters analyze petitioner's complete medical records as filed into the record. 42 U.S.C. § 300aa-11(c)(2). Medical records created contemporaneously with the events they describe are generally considered to be trustworthy. *Cucuras v. Sec'y of Health and Human Servs.*, 993 F.2d 1525, 1528

(Fed. Cir. 1993); *but see Kirby v. Sec'y of Health & Human Servs.*, 993 F.3d 1378, 1382-83 (Fed. Cir. 2021) (clarifying that *Cucuras* does not stand for proposition that medical records are presumptively accurate and complete). Subsequent statements made by third parties that contradict contemporaneous medical records are less persuasive to special masters than the medical records. *Campbell ex rel. Campbell v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 775, 779 (2006).

Petitioner argues she has established that she suffered and continues to suffer from TM through her treating physicians. Pet. Response at 11-12; Pet. Ex. 2 at 25, 49; Pet. Ex. 5 at 7. Petitioner offers citations to her medical records including, "The only explanation for the above is monophasic transverse myelitis", "patient with complicated history suggestive of transverse myelitis…" "Hx of Transverse Myelitis…", "Pt is a 51 yo female with previous dx of transverse myelitis…". Pet. Response at 11-12 (citing Pet. Ex. 2 at 49; Pet. Ex. 10 at 6; Pet. Ex. 6 at 6[14]; Pet. Ex. 4 at 15).

Petitioner's references in support of her TM diagnosis are taken out of context or are incomplete statements. When read in their entirety, the medical records upon which petitioner relies include: "I'm convinced she had an episode of transverse myelitis or *something very similar to it-incomplete a year ago*." Pet. Ex. 2 at 25 (emphasis added). Another record states:

> …there is no neuromyelitis optic and there is no severe transverse myelitis, however, the only explanation for the above is a monophasic transverse myelitis. Her oligoclonal bands are negative-her CSF protein was completely normal the CSF was appropriately obtained without contamination and there are 0 white blood cells indicating without doubt-no CNS infectious process.

Pet. Ex. 2 at 49. Reference is made to billing codes, which are used for purposes of payments for services, and included acute transverse *myelopathy*, muscle weakness, blurry vision, expressive aphasia, numbness, and Vitamin D12 deficiency. Pet. Ex. 5 at 7 (emphasis added). In another record, a section titled "Counseling" documents that "petitioner's diagnosis remains unclear but is unlikely MS", that it was "less likely she would have subsequent events", and "[d]iscussed transverse myelitis. Reassured her that she does not have ALS." Pet. Ex. 10 at 6. In the "Assessment" section of the same record, an entry contains, "Puzzling case. Bilateral lower extremity weakness with preserved reflexes developing after flu shot with normal MRI's of the brain and spine. Improved since initial attack but still with persistent weakness." *Id.* It is unknown from this record what was discussed regarding TM or whether petitioner was reassured that she did not have TM, like she was reassured she did not have ALS. Finally, petitioner relies on the content of the Tulane ER record which mentions TM, but that mention was part of the history petitioner provided upon presentation. Pet. Ex. 4 at 15.

The literature petitioner filed in support of her claim is more persuasive in showing that she did not have TM. None of the diagnostic criteria for a finding of TM proposed by the

[14] There is no page 6 of this record and no reference to TM on the other pages.

Transverse Myelitis Consortium Working Group and discussed in the literature filed—bilateral sensory, motor, or autonomic dysfunction attributable to the spinal cord, clearly defined sensory level, and peaking of symptoms within 4 hours to 21 days—exists in this case. *See* Pet. Ex. 18.

In weighing evidence, special masters are expected to consider the views of treating doctors. *Capizzano*, 440 F.3d at 1326. Treating doctors' views about the appropriate diagnosis are often persuasive because the doctors have direct experience with the patient they are diagnosing. *See McCulloch v. Sec'y of Health & Human Servs.*, No. 09-293V, 2015 WL 3640610, at *20 (Fed. Cl. Spec. Mstr. May 22, 2015). However, as respondent accurately highlighted, though petitioner's local neurologist Dr. Ricalde diagnosed petitioner with transverse myelitis, he did so without any supporting objective testing: petitioner's MRIs, CSF, and EMG/NCS testing were all normal. Resp. Rpt. at 8; Pet. Ex. 2 at 7, 9, 14, 17, 67, 70, 79; Pet. Ex. 4 at 44. Dr. Ricalde later questioned the diagnosis of TM, adding that petitioner had TM "or something very similar to it." Pet. Ex. 13 at 24. He also began referring to her condition as myelopathy rather than myelitis. Further, petitioner presented with no sensory deficits, full strength of all limbs, and symptoms that did *not* peak within 4 to 21 days. Rather, according to petitioner's reports to her physicians, her symptoms progressed in the weeks that followed, with increasing weakness that required a walker and then a wheelchair. Finally, she was not treated with any treatment typically used for illnesses thought to be autoimmune in origin, but rather was prescribed only physical therapy.

Further, after testing and examination, the neurologist at Tulane concluded that petitioner did not have a "primary neurologic condition." Pet. Ex. 4 at 50.

Petitioner has failed to meet her burden of showing a defined and recognized injury. Petitioner has undoubtedly suffered from a host of symptoms as documented over the years, including but not limited to weakness, numbness, dizziness, aphasia, memory deficits, and visual problems. *See* Pet. Ex. 1 at 3-4; Pet. Ex. 5 at 3; Pet. Ex. 7; Pet. Ex. 10 at 6. However, she has not been provided with a definitive diagnosis, has not been treated for an immune mediated disease, and does not fulfill the criteria for TM.

C. Six-Month Requirement

The Vaccine Act requires petitioners to show by preponderant evidence that the "residual effects or complications" of the alleged vaccine-related injury lasted for more than six months. 42 U.S.C. § 300aa-11(c)(1)(D)(i). In *Cloer v. Sec'y of Health and Human Servs.*, the Federal Circuit explained that the six-month requirement is "a condition precedent for filing a petition for compensation" in the vaccine program and serves as a restriction on eligibility for compensation in the Program. 654 F.3d 1322, 1335 (Fed. Cir. 2011). Congress intended this duration requirement "to limit the availability of the compensation system to those individuals who are seriously injured from taking a vaccine." *Id.* (quoting H.R. Rep. No.100-391(I), at 699 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-1, -373.

Petitioner argues that the six-month requirement is met because she experienced onset of symptoms on December 14, 2015, four days after her alleged receipt of the flu vaccine on December 14, 2015, and these symptoms continued through November 22, 2017 as evidenced by her medical records. Pet. Response at 12. She further submits that as of November 22, 2017, her symptoms were still attributed to her December 10, 2015 flu vaccine. *Id*. at 6.

Petitioner's medical records do not, in fact, support her claim that the six-month requirement is satisfied. Petitioner claims to have received her flu vaccine on December 10, 2015 and presented with weakness on December 14, 2015. Pet. Ex. 1 at 4. When she saw Dr. Ricalde on March 5, 2016, petitioner complained of ringing in her ears and anxiety; she reported no other issues. Pet. Ex. 13 at 18. At that time, Dr. Ricalde wrote that she had "returned to-baseline…", she could return to work and was cleared to do so. Pet Ex. 2 at 36; Pet. Ex. 13 at 18. Petitioner did return to work full time and when she presented two months later on May 4, 2016, reporting numbness, weakness, and headache, Dr. Ricalde specifically referred to her symptoms as a "fatigue related phenomenon", not an exacerbation of her prior condition. Pet. Ex. 2 at 32; Pet. Ex. 13 at 21. Petitioner returned to Dr. Ricalde on May 19, 2016, but there was no record filed of an assessment on that date. Pet. Ex. 2 at 28-31.

Thereafter, petitioner did not seek care for six months, until she returned to Dr. Ricalde on November 22, 2016, with a new complaint of "bad tinnits (sic), feel stronger, fatigue" but was noted to be "doing very well." Pet. Ex. 13 at 22, 24. Her exam was benign. Pet. Ex. 2 at 25; Pet. Ex. 13 at 24.

Petitioner had no further treatment for nine months, until she presented as a new patient to Living Well Family Clinic for a wellness check on August 29, 2017 and a woman's check up on August 30, 2017. By her own reported history, she claimed to have suffered from transverse myelitis diagnosed in 2016, "episodes started 12/2015 with muscle spasms/weakness/Testing and treatments went on through 12-2015/3-2017." Pet. Ex. 3 at 11. At that time, she reported having episodes of muscle weakness more often, decreased hearing, muscle spasms, headaches, and memory/recall problems. She described spacing out, blanks out, eye blinking, vision changes, blurry, sensitive to light, eyes feeling weak, and recent episodes of incontinence, and expressive aphasia. *Id.* She was sent directly to her neurologist since her insurance would lapse the following day. *Id*. at 13; *see also* Pet. Ex. 5 at 10-14.

Upon presenting to Dr. Ricalde on August 30, 2017, she reported that her symptoms *started six weeks ago*. Pet. Ex. 2 at 20; Pet. Ex. 13 at 26 (emphasis added). She reported "completely new jerking of the muscles in the legs with standing," some stiffness in her arms and the legs, some blurring of the right eye and perhaps some diplopia about two weeks ago. Pet. Ex. 13 at 27. Dr. Ricalde's assessment was "almost classically – symptomatically and physiologically MS."[15] Pet. Ex. 2 at 21; Pet. Ex. 13 at 29.

On September 3, 2017, petitioner presented to Tulane reporting lower extremity weakness, leg spasms, hand and foot numbness, and an 8-month history of intermittent episodes of "legs

[15] This entry appeared in all capital letters in the record.

locking up", fatigue, tingling, and numbness in different areas of her body.[16] She reported a history of TM and Meniere's disease and that her current symptoms were similar to those she had 2015 when she was diagnosed with TM. Pet. Ex. 4 at 13, 15. MRIs of the brain and spine were normal as were her labs, and a neurological examination revealed "giveway weakness and normal reflexes." The neurologist wrote, "This is not a primary neurological condition…" Pet. Ex. 4 at 50.

When she presented to LSU Healthcare Network on November 22, 2017 to be evaluated for MS, petitioner reported on "12/2015 she had an episode; she had a flushot (sic) with unusual reaction followed by extreme fatigue. She then had severe nausea, impaired balance and weakness on the legs." Pet. Ex. 6 at 1. She reported that she started noticing increased fatigue, decreased hearing, and vision issues in August 2017, and "went to Tulane when she woke up with complete numbness to the hands and weakness on the legs." She noted increased urinary urgency and leg spasms. *Id*. Examination and testing were normal/negative. The record notes a "[p]uzzling case. Bilateral lower extremity weakness with preserved reflexes developing after flu shot with normal MRI's of brain and spine. Improved since initial attack but still with persistent weakness." *Id.* at 3. In a discussion with petitioner, it was explained that the diagnosis was unclear, but it was unlikely to be MS and unlikely she would have subsequent events. "Discussed transverse myelitis. Reassured her that she does not have ALS." *Id*.

Thereafter, in 2018, she continued to complain of impaired balance and weakness of her bilateral lower extremities and low back pain radiating into her left leg. The impression after EMG/NCS was significant chronic L5 radiculopathy. Pet. Ex. 6 at 4; Pet. Ex. 12 at 9.

Petitioner's own reports of her history repetitively show that her complaints of bilateral weakness in her lower extremities had resolved by the beginning of March 2016, when Dr. Ricalde noted that she had returned to baseline. Further, Dr. Ricalde did not believe that the symptoms she experienced in May 2016 were an exacerbation of her prior condition. It was not until 2017 that she presented again reporting an onset of symptoms eight months prior, which were similar to those she experienced after her flu shot in 2015.

Based on the records in their entirety, I find that petitioner has failed to establish that the residual effects of her alleged vaccine-related injury lasted for more than six months as required under the Vaccine Act. In fact, the record supports that her alleged injury resolved in less than three months. However, even if petitioner's symptoms were deemed to have continued in excess of six months, there is still no definitive diagnosis of what those symptoms represented, no objective testing to support a diagnosis of TM or other definable neurologic disease, no treatment to suggest that they were thought to be an immune mediated condition, and no indication that what she suffered was related to the December 10, 2015 flu vaccine she allegedly received.

[16] Eight months from this date would be January 2017.

D. *Althen* Criteria

Petitioner has failed to provide proof of vaccination and a definitive diagnosis or injury that has lasted longer than the requisite six months. Typically, "[i]n the absence of a showing of the very existence of any specific injury of which petitioner complains, the question of causation is not reached." *Lombardi*, 656 F.3d at 1353. However, even if petitioner had been able to provide proof of vaccination and shown a definable injury that lasted at least six months, she would be unable to sustain her burden of proving causation under the three-pronged test established in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). *Althen* requires that petitioner establish by preponderant evidence that the vaccination she received caused her injury "by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* Together, these prongs must show "that the vaccine was 'not only a but-for cause of the injury but also a substantial factor in bringing about the injury.'" *Stone v. Sec'y of Health & Human Servs.*, 676 F.3d 1373, 1379 (Fed. Cir. 2012) (quoting *Shyface*, 165 F.3d at 1352-53). In this case, petitioner fails on all three prongs.

1. Reputable Medical Theory

The first *Althen* prong requires petitioner to provide a "reputable medical theory" demonstrating that the vaccine received *can* cause the type of injury alleged. *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006) (citation omitted). To satisfy this prong, petitioner's "theory of causation must be supported by a 'reputable medical or scientific explanation.'" *Andreu ex rel. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009) (quoting *Althen*, 418 F.3d at 1278). This theory need only be "legally probable, not medically or scientifically certain." *Id.* at 1380 (emphasis omitted) (quoting *Knudsen*, 35 F.3d at 548). Nevertheless, "petitioners [must] proffer trustworthy testimony from experts who can find support for their theories in medical literature." *LaLonde*, 746 F.3d at 1341.

On Prong I, petitioner submits that numerous case studies have provided a medical theory causally connecting the flu vaccine and TM, with a majority of cases manifesting within several days of vaccination. She relied on the article she submitted, which provides, "'The pathogenesis of transverse myelitis is mostly of an autoimmune nature, triggered by various environmental factors, including vaccination . . . The association of different vaccines with a single autoimmune phenomena allude to the idea that a common denominator of these vaccines, such as an adjuvant, might trigger this syndrome."' Pet. Response at 7 (quoting Pet. Ex. 18). Therefore, her weakness, numbness, and fatigue four days after the flu vaccine were manifestations of TM. *Id*.

Absent a persuasive medical or scientific theory establishing that, in this case, the flu vaccine can cause TM as alleged by petitioner, any suggestion that the vaccine did cause such an injury is mere speculation. Nothing in petitioner's medical records suggest that the flu vaccine was the actual cause of petitioner's condition. Therefore, on the existing record, petitioner has failed to

establish by preponderant evidence that she suffered from a vaccine-related injury. *See* 42 U.S.C.§300aa-12(a)(1).

Under the Act, petitioner may not be given a Program award based solely on the petitioner's claims alone. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 13(a)(1). In this case, because the medical record is insufficient to support petitioner's claim, a medical opinion must be offered in support. However, petitioner has offered no such opinion that supports a finding of entitlement. While petitioner filed medical literature on post-vaccination TM, the literature outlines diagnostic criteria for TM including bilateral sensory, motor, or autonomic dysfunction attributable to the spinal cord, a clearly defined sensory level, and peaking of symptoms within 4 hours and 21 days, none of which petitioner satisfies. *See* Pet. Ex. 18 at 1.

Because TM is not a table injury associated with flu vaccine, petitioner must provide the evidence necessary to support her claim that her alleged TM or any other neurological disease was associated with the flu vaccine she received. Petitioner has not filed an expert in this case. Further, even if I were to accept Dr. Ricalde's diagnosis of TM, there is no evidence filed in this case that supports a finding that flu vaccine can cause TM. Petitioner has failed to satisfy Prong I.

2. Logical Sequence of Cause and Effect

The second *Althen* prong requires proof of "[a] logical sequence of cause and effect." *Capizzano*, 440 F.3d at 1326 (quoting *Althen*, 418 F.3d at 1278). In other words, even if the vaccination can cause the injury alleged, petitioner must show "that it did so in [this] particular case." *Hodges v. Sec'y of Health & Human Servs.*, 9 F.3d 958, 962 n.4 (Fed. Cir. 1993) (citation omitted). "A reputable medical or scientific explanation must support this logical sequence of cause and effect," *id.* at 961 (citation omitted), and "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," *Paluck v. Sec'y of Health & Human Servs.*, 786 F.3d 1373, 1385 (Fed. Cir. 2015) (quoting *Andreu*, 569 F.3d at 1375).

Petitioner relies on *Capizzano v. Sec'y of Health & Human Servs*., 440 F.3d 1317, 1326 (Fed. Cir. 2006), arguing that where a petitioner has satisfied Prongs I and III as she has, it is logical to conclude that there "is a logical sequence of cause and effect linking the influenza vaccine to [petitioner's] transverse myelitis.", and she has therefore satisfied Prong II. Pet. Response at 9.

As petitioner cannot satisfy Prong I, her argument as to Prong II is not persuasive. Further, petitioner fails on this prong because the medical records show that while Dr. Ricalde initially referred to petitioner as having TM despite all objective testing being normal or negative, he later referred to her as having myelopathy or something like TM. Even if Dr. Ricalde's initial diagnosis of TM is accepted, he did not treat her for TM. He also found that she had returned to baseline by the end of March 2016, attributing her new symptoms in May 2016 to stress and fatigue. In 2017,

Dr. Ricalde referred to her symptoms as possible MS. Petitioner's other treating physicians questioned her diagnosis, referring to her presentation and complaints as "puzzling" and not a primary neurologic disease. The failure of any objective testing confirming any neurological disease begs the question, what, if anything, did the flu vaccine in this case cause? While petitioner's treating physicians may have documented her receipt of flu vaccine in December of 2015, they did so based on her reported history, and none implicated the flu vaccine in her presenting complaints.

The literature submitted by petitioner discusses the Transverse Myelitis Working Group's criteria for a diagnosis of TM, which petitioner does not fulfill. Petitioner has failed to satisfy Prong II.

3. Proximate Temporal Relationship

To satisfy the third *Althen* prong, petitioner must establish a "proximate temporal relationship" between the vaccination and the alleged injury. *Althen*, 418 F.3d at 1281. This "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan v. Sec'y of Health & Human Servs.,* 539 F.3d 1347, 1352 (Fed. Cir. 2008). Typically, "a petitioner's failure to satisfy the proximate temporal relationship prong is due to the fact that onset was too late after the administration of a vaccine for the vaccine to be the cause." *Id.* However, "cases in which onset is too soon" also fail this prong; "in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked." *Id.*; *see also Locane v. Sec'y of Health & Human Servs.*, 685 F.3d 1375, 1381 (Fed. Cir. 2012) ("[If] the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness.").

Petitioner argues that, like her case, the majority of TM cases manifest within several days of vaccine with symptoms of fatigue, weakness, and leg tremors, which she had. Therefore, she has met her burden under Prong III because her medical records and medical literature support her four-day onset following vaccination. Pet. Response at 8; *see* Pet. Ex. 18.

The literature filed by petitioner discussing TM provides for the onset of symptoms within a month. *See* Pet. Ex. 18. If one were to accept that petitioner received a high dose flu vaccine on December 10, 2015 and presented on December 14, 2015 with symptoms that were ultimately diagnosed as TM and supported by objective testing, then petitioner would have satisfied Prong III. However, there is no proof of vaccine, and no definable injury to access a reasonable medical timeframe for onset. Therefore, petitioner fails to satisfy Prong III.

V. Conclusion

The analysis in this case resulted from the filing of an Order to Show Cause, providing petitioner with the opportunity to cure the many deficiencies in her case. After review of the

medical records, medical literature, and submissions of counsel, it is clear that petitioner has failed to provide sufficient evidence to demonstrate: (1) that she received a high dose flu vaccine on December 10, 2015; (2) that she suffered TM following the high dose or any influenza vaccination; (3) that the injuries alleged to have occurred lasted in excess of the requisite six months; and (4) that the influenza vaccine can and/or did cause her to suffer TM injury within an appropriate timeframe in order to satisfy the *Althen* criteria. There is no doubt that petitioner has suffered greatly. However, despite my sympathy for petitioner, my decision must reflect a thorough analysis of the evidence presented and the application of the law based upon probative weight and persuasiveness. The dismissal of petitioner's case is not a sanction or penalty, but rather the result of a lack of evidence sufficient to support a finding of entitlement.

For these reasons, I find that petitioner has not established entitlement to compensation, and accordingly, her petition must be **dismissed.** In the absence of a timely filed motion for review pursuant to Vaccine Rule 23, the Clerk is directed to enter judgment consistent with this decision.[17]

IT IS SO ORDERED.

s/ Mindy Michaels Roth
Mindy Michaels Roth
Special Master

[17] Pursuant to Vaccine Rule 11 (a), if a motion for review is not filed within 30 days after the filing of the special master's decision, the clerk will enter judgment immediately.