In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 19-964V

Filed: September 16, 2025

* * * * * * * * * * * * *

JACQUELINE RICE-MCKENZIE, *

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Petitioner, *

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v. *

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SECRETARY OF HEALTH *
AND HUMAN SERVICES, *

*

Respondent. *

* * * * * * * * * * * * *

Laura Levenberg, Esq., Muller Brazil, Dresher, PA, for petitioner.
Mitchell Jones, Esq., U.S. Department of Justice, Washington, DC, for respondent.

DECISION[1]

Roth, Special Master:

On July 3, 2019, Dr. Jacqueline Rice-Mckenzie ("petitioner") filed a petition under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10 *et seq.*[2] ("Vaccine Act" or "the Program"). Petitioner initially alleged that the influenza ("flu") vaccination she received on August 30, 2016 caused her to suffer on-Table Guillain-Barre Syndrome ("GBS"). *See* Petition ("Pet."), ECF No. 1. Though it was ordered, an amended petition was not filed. ECF No. 44. Nevertheless, in her Motion for Ruling on the Record, petitioner alleged that the flu vaccine caused her to develop "post-vaccination polyradiculopathy" and that GBS is a form of polyradiculopathy. Motion, ECF No. 49.

[1] Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned finds that the identified material fits within this definition, such material will be redacted from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

Having considered the entire record in this case, including arguments made by the parties in their respective briefs, I find that petitioner has failed to provide preponderant evidence of causation.

I. Procedural History

Petitioner filed her petition and medical records on July 3, 2019. The case was assigned to the Special Processing Unit ("SPU"). Petitioner's Exhibits ("Pet. Ex.") 1-9, ECF Nos. 1, 4. Petitioner filed medical records through August 2020 with an amended statement of completion. Pet. Ex. 10-13, ECF No. 18.

Respondent filed his Rule 4(c) Report on December 11, 2020, following several extensions. ECF Nos. 20-22. Respondent argued that the case was not appropriate for compensation because petitioner was not diagnosed with GBS and therefore could not satisfy the criteria for on-Table GBS. He also identified several outstanding medical records. ECF No. 22.

The matter was reassigned to the undersigned on March 18, 2021. ECF No. 24. That same day, petitioner was ordered to file the outstanding medical records. ECF No. 25. By status report filed on May 17, 2021, petitioner advised that the requested records were either already filed or did not exist. ECF No. 27. By status report filed on June 16, 2021, respondent advised that he was satisfied the record was complete. ECF No. 28.

A status conference was held on October 12, 2021 to discuss various issues including that petitioner's medical records did not support a diagnosis of GBS. ECF No. 33. In a status report filed on November 29, 2021, petitioner submitted that she still experiences numbness and tingling daily, was never offered the mitochondrial testing or repeat lumbar puncture as referenced in the medical records, and that her October 11, 2016 EMG was most consistent with post-vaccination polyradiculopathy. ECF No. 34. The same day, she filed a record from her neurologist in support of a GBS diagnosis. Pet. Ex. 14, ECF No. 35. On January 28 and March 29, 2022, petitioner filed additional medical records. Pet. Ex. 15-17, ECF Nos. 36, 38. In his status report filed on July 11, 2022, respondent maintained his position that the case was not appropriate for compensation and requested a status conference to discuss how to proceed. ECF No. 43.

As requested, a status conference was held on July 27, 2022. ECF No. 44. The issues in the case including petitioner's diagnosis were again discussed. Petitioner's counsel advised that an amended petition would be filed to reflect a diagnosis of post-vaccination polyradiculopathy and peripheral demyelinating neuropathy. I noted several concerns, including a two-year gap in symptoms that led to questions regarding the continuity of her claimed injury and the fact that all objective testing was normal. Petitioner was ordered to file an amended petition and an expert report in support of her claim. *Id*.

Thereafter, petitioner filed a status report requesting a status conference which was held on November 7, 2022. ECF Nos. 46-47. During the status conference, petitioner advised that she would not be filing an expert report. Petitioner's counsel was ordered to discuss the options for exiting the Program with petitioner and to file either a motion to dismiss or a motion for ruling on the record. ECF No. 47.

Petitioner filed her Motion for Ruling on the Record on February 17, 2023. Motion, ECF No. 49. Respondent filed his response on March 27, 2023. Response, ECF No. 51. Petitioner did not file a reply. At no point did petitioner file an amended petition.

The matter is now ripe for decision.

II. Medical Terminology

Paresthesia is "an abnormal touch sensation, such as burning, prickling, or formication, often in the absence of an external stimulus." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1362 (33rd ed. 2020) [hereinafter *Dorland's*]. Demyelination is "destruction, removal, or loss of the myelin sheath of a nerve or nerves." *Dorland's* at 480. A myelin sheath is "the cylindrical covering on the axons of some neurons". *Dorland's* at 1673.

Guillain-Barré Syndrome ("GBS") is "rapidly progressive ascending motor neuron paralysis of unknown etiology, frequently seen after an enteric or respiratory infection. An autoimmune mechanism following viral infection has been postulated. It begins with paresthesias of the feet, followed by flaccid paralysis of the entire lower limbs, ascending to the trunk, upper limbs, and face". *Dorland's* at 1802. Acute inflammatory demyelinating polyradiculoneuropathy ("AIDP") is one form of GBS. 42 C.F.R. § 100.3(c)(15).

Neuropathy refers to "a functional disturbance or pathologic change in the peripheral nervous system". *Dorland's* at 1250. Polyneuropathy, also known as peripheral neuropathy, is "neuropathy of several peripheral nerves simultaneously". *Dorland's* at 1468. Polyradiculopathy is "disease of several spinal nerve roots." *Dorland's* at 1470.

III. Factual Record

A. Medical History

Petitioner's prior medical history was noncontributory. Respondent agreed.

Petitioner received the subject flu vaccine on August 30, 2016. Pet. Ex. 1 at 2.

One month later, on September 30, 2016, she presented to the emergency room ("ER") reporting a history of sporadic finger/hand twitching over the past month and right-sided numbness and tingling that started the night before and traveled to her tongue and upper mouth at about 2:00 that morning. She also reported a family history of Parkinson's disease and multiple sclerosis. Pet. Ex. 3 at 10. Neurological examination was normal for muscle tone, reflexes, and gait. There were no tremors. *Id*. at 23. Lumbar puncture ("LP") for cerebral spinal fluid ("CSF"), MRI of the brain and cervical spine, MRA, and EMG were performed and were all normal. *Id*. at 20-21, 23-24, 26, 31-34, 62-63. It was noted that normal CSF testing ruled out "Guillain-Barre type syndrome". *Id*. at 62. Her weakness subjectively improved, but objectively she had 5/5 strength. It was noted that her symptoms seemed to alternate sides and were thought to be "more of a generalized metabolic process such as hypocalcemia". She was given gentle IV fluid hydration and repeat CPK levels

were ordered. *Id*. Her symptoms and CK[3] levels improved with IV steroids. *Id*. at 63. The admitting diagnoses included right-sided paresthesia, weakness, fatigue, hypocalcemia, and elevated CK levels. *Id*. at 62. Elevated CK suggested either painless myositis[4] or, because the CSF was normal, a distally targeted primary myositis with early dysesthetic pain and numbness or significant denervation. *Id*. at 35. Petitioner reported that her symptoms seemed to progressively worsen after receiving a flu vaccine. *Id*. at 62. At discharge, neurologists Dr. Patel and Dr. Smith noted "[f]indings suggestive of acute vaccination syndrome, appearing to target distal sensory and motor nerves leading to elevated CK and sensory dysesthesias distal weakness. LP was normal, suggesting lack of root involvement/damage." *Id*. at 53. Etiology remained unclear. *Id*. at 56. Petitioner was discharged on October 4, 2016 with a diagnosis of bilateral (right greater than left) paresthesia, weakness, fatigue, hypocalcemia,[5] elevated CK levels, vitamin D deficiency, and hypotension. *Id*. at 62. The diagnoses did not include GBS, CIDP, polyradiculopathy, or other demyelinating disease.

Dr. Smith performed EMG/NCS testing on October 11, 2016. His impression based on the reported history and findings was "[b]orderline" results with evidence of inactive, mild polyradiculopathy affecting multiple upper and lower extremities; and rare short duration, myopathic motor units observed only in the tested trapezius muscle. The "findings are most consistent with a post-vaccination polyradiculopathy. She does not meet criteria for AIDP at this time. Note that while termed polyradiculopathy, very distal process can also produce similar findings on needle exam." Pet. Ex. 14 at 36.

Petitioner attended 12 physical therapy ("PT") sessions between October 17, 2016 and December 9, 2016 for generalized muscle weakness and unspecified lack of coordination. *See* Pet. Ex. 4 at 1-101.[6] She reported a history of GBS with numbness and tingling throughout her body. Pet. Ex. 14 at 23-24. She was discharged having met all goals and was independent with a home exercise program. *Id*. She returned for re-evaluation on December 23, 2016 with improved strength throughout her upper extremities. Grip strength was limited by muscle endurance. The plan was to continue with treatment.[7] *Id*. at 29.

Petitioner's next medical visit was on November 7, 2017 when she presented with complaints of memory issues to her colleague, Dr. Patton, a neurologist. Petitioner filled out an intake form documenting a history of Guillain Barre secondary to flu shot. Pet. Ex. 5 at 6; Pet. Ex. 14 at 44. Petitioner reported to Dr. Patton that in September 2016 after she received a flu shot, she developed weakness and numbness that started with fasciculations in her thumb, then jerking in her cheek, then progressed to numbness in her arms and feet. She was evaluated at the hospital and diagnosed with acute inflammatory demyelinating polyneuropathy. All testing was normal, and she was treated with five days of IV methylprednisolone which "leveled out her symptoms." Her

[3] Creatine kinase (CK) is an Mg^{2+}-activated enzyme of the transferase class that catalyzes the phosphorylation of creatine by ATP to form phosphocreatine. Dorland's at 423-24. An elevated CK level may indicate muscle or nerve cell injury. MOSBY'S MANUAL OF DIAGNOSTIC AND LABORATORY TESTS 167-69 (6th ed. 2018).
[4] Myositis is inflammation of a voluntary muscle. Dorland's at 1208.
[5] Hypocalcemia is reduction of the blood calcium below normal, with manifestations including hyperactive deep tendon reflexes, muscle and abdominal cramps, and carpopedal spasm. Dorland's at 889.
[6] Petitioner seems to have inadvertently labeled the PT records from Memorial Hermann as Exhibit 3 when, according to the exhibit list, it should be Exhibit 4. In this Decision, Exhibit 4 refers to those PT records.
[7] Based on the records filed, it does not appear that petitioner continued PT.

residuals included paresthesias of her face worse on the right, numbness and tingling of her feet, and intrinsic hand weakness. She had cognitive abnormalities including problems with getting words out, calculations, and recall, and over the past month, numbness and tingling in her fingertips. Her balance issues had improved but had not resolved, and she complained of tiredness, fatigue, and muscle soreness. She reported a normal rheumatological workup.[8] *Id*. In an addendum, Dr. Patton wrote that the patient is a physician, and her memory loss has affected her ability to work. She also has a history of "other autoimmune diseases."[9] Her examination was normal. Pet. Ex. 5 at 6-9. The plan was for an MRI of the brain to look for demyelination, an EMG, and exercise. *Id*. at 10.

In a letter dated November 7, 2017, Dr. Patton wrote that he had seen petitioner for an initial evaluation for her memory. The remainder of the letter mirrored his office record and included a past medical history of GBS. Pet. Ex. 14 at 57-61.

On November 17, 2017, Dr. Patton appealed a denial of the MRI ordered, writing that imaging studies were important to rule out multiple sclerosis or central nervous system etiology in a symptomatic patient with a history of autoimmune disease.[10] Pet. Ex. 14 at 48. The MRI was subsequently approved. *Id*. at 50.

Petitioner returned to Dr. Patton on November 28, 2017 to discuss her test results. Pet. Ex. 5 at 24, 27. EMG/NCS testing revealed "no clear pattern of active peripheral neuropathy. The prolongation of the H-reflex latencies could represent residual nerve damage from history of acute inflammatory demyelinating polyneuropathy". There was left acute to sub-acute mild C7/C8 radiculopathy and no evidence of plexopathy or myopathy. *Id*. at 40-41.

A brain MRI performed on December 14, 2017 was unremarkable and unchanged when compared to the September 2016 MRI. Pet. Ex. 3 at 230; Pet. Ex. 5 at 39.

The next medical visit was seven months later, on July 25, 2018 when petitioner presented to the hospital with suspected Transient Ischemic Attack ("TIA"), a stroke. Pet. Ex. 3 at 251. She reported clinical presentation of AIDP in 2016 with normal LP that was treated with steroids, and residual memory loss affecting her ability to be an ER doctor. She was at work today when she experienced a sudden onset of right sided facial tingling that progressed to her right upper and lower extremities. She also had intermittent right hip pain for 6 months. *Id*. at 256. She reported weakness, malaise/fatigue, visual disturbance, and occasional flashing in her right eye. *Id*. at 258. Examination revealed 5/5 strength in all extremities, intact sensation, and normal reflexes. *Id*. at 259, 282. Echocardiogram was normal. CT angiogram of the head for suspected stroke was normal. CT angiogram of neck was normal. MRI of the brain was normal. *Id*. at 291-95. She was ultimately diagnosed with migraine, Vitamin D deficiency, paresthesia of the skin, acidosis, pain in her right hip, anemia, and other longer term (current) drug therapy.[11] *Id*. at 251.

[8] No records of a rheumatological workup were found.
[9] It is unclear whether Dr. Patton is referring to GBS as the autoimmune disease or another autoimmune disease for which no medical records were filed.
[10] *Id*.
[11] It is not clear what "drug therapy" refers to.

Dr. Patton performed another EMG/NCS on July 31, 2018, which again showed no evidence of peripheral neuropathy, nerve entrapment, lumbosacral radiculopathy, or myopathy. Pet. Ex. 16 at 63-67. Dr. Patton documented a 41-year-old with a history of AIDP who recently had worsening symptoms and was admitted to the hospital with a workup that did not show any significant abnormalities. *Id*. at 71.

Petitioner underwent thoracic, lumbar, and cervical spine MRIs on August 10, 2018. Pet. Ex. 16 at 55-62. All three MRIs were unrevealing. *Id*.

Petitioner returned to Dr. Patton on September 4, 2018 reporting some residual neuropathic symptoms from AIDP. A skin biopsy was ordered to rule out small fiber peripheral neuropathy. Pet. Ex. 16 at 54.

On September 10, 2018, petitioner presented to Dr. Volpi for follow up from her hospitalization and use of antithrombotic medications. She had no stroke-like symptoms since, no acute vision loss, slurred speech, weakness, falls, or vertigo. Pet. Ex. 8 at 3-7. She was noted to be a 41-year-old woman with "migratory sensory symptoms" and possible complicated migraines who reported a history of AIDP in 2016. *Id*. at 7. Following her July 2018 hospital admission, she had a few weeks of improving sensory symptoms that plateaued with some sensory loss predominantly in the right side of her face. She reported continued difficulty with balance and trouble riding a bike. She had not fallen because she took extra care with her balance. She had no headaches but continued to report word finding concerns. She had seen Dr. Patton who offered an LP, IVIG, and steroids but has not yet done any of those. MRIs of the cervical, thoracic, and lumbar spine were unrevealing. *Id*.; Pet. Ex. 16 at 55-63. Following examination, Dr. Volpi's assessment was atypical migratory symptoms with no ischemic cause. Dr. Volpi agreed with Dr. Patton to do mitochondrial testing. Pet. Ex. 8 at 9.

A muscle biopsy to evaluate for small fiber neuropathy was performed on September 19, 2018 and was negative. Pet. Ex. 16 at 44-45, 49-50.

A neuropsychological evaluation was conducted on October 3, 2018 and ruled out cognitive impairment. Pet. Ex. 16 at 39, 42. Her only identified weakness was in right-hand motor skills, likely due to her history of AIDP. *Id*. at 42. "Her self-report of depressive and anxiety symptoms was nil." Mild depressive symptoms were evident. *Id*. Overall, she demonstrated excellent cognitive health and several strengths without suggestion of cerebral dysfunction impacting cognition and performed "very well" on measures sensitive to cerebral dysfunction. Her experience with AIDP took a slight emotional toll and resulted in mild depressive symptoms that affected her subjective cognitive functioning. *Id*. at 43. Antidepressant medication and exercise were recommended, as was remaining cognitively, socially, and physically active. *Id*.

Petitioner exchanged messages with Dr. Volpi on the patient portal on November 13, 2018 about ongoing sequela since her hospitalization 4 months before. She reported improvement with steroids. She also reported difficulty in scheduling with a neuromuscular specialist because she was uninsured. Pet. Ex. 15 at 9-10.

Petitioner presented to Dr. Highley on March 3, 2019, and reported a history of chronic demyelinating polyneuropathy. Pet. Ex. 9 at 2. She advised that, though she was a physician who could self-prescribe, she wanted official orders for medical care from someone else. She reported a history of AIDP four weeks after a flu vaccine in 2016 and that all testing was normal. The neurologist suspected an inflammatory process, as CPK levels decreased with IV Solumedrol. EMG showed possible polyneuropathy, although the specialist felt it was normal. She was able to return to work and to her daily activities. *Id*. at 2-3. Repeat brain MRI and MRA in December of 2017 were normal. Repeat EMG was improving. She stated that "[o]ver the course of almost 2 years, my only noticeable residual symptom was numbness at the very tip of my fingers." *Id*. at 3. Recently, she had an upper respiratory infection without fever that went away, but on August 24, 2018, she began having numbness on the lower right side of her face, arm, and leg that gradually worsened to include all distal extremities and bilateral face/mouth/tongue right greater than left. She was hospitalized for stroke work up which was negative. The vascular neurologist suggested a neuromuscular specialist since the symptoms looked like a polyneuropathy flare but getting appointments with specialists had proven difficult. She was in a support group for others who suffer from demyelinating polyneuropathies and learned that spine MRI is the standard test to look for nerve root enlargement or lesions that could cause neuropathy when CSF and EMG are inconclusive and no definitive diagnosis has been found. Thus, she requested an MRI of the cervical, thoracic, and lumbar spine, as she never had one.[12] *Id*. at 3.

Petitioner followed up with Dr. Patton on April 9, 2019 for memory loss due to AIDP. She complained of joint stiffness and pain, muscle cramps, arm, hand, and leg weakness, decreased concentration, difficulty in speech, difficulty writing, numbness, tingling, burning, and difficulty with balance. Pet. Ex. 6 at 12-14. No abnormalities were noted on examination. There was some decreased sensation to light touch in the left upper extremity when compared to the right with some general dysesthesias. She had normal vibration sensation. *Id*. at 15. The assessment was a 41-year-old with a history of AIDP with residual symptoms. Vitamin B complex and repeat EMG/NCS in 4 months was recommended. *Id*. at 16.

Repeat EMG/NCS testing was performed on August 2, 2019. Pet. Ex. 16 at 27-32. The NCS results were within normal limits. The EMG showed "no evidence of a generalized peripheral neuropathy, entrapment neuropathy, or radiculopathy in the bilateral lower extremities and the right upper extremity. Lack of F-wave responses could reflect residual proximal nerve root abnormality such as residual proximal neuropathy. Considering patients [sic] history of acute inflammatory polyneuropathy this should be monitored and probably residual changes secondary to this. No evidence of active disease." *Id*. at 27. Dr. Patton's assessment again included AIDP, recommending vitamin B complex and repeat EMG/NCS. *Id*. at 35.

Petitioner returned to Dr. Patton on December 10, 2019 and reported being stable since her last visit. Her right facial numbness had improved, but she still had problems with taste, intrinsic hand muscles, and fine motor functioning of her hands. Her memory and cognition were the same. She had sensory changes in the right lower extremity up to the mid-thigh and in the right forearm. Pet. Ex. 16 at 10-11. The assessment again included a history of AIDP that was clinically stable.

[12] Petitioner had at least four MRIs of the spine by this point, including two cervical spine MRIs, one of the thoracic spine, and one of the lumbar spine. Pet. Ex. 3 at 24, 62; Pet. Ex. 16 at 55-62.

Id. at 12. The diagnosis now was peripheral demyelinating neuropathy. She was to continue taking vitamin B and exercise. *Id*.

At a telehealth visit with Dr. Patton on June 9, 2020, petitioner reported continued neuropathy or weakness in her upper extremity causing her to drop things. She was exercising more and had lost some weight, was taking vitamin B, and had occasional leg cramps. Pet. Ex. 16 at 7. She reported malaise, muscle aches, arthralgias/joint pain, changes in her hair and nails, numbness, unsteady walk, muscle stiffness, memory loss, hair loss, and cold intolerance. *Id*. at 7-8. Dr. Patton's assessment remained the same with a past medical history of AIDP that was clinically stable but with dysesthesias in the right upper and lower extremity compared to the left. *Id*. at 8.

A functional capacity evaluation was conducted on September 29, 2020. Pet. Ex. 16 at 14-26. She reported constant numbness of the bilateral upper and lower extremities throughout the testing. *Id*. at 14. She had minimal anxiety and depression. *Id*. She was determined to be of "medium work classification". *Id*. at 26.

Petitioner returned to Dr. Patton on March 25, 2021 for follow up. Pet. Ex. 16 at 2. She was last seen 9 months ago. *Id*. at 3. She reported continuing neuropathy or weakness of the upper extremity causing her to drop things and occasional pain on the bottom of her feet. She had muscle aches and cramps, dry skin, weakness, numbness, fatigue, and cold intolerance. *Id*. She was noted to be clinically stable with dysesthesias in the right upper and lower extremity when compared to the left. *Id*. at 4. The diagnosis remained peripheral demyelinating neuropathy. *Id*.

On January 4, 2022, petitioner was referred to a new neurologist, Dr. Biliciler, after Dr. Patton retired. The record included a 2016 onset of symptoms, 2 weeks after a flu vaccine for which she was hospitalized and treated, all testing was unremarkable, an EMG/NCS one week after discharge was unremarkable, and at that point symptoms had mostly resolved. Pet. Ex. 17 at 2. She had a second episode consistent with the first in 2018, had a negative stroke workup, and was treated again with steroids with limited response. She had since had two unremarkable EMG/NCS studies. *Id*. She reported improvement now with about 50% sensory loss in the bilateral legs to mid-thigh, right upper extremity to elbow, and left upper extremity to mid-forearm. She denied weakness but did have tingling and burning in her feet with prolonged standing. She now only does telehealth because she feels her fine motor is worsening and she had short term memory issues. *Id*. Following an examination, it was noted that petitioner had "clinically diagnosed AIDP in 2016" with a similar episode in 2018 with residual peripheral neuropathy, three negative EMGs, negative skin biopsy, and negative MRIs of the brain and full spine. "Still concerns for possible rheumatological/immune mediated process". Dr. Biliciler wanted access to her full initial work up. *Id*. at 4.

The remainder of the records filed seem to be copies of petitioner's prior medical records.

B. Petitioner's Affidavit

Petitioner affirmed being in good health, eating well, training for a half marathon, and having started Crossfit on August 29, 2016 prior to the August 30, 2016 flu vaccination. Other than a wrist injury, "[l]ife was good." Pet. Ex. 2 at 1.

Petitioner affirmed that while at work at her desk on September 19, 2016, her right thumb began to twitch for less than a minute. It gave her pause, but she had no other symptoms. Pet. Ex. 2 at 1. However, she kept thinking about it, having just finished taking her American Board of Emergency Medicine recertification and thought ALS and googled ALS symptoms on September 20, 2016 at 2:37am. *Id*. at 1-2; Pet. Ex. 10 at 2.

According to petitioner, the twitching was sporadic over the next week and half, and she considered seeing a specialist. Pet. Ex. 2 at 2. Then on September 28, 2016, her thumb began to twitch and her cheek began to spasm. As she was getting dressed to go to the ER, it stopped. She was scheduled to work a 24-hour shift the next morning and had no one to cover for her, so she decided to seek care after her shift. She did another Google search on September 28, 2016. *Id*.; Pet. Ex. 10 at 2.

Petitioner affirmed that the next morning she had a brief but shocking pain in her right arm when she reached for her bag then had numbness in her right hand and forearm. She then had numbness in both feet while driving to work. She called a neurologist for an appointment during her break but was told that a head CT needed to be done before the visit. Pet. Ex. 2 at 2. She discussed this with her colleague who would be taking on her patients when her shift was done. They agreed she should check in as a patient, and he would order all the tests needed. She also spoke to her colleague, Dr. Patton, about her symptoms. He recommended neurologists and if symptoms progressed to go to the ER. *Id*. at 3.

Petitioner affirmed that at approximately 1:45am during her shift, she experienced a "prickly sensation of paresthesias [that] began on my face and on my tongue, and my feet and lower leg numbness worsened." She called Dr. Girgis to come in early, met her husband in a local parking lot, and went to Methodist Medical Center which has neurology services. Pet. Ex. 2 at 3.

Petitioner affirmed that she provided a full history upon arrival at the ER including the twitching of her thumb in September, but she could not remember the specific date. "I just knew that the twitching first happened at work, during the month of September, and that the numbness and tingling started the day before. I did not mention the flu shot at this time. I did not remember it until after I was upstairs in an inpatient room." Pet. Ex. 2 at 3.

Petitioner affirmed knowing that something was wrong when the physician in the ER asked her to lift each leg and hold it, and her legs were extremely shaky and weak. Pet. Ex. 2 at 3. She was given IV calcium, thinking low calcium could be the cause. *Id*. at 4.

According to petitioner, after being examined, she thought about her symptoms and GBS came to mind and recalled that GBS could be an adverse effect from a flu vaccine. She then searched her phone for when she received the flu vaccine. Shortly thereafter, Dr. Smith, a

neuromuscular neurology specialist came in with his medical student to examine her. She did not mention the flu vaccine because she wanted to hear his opinion after he examined her. Dr. Smith had no definite etiology for her numbness but thought it could be metabolic. He mentioned that diabetes can start as peripheral numbness years before a diagnosis and advised her to be mindful of her diet. Testing was ordered. Pet. Ex. 2 at 4. She then mentioned the flu vaccine to Dr. Smith, and he did additional testing on her legs to pinpoint the exact level of numbness. He discussed the pros and cons of doing a lumbar puncture and EMG/NCV, noting that it may be too early for anything to show up. They decided to do the lumbar puncture "given the 'temporal relationship', as he called it, to the flu shot." The lumbar puncture was done later that day. *Id*.

According to petitioner, her weakness, numbness, and paresthesia slowly worsened overnight, and she developed a prickly sensation in the back of her mouth and down her throat that was slightly worse on the left side of her face. Her husband alerted the staff and a fellow or resident came to examine her. There was no intervention because she was not having trouble breathing or swallowing. The prickly feeling resolved over the next day and was replaced by numbness. Pet. Ex. 2 at 5.

Petitioner affirmed that on October 1, her fingers felt like they were asleep, and she could not open or squeeze a condiment package. Over the course of that day, numbness and weakness slowly worsened, but she was able to ambulate without assistance. No interventions were ordered while the test results were pending. Pet. Ex. 2 at 5.

Petitioner affirmed that on October 2, Dr. Smith initiated a 5-day course of high dose steroids due to progressive symptoms and an increasing CPK level. By the next day, the prickly paresthesias had resolved but she had increased left facial numbness. By October 4, there was definite improvement of the numbness and weakness, and she was discharged home with oral steroids. An EMG/NCV was scheduled for the following week. Pet Ex. 2 at 5.

At the time she signed her affidavit in 2019, she still had numbness of her face, hands, feet and lower legs, decreased taste, and memory deficits. Pet. Ex. 2 at 5.

C. Google searches

Petitioner conducted google searches on ALS on September 20, 2016 and September 28, 2016; GBS on October 2, 2016; and CIDP and ALS on October 14, 2016. Pet. Ex. 10 at 1-2.

IV. Parties' Arguments

A. Petitioner's Motion

In her Motion for Ruling on the Record, petitioner asserted that she provided sufficient evidence to satisfy her burden of proof establishing that she suffered post-vaccination polyradiculopathy caused by the August 30, 2016 flu vaccine. Motion at 1.

Petitioner acknowledged that she alleged in her petition that she suffered from GBS resulting from her flu vaccine and that respondent had argued in his Rule 4(c) Report there was

insufficient evidence to support GBS as the injury. Motion at 1-2; ECF No. 22. Petitioner further acknowledged that she was unable to obtain an expert to support her claim based on the record. Motion at 2.

Petitioner summarized her medical history, highlighting certain records to support a vaccine related injury including: Dr. Smith's note on October 4, 2016, that "[f]indings [were] suggestive of acute vaccination syndrome, appearing to target distal sensory and motor nerves leading to elevated CK and sensory dysesthesia distal weakness." Motion at 3; Pet. Ex. 3 at 53; Dr. Gadiraju's note that '"[n]eurology felt that perhaps the patient's symptoms were secondary to acute vaccination syndrome with distal sensory and motor notes (sic) affected.'" Motion at 3-4; Pet. Ex. 3 at 63; Dr. Smith's interpretation of the EMG findings on October 11, 2016, was most consistent with post-vaccination polyradiculopathy. Motion at 4; Pet. Ex. 14 at 36; physical therapy findings of diminished grip strength, tingling, and diminished sensation. Motion at 4; Pet. Ex. 4 at 21, 207; Dr. Patton's November 7, 2017 note included residual symptoms of AIDP including facial paresthesia and numbness, tingling in her feet, decreased sensation to light touch, pinprick above the ankle on the right side and up to the ankle on the left, and decreased vibration in the toes. Motion at 4; Pet. Ex. 5 at 6.

Petitioner further submitted that Dr. Patton ordered another EMG of the extremities and a brain MRI. The EMG revealed no clear pattern of active peripheral neuropathy, but the prolongation of the H-reflex latencies could represent residual nerve damage from history of AIDP. There was no myopathy or plexopathy found. Motion at 4-5; Pet. Ex. 5 at 6, 40-41. The brain MRI was unremarkable. Motion at 5; Pet. Ex. 5 at 39. Another EMG done on August 1, 2018 was normal. Motion at 5; Pet. Ex. 16 at 63-64, 67.

When she saw Dr. Volpi on September 10, 2018 with continued complaints of sensory loss and balance issues, the diagnosis was atypical migratory symptoms. Motion at 5; Pet. Ex. 15 at 31-33. A skin biopsy performed on September 19, 2018 was normal. Motion at 5; Pet. Ex. 16 at 44-45. She returned to Dr. Patton on April 12, 2019 with numbness, balance issues, and memory deficits. Dr. Patton noted ongoing symptomology with some generalized hypo-reflexia. Motion at 5; Pet. Ex. 6 at 16. She presented again on August 1, 2019 with neuropathic symptoms and another EMG was performed showing no active disease. Motion at 6; Pet. Ex. 16 at 27-35. Dr. Patton then diagnosed her with demyelinating neuropathy in December of 2019. Motion at 6; Pet. Ex. 16 at 10-12. She continued to present to Dr. Patton on June 9, 2020 and March 25, 2021 with neuropathy and weakness. Motion at 6; Pet. Ex. 16 at 7-8, 2-5.

Petitioner submitted that in October of 2021, she was referred to Dr. Biliciler, a neuromuscular specialist, with sensory loss of about 50% in her legs to her mid thighs, right upper arm to elbow, and left upper extremity to mid forearm. She denied weakness but did have tingling and burning in her feet with prolonged standing. Motion at 6; Pet. Ex. 17 at 2-4.

Petitioner argued that she satisfied prong one by providing a sound and reliable medical theory of causation demonstrating that the flu vaccine could have caused petitioner's post-vaccination polyradiculopathy. Motion at 10; *Althen*, 418 F. 3d at 1278. Petitioner conceded that she was not diagnosed with GBS and therefore could not meet the criteria for GBS. However, she argued that GBS is an acute polyradiculopathy and she was diagnosed with polyradiculopathy.

Since GBS from flu vaccine is a recognized Table injury with "a reputable medical theory causally connecting the vaccination and injury is clearly established and accepted by the government", she had satisfied prong one. Motion at 10; 42 C.F.R. § 100.3.

In support of prong two, petitioner argued she had no prior health issues and developed symptoms of post-vaccination polyradiculopathy approximately 29 days after the flu vaccine, which is consistent with the time period for a Table GBS claim. Motion at 11; Pet. Ex. 12 at 10-18.

Further, both Dr. Smith and Dr. Gadiraju described her symptoms as '"acute vaccination syndrome."' Motion at 11; Pet. Ex. 3 at 53, 57. Petitioner argued that treating physicians can opine on causation based on their observation of her condition in close proximity to the time of the vaccination and that multiple treating physicians opined that petitioner's "post-vaccination polyradiculopathy was in some way related to the flu vaccine." Motion at 11 (citations omitted).

Finally, petitioner argued that she satisfied prong three because the onset of her polyradiculopathy was 29 days after the flu vaccine. Therefore, there is a "proximate temporal relationship between vaccination and injury." Motion at 12; Pet. Ex. 12 at 10-18; *Althen*, 418 F. 3d at 1278. Petitioner argued that the evidentiary burden is a medically acceptable time frame that does not have to match perfectly with the dominant or consensus view in the medical community. Motion at 12. Therefore, petitioner had demonstrated that the onset of her post-vaccination polyradiculopathy symptoms occurred within a timeframe for which, given the understanding of the disorder's etiology, is medically acceptable to infer causation-in-fact. *Id*.

B. Respondent's Response

Respondent argued that petitioner had abandoned her allegation of GBS and instead now argues that she suffered a post-vaccination polyradiculopathy. Response at 2. He added that petitioner did not file an amended petition alleging causation-in-fact for post-vaccination polyradiculopathy. *Id*. at 2, note 1.

In summarizing petitioner's medical history, respondent pointed out that some of petitioner's doctors referred to findings as "suggestive of acute vaccination syndrome" or as most consistent with post-vaccination polyradiculopathy but did not diagnose her with GBS or other neurological condition. Response at 4, 5; Pet. Ex. 3 at 53; Pet. Ex. 14 at 36.

Further, following her discharge from her initial hospitalization, she reported a diagnosis of GBS when presenting for medical care, when the discharge diagnosis was bilateral paresthesias, weakness, and fatigue of unknown etiology. Response at 5, 8-11; Pet. Ex. 3 at 38, 46, 61-62, 256; Pet. Ex. 4 at 21, 37; Pet. Ex. 6 at 14, 16; Pet. Ex. 8 at 7; Pet. Ex. 9 at 2.

Respondent pointed out that, with petitioner's concession that she did not suffer from GBS but rather from a post-vaccination polyradiculopathy, she was required to satisfy the requirements for a causation-in-fact claim. In an off-Table claim, it is her burden to offer a reputable medical theory which often requires experts who can find support for their theories in medical literature. It

is not enough for petitioner to show that the vaccine "likely caused" or is a "plausible" or "possible" cause of the injury. Response at 12-15 (citations omitted).

Further, petitioner has not proven a definitive diagnosis or recognized injury. Petitioner had various working diagnoses including GBS, CIDP, MS, and electrolyte imbalance. In a letter to one of her treaters, petitioner acknowledged that the etiology of her symptoms was unclear with no definitive diagnosis found. Response at 14-15; Pet. Ex. 3 at 44, 46-47, 52, 56, 255, 259, 474; Pet. Ex. 9 at 3. A claim of a vaccine related injury "unsubstantiated by medical records or by medical opinion" is insufficient. Response at 15; § 300aa-13(a)(1).

Respondent argued that even if petitioner could establish a definitive diagnosis of polyradiculopathy, the medical records do not establish the flu vaccine as the cause, and she failed to provide an expert report in support of her claim. In fact, petitioner conceded that she was unable to obtain an expert to support her claim on the current record. Response at 14-15.

Respondent disagreed with petitioner's assertion that because GBS is an acute polyradiculopathy that can be caused by flu vaccine and is a Table injury, a reputable medical theory causally connecting the vaccination and injury '"is clearly established and accepted by the government."' Response at 15. Respondent argued that this reasoning is contrary to binding precedent requiring petitioners in off-Table cases to demonstrate general causation by preponderant evidence, even where an injury is similar to one listed on the Table. *Id*. He then quoted the legislative history included in *Grant v. Sec'y of Health & Human Servs.*:

> If the petitioner sustained or had significantly aggravated an injury not listed in the Table, he or she may petition for compensation. If the petitioner sustained or had significantly aggravated an injury listed in the Table but not within the time period set forth in the Table, he or she may petition for compensation. In both of these cases, however, the *petition must affirmatively demonstrate that the injury or aggravation was caused by the vaccine*. Simple similarity to conditions or time periods listed in the Table is not sufficient evidence of causation; evidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation for such a petitioner. (Such a finding of causation is deemed to exist for those injuries listed in the Table which occur within the time period set forth in the Table.)

956 F.2d at 1144, 1147-48 (citations omitted) (emphasis in *Grant*). While *Grant* recognized that Congress relaxed the proof of causation for injuries satisfying the Table, it did not relax proof of causation in non-Table cases. Response at 15-16. Petitioner has not presented any evidence "overriding the directive of *Grant* and its progeny" and must therefore demonstrate general causation by preponderant evidence even if her injury is similar to one listed on the Table. She has failed to do so. *Id*. at 16.

Respondent argued that petitioner also failed to establish prong two. Response at 17. While conceding that Dr. Smith diagnosed petitioner with '"post-vaccination polyradiculopathy"' and that his opinion as a treating physician is probative, it is not binding on the special master to adopt those conclusions. Response at 17; § 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 & Human Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("[T]here 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.").

Respondent argued that Dr. Smith's opinion notwithstanding, the record as a whole shows that various doctors over multiple years had several working diagnoses with no single diagnosis or etiology determined. Response at 18; Pet. Ex. 3 at 44, 46-47, 52, 56, 255, 259, 474. Petitioner has therefore failed to satisfy prong two.

As for prong three, petitioner has not produced a medical theory causally connecting her alleged polyradiculopathy to the flu vaccine and thus has not provided a timeframe that could be temporally appropriate. Therefore, she has failed to satisfy prong three. Response at 19.

In conclusion, respondent argued that the petition should be dismissed. Response at 19.

V. Legal Standard

The Vaccine Act provides two avenues for petitioners to receive compensation. First, a petitioner may demonstrate a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the provided time period. § 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* § 13(a)(1)(B). In order to establish an on-Table GBS, petitioner must show:

> (A) Bilateral flaccid limb weakness and decreased or absent deep tendon reflexes in weak limbs;
>
> (B) A monophasic illness pattern;
>
> (B) An interval between onset and nadir of weakness between 12 hours and 28 days;
>
> (D) Subsequent clinical plateau (the clinical plateau leads to either stabilization at the nadir of symptoms, or subsequent improvement without significant relapse; however, death may occur without a clinical plateau); and
>
> (E) The absence of an identified more likely alternative diagnosis.

42 C.F.R. § 100.3(c)(15).

Where the alleged injury is not listed on the Vaccine Injury Table, a petitioner may demonstrate an "off-Table" injury, which 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* § 11(c)(1)(C)(ii). Initially, a petitioner must provide evidence that he or she suffered, or continues to suffer, from a definitive injury. *Broekelschen v. Sec'y of Health & Human Servs*., 618 F.3d 1339, 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. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

To prove causation for an "off-Table" injury, petitioners must satisfy the three-pronged test established in *Althen*. 418 F.3d at 1274. *Althen* requires that petitioners show by preponderant evidence that a vaccination petitioner received caused his or her injury "by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id*. at 1278. 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). Causation is determined on a case-by-case basis, with "no hard and fast per se scientific or medical rules." *Knudsen v. Sec'y of Health & Human Servs*., 35 F.3d 543, 548 (Fed. Cir. 1994). Petitioners are not required to identify "specific biological mechanisms" to establish causation, nor are they required to present "epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities." *Capizzano*, 440 F.3d at 1325 (quoting *Althen*, 418 F.3d at 1280). "[C]lose calls regarding causation are resolved in favor of injured claimants." *Althen*, 418 F.3d at 1280.

Each of the *Althen* prongs requires a different showing. The first *Althen* prong requires petitioners to provide a "reputable medical theory" demonstrating that the vaccines received *can* cause the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citation omitted). Establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of his or her claim. *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Petitioners' "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 v. Sec'y of Health & Human Servs.*, 746 F.3d 1334, 1341 (Fed. Cir. 2014).

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 vaccinations can cause the injury, petitioners 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). Petitioners are not, however, required "to eliminate alternative causes as part of establishing [their] prima facie case." *Doe v. Sec'y of Health & Human Servs.*, 601 F.3d 1349, 1357-58 (Fed. Cir. 2010); *see Walther v. Sec'y of Health & Human Servs.*,

485 F.3d 1146, 1152 (Fed. Cir. 2007) (holding that a "petitioner does not bear the burden of eliminating alternative independent potential causes").

To satisfy the third *Althen* prong, petitioners 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.").

A. Standard Regarding Fact Finding

The process for making determinations in Vaccine Program cases regarding factual issues begins with analyzing the medical records, which are required to be filed with the petition. § 11(c)(2). Medical records created contemporaneously with the events they describe are generally considered to be more trustworthy. *Cucuras v. Sec'y of Health & 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). While not presumed to be complete and accurate, medical records made while seeking treatment are generally afforded more weight than statements made by petitioners after-the-fact. *See Gerami v. Sec'y of Health & Human Servs*., No. 12-442V, 2013 WL 5998109, at *4 (Fed. Cl. Spec. Mstr. Oct. 11, 2013) (finding that contemporaneously documented medical evidence was more persuasive than the letter prepared for litigation purposes), *mot. for rev. denied*, 127 Fed. Cl. 299 (2014). Indeed, "where later testimony conflicts with earlier contemporaneous documents, courts generally give the contemporaneous documentation more weight." *Campbell ex rel. Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006); *see United States v. U.S. Gypsum Co*., 333 U.S. 364, 396 (1948).

Despite the weight afforded medical records, special masters are not bound rigidly by those records in determining facts such as the onset of a petitioner's symptoms. *Vallenzuela v. Sec'y of Health & Human Servs*., No. 90-1002V, 1991 WL 182241, at *3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); *see also Eng v. Sec'y of Health & Human Servs*., No. 90-175V, 1994 WL 67704, at *3 (Fed. Cl. Spec. Mstr. Feb 18, 1994) (explaining that § 13(b)(2) "must be construed so as to give effect to § 13(b)(1) which directs the special master or court to consider the medical record...but does not require the special master or court to be bound by them"); *see also Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

In short, "the record as a whole" must be considered. § 13(a). There were no expert reports or medical literature filed.

B. Standard for Ruling on the Record

Petitioner's claim is being resolved on the record. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v.Sec'y of Health & Hum. Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Hum. Servs*., No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Hum. Servs*., 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

VI. Analysis

Petitioner filed a petition alleging the Table injury of GBS resulting from a flu vaccine. Pet. Petitioner has since conceded that she did not suffer from GBS but rather from polyradiculopathy which she alleges was caused by the flu vaccine. Motion. Despite being ordered to do so, petitioner did not amend her petition to include the off-Table claim for polyradiculopathy. She conceded that she was unable to secure an expert to support her claim based on the record. *Id*.

A. Petitioner has not provided a sound and reliable theory for how a flu vaccine could cause polyradiculopathy.

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*, 451 F.3d at 1355-56 (citation omitted). To satisfy this prong, petitioner's "theory of causation must be supported by a 'reputable medical or scientific explanation.'" *Andreu*, 569 F.3d at 1379 (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.

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his or her claim. *Lampe*, 219 F.3d at 1361; *see also Caron v. Sec'y of Health & Human Servs*., No. 15–777V, 2017 WL 4349189, at *10 (Fed. Cl. Spec. Mstr. Sept. 7, 2017) (denying entitlement and dismissing a petition where the petitioner failed to provide an

expert report to support her claim that the vaccinations caused her son's injuries and the medical evidence did not support her claim), *mot. for rev. denied*, 136 Fed. Cl. 360 (2018).

Petitioner argued that she suffers from polyradiculopathy and claimed that GBS is an acute polyradiculopathy that can be caused by the flu vaccine as evidenced by its presence on the Vaccine Injury Table. Being on-Table, a reputable medical theory that flu vaccine can cause GBS has been clearly established and accepted by the government. Therefore, it can be inferred that polyradiculopathy can also be caused by flu vaccine. Motion at 10.

Respondent disagreed, arguing that such reasoning is contrary to precedent that requires petitioners in off-Table cases to demonstrate general causation by preponderant evidence, even where an injury is similar to one listed on the Table. Response at 15-16. Despite the relaxed proof of causation for Table injuries recognized in *Grant*, that relaxed proof was not extended to off-Table cases. Petitioner did not suffer from a Table GBS injury, and therefore she must prove causation by preponderant evidence. *Id*.

Petitioner seeks a finding that the flu vaccine can cause polyradiculopathy because flu vaccine can cause GBS. Her argument fails for several reasons, the first of which is that she provided no support for the analogy between polyradiculopathy and GBS. The Qualifications and Aids to Interpretation ("QAI") to the Vaccine Injury Table provide that there are four subtypes of GBS and identifies several elements associated with each subtype in order to be considered an on-Table injury. The four subtypes are AIDP, acute motor axonal neuropathy, acute motor and sensory neuropathy, and Fisher Syndrome—none of which mention polyradiculopathy. 42 C.F.R. § 100.3(c)(15). Not only did petitioner provide no evidence to support that polyradiculopathy is akin to GBS, but at least one form of polyradiculopathy (CIDP) is listed as an exclusionary diagnosis for all four subtypes of an on-Table GBS. *Id*. at § 100.3(c)(15)(vi).

Even if petitioner had proven that polyradiculopathy was analogous to GBS, vaccine caselaw is clear that petitioner must provide preponderant evidence that the subject vaccine can cause the injury alleged in an off-Table claim. *Grant,* 956 F.2d at 1147-48. Polyradiculopathy is not listed as a Table injury associated with any vaccination. 42 C.F.R. § 100.3. Thus, petitioner was required to provide a sound and reliable medical theory connecting the vaccination and the injury she alleged. *See Broekelschen,* 618 F.3d at 1344, 1346 (upholding the special master's denial of entitlement when he made a factual determination that the condition that Dr. Broekelschen actually suffered was not the one for which he had claimed or presented causation evidence). Doing so requires "trustworthy testimony from experts who can find support for their theories in medical literature". *LaLonde*, 746 F.3d at 1341; *see also de Bazan*, 539 F.3d at 1351. Here, petitioner conceded that she could not secure an expert on the evidentiary record. Motion at 2.

To the extent that petitioner relied on her treating physicians' visit notes to satisfy prong one, the opinions of her treaters are insufficient to meet the preponderant evidence standard. While her records show that some of her treaters associated her symptoms with vaccination, they relied on the history provided to them by petitioner herself, which was frequently in conflict with the prior medical records and the objective test results.[13] Additionally, they provided no scientific

[13] This is more thoroughly addressed in the analysis of prong two.

basis for the conclusion that her symptoms were caused by the flu vaccine. *Veryzer v. Sec'y of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd,* 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion,* 475 F. Appx. 765 (Fed. Cir. 2012).

Accordingly, petitioner failed to provide preponderant evidence of a sound and reliable theory that a flu vaccine can cause polyradiculopathy. As such, petitioner failed to satisfy *Althen* prong one.

B. Petitioner has not proven a logical sequence of cause and effect between her flu vaccine and her polyradiculopathy.

Having found that the petitioner failed to provide preponderant evidence that the flu vaccine can cause polyradiculopathy that is not GBS, the remainder of petitioner's claim necessarily fails. *Boatmon v. Sec'y of Health & Human Servs*., 941 F.3d 1351, 1360-62 (Fed. Cir. 2019); *see also Hibbard v. Sec'y of Health & Human Servs*., 698 F.3d 1355, 1364 (Fed. Cir. 2012). But for the sake of thoroughness, the remaining prongs will be briefly addressed.

To satisfy the second prong of *Althen*, a petitioner must establish a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Althen*, 418 F.3d at 1278. The sequence of cause and effect need only be "logical and legally probable, not medically or scientifically certain." *Knudsen*, 35 F.3d at 548-49; *accord Capizzano*, 440 F.3d at 1326. In other words, even if the vaccination can cause the injury alleged, petitioner must show "that it did so in [this] particular case." *Hodges*, 9 F.3d at 962 n.4 (citation omitted).

Generally, "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*, 786 F.3d at 1385 (internal citations omitted). However, special masters are directed to consider the evidence as a whole and are not bound by the notes of treating physicians within the medical record. *See Snyder*, 88 Fed. Cl. at 746 n.67 ("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 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. *Hibbard v. Sec'y of Health & Human Servs.,* 100 Fed. Cl. 742,749 (2011), *aff'd,* 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer*, No. 06-522V, 2011 WL 1935813, at *17. A treating providers' mere suspicion that the vaccine was the cause of petitioner's injury is not enough. *Paluck*, 786 F.3d at 1385 (quoting *Andreu*, 569 F.3d at 1375); *Fesanco v. Sec'y of Health & Human Servs.*, 99 Fed. Cl. 28, 34 (2011).

Petitioner argued that her treating physicians diagnosed her with post-vaccination polyradiculopathy. She cited to various entries in the medical record to support this argument, including Dr. Smith's note on October 4, 2016, that "[f]indings [were] suggestive of acute vaccination syndrome"; Dr. Gadiraju's note that "'[n]eurology felt that perhaps the patient's

symptoms were secondary to acute vaccination syndrome"; and Dr. Smith's interpretation of the EMG findings on October 11, 2016, as most consistent with post-vaccination polyradiculopathy. Motion at 3-4, 11; Pet. Ex. 3 at 53, 57, 63; Pet. Ex. 14 at 36.

When petitioner presented 29 days after receiving the subject flu vaccination, she underwent neurological examination, lumbar puncture, brain and cervical spine MRIs, and EMG, all of which were normal. Pet. Ex. 3 at 20-21, 23-24, 26, 31-34, 62-63. Her diagnoses at discharge included bilateral (right greater than left) paresthesia, weakness, fatigue, hypocalcemia, elevated CK levels, vitamin D deficiency, and hypotension, with no mention of GBS, AIDP, or polyradiculopathy. *Id*. at 62.

An EMG performed on October 11, 2016 showed "evidence of inactive, mild polyradiculopathy", "most consistent with a post-vaccination polyradiculopathy" but not meeting the criteria for AIDP. Dr. Smith also noted that a "very distal process" could look like polyradiculopathy on EMG. Pet. Ex. 14 at 36.

Petitioner presented to her colleague, Dr. Patton, a year later for memory loss. She reported being diagnosed with AIDP in 2016 after a flu shot but that all test results were negative. Pet. Ex. 5 at 6. Dr. Patton ordered labs, an MRI to rule out MS, and EMG testing of the extremities "[b]ecause of the question of acute inflammatory demyelinating polyneuropathy". *Id*. at 10. The EMG revealed left acute to subacute, mild C7/C8 radiculopathy with no evidence of plexopathy or myopathy and no clear pattern of active peripheral neuropathy. *Id*. at 40-41. The MRI was normal. *Id*. at 39.

Petitioner had another episode of tingling in her face and extremities two years later in July 2018. There were no neurological deficits on examination and no clear etiology for her symptoms. Pet. Ex. 3 at 251, 256, 258-59, 282. The treating physicians noted that she "had questionable [diagnosis] of GBS in 2016" with a normal lumbar puncture, normal MRI, and an EMG that purported to show polyneuropathy, but all workup at the time was inconclusive and "nondiagnostic". *Id*. at 255-56. CT angiograms of the head and neck, echocardiogram, and brain MRI to rule out stroke were all normal. *Id*. at 291-95. The discharge diagnosis was migraine with aura. *Id*. at 290-94.

Another EMG performed during the summer of 2018 was normal. Pet. Ex. 16 at 63-67. Skin biopsy ruled out small fiber peripheral neuropathy. *Id*. at 44-45, 49-50, 54.

In September of 2018, Dr. Volpi referred to her symptoms as "migratory sensory symptoms". Pet. Ex. 8 at 7, 9.

A neuropsychological evaluation showed excellent cognitive health without suggestion of cerebral dysfunction impacting cognition, and she performed "very well" on measures sensitive to cerebral dysfunction. Pet. Ex. 16 at 39, 43.

Another EMG/NCS performed in August of 2019 was within normal limits with normal reflex latencies. Pet. Ex. 16 at 27-32. There was "no evidence of a generalized peripheral neuropathy, entrapment neuropathy, or radiculopathy in the bilateral lower extremities and the

right upper extremity. Lack of F-wave responses could reflect residual proximal nerve root abnormality such as residual proximal neuropathy. Considering patients history of acute inflammatory polyneuropathy this should be monitored . . . No evidence of active disease." *Id*. at 27. Dr. Patton's assessment included AIDP. *Id*. at 35.

In December of 2019, petitioner followed up with Dr. Patton, reporting that facial numbness had improved but she still had problems with her hand muscles. Pet. Ex. 16 at 10-11. The assessment was a history of AIDP that was clinically stable. The diagnosis now was peripheral demyelinating neuropathy. *Id*. at 12.

Petitioner returned to Dr. Patton in March of 2021, reporting continued "neuropathy or weakness" of the upper extremity causing her to drop things with occasional pain on the bottom of her feet. Pet. Ex. 16 at 2-3. She was noted to be clinically stable with dysesthesias in the right upper and lower extremity when compared to the left. *Id*. at 4. The diagnosis remained peripheral demyelinating neuropathy. *Id*.

Petitioner saw Dr. Biliciler, a new neurologist, on January 4, 2022. Pet. Ex. 17 at 2. Following an examination, he noted that petitioner reported clinically diagnosed AIDP in 2016 and a similar episode in 2018 with residual peripheral neuropathy, three negative EMGs, negative skin biopsy, and negative MRIs of the brain and full spine. He noted continuing "concerns for possible rheumatological/immune mediated process". *Id*. at 4.

The medical records show that petitioner had various working diagnoses, including but not limited to GBS, MS, electrolyte imbalance, metabolic disorder, polyradiculopathy, and small fiber neuropathy. However, her treaters acknowledged that the etiology of her symptoms was unclear, all testing was unremarkable/normal, and a definitive diagnosis was never determined. Pet. Ex. 3 at 56; Pet. Ex. 5 at 40-41; Pet. Ex. 8 at 9; Pet. Ex. 16 at 71. Though petitioner reported to several providers that she had a history of GBS and/or AIDP, normal CSF on lumbar puncture ruled out GBS and Dr. Smith noted that she did "not meet criteria for AIDP". *Id*. at 62, 256; Pet. Ex. 5 at 6; Pet. Ex. 8 at 7; Pet. Ex. 14 at 23-24, 36, 44, 57-61; Pet. Ex. 16 at 54, 71.

While I recognize the probative value of treating physicians' opinions particularly related to prong two, I am not required to accept their opinions as sacrosanct. *See Snyder*, 88 Fed. Cl. at 746 n.67. Rather, it is my job to consider their opinions in the context of the evidence as a whole and weigh their opinions accordingly. *Hibbard,* 100 Fed. Cl. at 749 (citations omitted). Here, the records petitioner cited in her Motion to support post-vaccination polyradiculopathy do not explain how this conclusion was reached and were in the context of normal testing/imaging despite subjective complaints. The records themselves read as though the treaters could not determine a definitive diagnosis, thus they referred to her symptoms as "post-vaccination polyradiculopathy" or "acute vaccination syndrome" based on petitioner's report of her symptoms and onset after receiving a flu vaccine. Pet. Ex. 3 at 53, 56, 62; Pet. Ex. 14 at 36. Even when Dr. Smith characterized her EMG as "post-vaccination polyradiculopathy", he cautioned that a "very distal process" could look like polyradiculopathy on EMG. Pet. Ex. 14 at 36. He also specifically noted that she did not meet the criteria for AIDP. *Id*. Thereafter, petitioner, who is a trained ER doctor, reported to subsequent providers that she was diagnosed with AIDP or GBS. This inaccurate

history did not seem to be questioned by her treaters, despite their documenting that all objective testing was normal.

Petitioner had many proposed diagnoses over the relevant timeframe, most of which were ruled out by objective testing. The etiology of her symptoms remains unknown, and she never received a definitive diagnosis. Furthermore, petitioner failed to provide a medical theory causally connecting the vaccination and her alleged injury. As such, she has also failed to provide a logical sequence of cause and effect between the flu vaccination she received and the symptoms with which she later presented. Petitioner has failed to satisfy prong two.

C. Petitioner has not provided a medically reasonable timeframe for a flu vaccine to cause polyradiculopathy.

The third *Althen* prong requiring an appropriate temporal relationship contains two parts. First, a petitioner must establish the "timeframe for which it is medically acceptable to infer causation" and second, she must demonstrate that the onset of the disease occurred in this period. *Shapiro v. Sec'y of Health & Human Servs.,* 101 Fed. Cl. 532, 542-43 (2011), *recons. denied after remand on other grounds*, 105 Fed. Cl. 353 (2012), *aff'd without op.,* 503 F. App'x 952 (Fed. Cir. 2013). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury utilized to satisfy the first prong. *Id.* at 542; *Koehn v. Sec'y of Health & Hum. Servs*., No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

Having failed to provide a medical theory causally connecting her flu vaccine to her alleged injury, she provided no medically acceptable timeframe between the vaccine and her alleged injury. The best (and only) evidence petitioner provided was that she received a flu vaccine and developed symptoms a month later. A mere demonstration of temporal proximity between a vaccination and injury is insufficient to meet petitioner's burden. *Grant,* 956 F.2d at 1148. Therefore, petitioner failed to satisfy *Althen* prong three.

VII. Conclusion

Despite my sincere sympathy for petitioner for what she has experienced, my decision must be based on a thorough analysis of the evidence presented and the applicable legal standards. After a thorough review of the medical records and submissions of both parties, it is clear that petitioner has failed to provide sufficient evidence to demonstrate that a flu vaccine can cause and did cause petitioner's alleged injuries or did so within a medically reasonable timeframe in order to satisfy her burden under *Althen*.

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.[14]

IT IS SO ORDERED.

[14] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party filing a notice renouncing the right to seek review.

s/ Mindy Michaels Roth
Mindy Michaels Roth
Special Master