In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 18-1772V
Filed: April 12, 2024

HATIM M. SALAH,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent

Ryan Mahoney, Mahoney Law Firm LLC, Glen Carbon, IL, for Petitioner
Dorian Hurley, U.S. Department of Justice, Washington, DC, for Respondent

DECISION ON ENTITLEMENT[1]

Oler, Special Master:

On November 16, 2018, Hatim Salah ("Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq*.[2] (the "Vaccine Act" or "Program"). Petitioner alleges that he developed transverse myelitis ("TM") as a result of the influenza ("flu") vaccine he received on October 21, 2016. Pet. at 1. For the reasons discussed in this decision, I find that Petitioner has not demonstrated that the flu vaccine caused his condition. Specifically, there is preponderant evidence that Petitioner had a viral infection approximately

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

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

eight days before he first developed symptoms of TM. The existence of this infection prevents him from meeting his burden of proof under the second *Althen* prong. The petition is accordingly dismissed.

I. Procedural History

Petitioner filed a petition on November 16, 2018. Pet., ECF No. 1. He filed medical records on January 11, 2019 and November 26, 2019. Exs. 1-9, ECF Nos. 8, 9, 17.

Respondent filed a Rule 4(c) Report on March 9, 2020 recommending against compensation. Resp't's Rep., ECF No. 19. Respondent contended that Petitioner has not satisfied the six month severity requirement,[3] the record supports other etiologies of his condition, and Petitioner's medical providers have not reached consensus on his proper diagnosis. *Id.* at 6-7.

After that, the parties filed a series of expert reports from their respective neurologists. Petitioner filed reports from Dr. David Simpson, while Respondent filed a report from Dr. Raymond Price. Exs. 10, A, 12.

I held an entitlement hearing on October 27-28, 2022. Minute Entry dated 10/28/2022. Petitioner, Petitioner's wife, Dr. Simpson, and Dr. Price testified at the hearing.

On January 18, 2023 and March 2, 2023, I admitted Court Exhibits 1001-03 into the record. ECF Nos. 70, 71. I gave the parties time to file supplemental expert reports addressing the court exhibits entered into the record. On May 19, 2023, the parties each filed one expert report from Drs. Simpson and Price. Exs. F, 23.

The parties then filed post-hearing briefs on August 21, 2023 and October 19, 2023. ECF Nos. 79, 80.

On December 19, 2023, I directed Respondent to subpoena certified copies of all of Petitioner's medical records from Dr. James Wade from October 21, 2016 through present day. *See* Scheduling Order dated December 19, 2023. I also directed Petitioner to file objective evidence (for example, employment records) which substantiates his testimony that he was too ill to work in November of 2016. *Id.*

Petitioner filed employment records on January 18, 2024. Ex. 24. Respondent filed certified records from Dr. Wade on April 1, 2024. Ex. I. This matter is now ripe for adjudication.

II. Transverse Myelitis

Transverse means "acting, lying, or being across."[4] Myelitis refers to inflammation of the

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[3] At the entitlement hearing, Respondent conceded that the severity requirement had been satisfied. Tr. at 183-84. I agree with this assessment, and thus have not analyzed the issue further.

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

spinal cord.[5] Accordingly, transverse myelitis is a "myelitis in which the functional effect of the lesions spans the width of the entire cord at a given level."[6] Transverse myelitis is a heterogeneous group of inflammatory disorders of the spinal cord resulting in "paresis, a sensory level, and autonomic (bladder, bowel, and sexual) impairment below the level of the lesion." Beh et al., *Transverse Myelitis*, 31 NEUROL CLIN 79-138 (2013) (filed as Ex. C-1).

TM can have different underlying causes; as a result, it can present as "a multi-focal central nervous system (CNS) disease (e.g. multiple sclerosis), a result of direct injury to the spinal cord (e.g. radiation, spinal cord infarct), as part of a systemic (e.g. malignancy) or autoimmune disease (i.e. systemic lupus erythematosus), or as an isolated entity." Agmon-Levin et al., *Transverse myelitis and vaccines: a multi-analysis*. 18 LUPUS at 1198, 1198-1204, (2009) (filed as Ex. 17) (hereinafter "Agmon-Levin").

The parties agree that Petitioner was correctly diagnosed with TM. Joint Pre-Hearing Submission at 2.

III. Medical Records

Petitioner was 29 years old at the time of vaccination. He was a police officer who was in good health with an uneventful medical history.

On October 21, 2016, Petitioner received the influenza vaccine at the office of his primary care physician ("PCP"), Dr. James Wade. Ex. 2 at 12.

Petitioner visited Dr. Wade on November 16, 2016.[7] Ex. I at 84. The reason for his appointment is listed as "1. Chills 2. Hot flashes 3. SOB 4. Body aches 5. Chest tightness" *Id.* The record further documents that Petitioner "returns to the office with cc of fever, chills, body aches and weakness that has been present over the past 2 days and is getting worse. [S]tates that he has been running a fever and has been in bed." *Id.* Petitioner had a temperature of 100.5° at the appointment. *Id.* Dr. Wade assessed Petitioner with a viral syndrome as his primary condition and also with dehydration. *Id.* Dr. Wade administered two bags of IV liquids and two 40 mg doses of Depo-Medrol.[8] *Id.* Petitioner was instructed to follow up in one day. *Id.*

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[5] DORLAND'S MEDICAL DICTIONARY ONLINE, www.dorlandsonline.com/dorland/definition?id=32680&searchterm=myelitis (last visited September 19, 2023) ("DORLAND'S").

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

[7] This record was not filed with the other medical records presented by Petitioner. Because the record's absence was notable, I asked Respondent to subpoena Dr. Wade's medical records and file a certified copy of these documents into the record. The visits from November 16 and November 17, 2016 were contained in the certified records filed by Respondent, but not in the records filed by Petitioner.

Petitioner followed up with Dr Wade on November 17, 2016. The reason for the appointment is listed as "Nausea". Ex. I at 83. The record documents that Petitioner "returns to the office for repeat evaluation. [S]tates that he is feeling much better today and the nausea is resolved. [S]tates that the muscle pain is better. [A]ppetite is slowly returning." *Id.* Dr. Wade again assessed Petitioner with a viral syndrome and instructed him to drink plenty of fluids. *Id.*

On November 23, 2016, Petitioner returned to Dr. Wade's office complaining of loss of appetite, pain all over, and that his feet felt numb. Ex. 2 at 9. Under history of present illness ("HPI"), Dr. Wade noted that Petitioner "returns to the office for repeat evaluation. states that he was feeling good after the last treatment but now hurts all over and states that he is numb everywhere. has no appetite and [is experiencing] weakness." *Id.* Petitioner had a temperature of 100.2° F. *Id.* Dr. Wade's assessment was that he had a fever, body aches, abdominal pain, a viral syndrome, and dehydration. *Id.* Petitioner tested negative for the flu and received an IV saline drip and a Toradol[9] shot. *Id.* at 10.

On the same day, Petitioner went to the Memorial Hospital emergency room in Belleville, Illinois reporting five to seven days of a "febrile illness associated with generalized malaise and headache." Ex. 3 at 20. Petitioner had an intermittent fever with maximum of 101.2ºF, chills, and neck stiffness. *Id.* at 32. Petitioner reported that it progressed to bilateral lower extremity numbness, difficulty urinating, neck stiffness, mild photosensitivity, and nausea. *Id.* Petitioner had been taking ibuprofen. *Id.* at 21. Upon discharge, it was noted that Petitioner had been previously treated with IV fluids and steroids with temporary improvement. *Id.* at 25. However, Petitioner's fever came back along with aforementioned symptoms. *Id.* He underwent a lumbar puncture, CT scan, and an MRI which were not significant, except for an elevated white blood cell count. *Id.* Petitioner was to be transported to Barnes Jewish Hospital ("BJC") in St. Louis, Missouri for further management. *Id.* Petitioner's problem list included acute urinary retention, fever, myalgia, abdominal pain. headache, aseptic meningitis, and systemic inflammatory response syndrome ("SIRS"). *Id.* at 30.

On November 24, 2016, Petitioner's fever had been reduced to 99.3ºF. Ex. 3 at 43. Petitioner's updated assessment was "febrile illness secondary to early aseptic meningitis with CSF showing mild pleocytosis associated with elevated protein and normal glucose consisted with aseptic meningitis." *Id.* Petitioner was to be transported to BJC for further management. *Id.* at 25.

Petitioner was admitted to BJC on the night of November 24, 2016. Ex. 4 at 6. Petitioner's principal diagnosis was acute transverse myelitis. *Id.* Petitioner was first evaluated by neurologist Dr. Jin-Moo Lee. *Id.* at 53. Petitioner's medical history was as follows:

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[8] Trademark for preparations of methylprednisolone acetate, "the 21-acetate ester of methylprednisolone" which is administered intramuscularly as an anti-inflammatory and immunosuppressant. DORLAND'S, www.dorlandsonline.com/dorland/definition?id=89217 (last visited April 5, 2024).

[9] Toradol or the trademark preparation of ketorolac tromethamine is "a nonsteroidal anti-inflammatory drug administered intramuscularly, intravenously, or orally for short-term management of pain." DORLAND'S, https://www.dorlandsonline.com/dorland/definition?id=26960 (last visited December 7, 2023).

> Patient developed myalgia, fatigue and temperature to 100F on 11/14/16. On 11/16/16, he presented to his PCP who gave him a "steroid shot" and IVF. He felt better in the days following and was able to return [to]work throughout the night as a police office on 11/21/16. However on 11/22/16, his myalgia returned with especially pronounced pain in the lower back and bilateral lower extremities. He also experienced allodynia ("pain when drying with a towel") of the back and paresthesia ("pins and needles") of the lower extremities. He also developed urinary retention ("straining for just a few drops") and constipation.
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> He was then admitted to Belleview Memorial. He was febrile to 102.6 and 101.9…. Labs there were notable for WBC=11.3, ESR=6, negative EBV, RPR, HIV, Flu A & B. An LP performed there revealed: WBC: 58, Glu 64, protein 94 (HSV, VDLR pending)…. He was on ceftriaxone (menigitic dosing) and acyclovir.
>
> He was transferred to BJC. Upon arrival, he appeared stable with the following vitals: T37.9 (100.2° F)… He was complaining of headache, neck pain, lower back pain, paresthesia of bilateral feet. And allodynia of the lower abdomen.
>
> Of note, he received a flu shot on 10/21/16. Following the vaccination he felt fatigued for several days. This was only the 2nd flu shot he has ever received.

Ex. 4 at 53. In the diagnosis plan section, Dr. Lee noted "Consider transverse myelitis of infectious vs. flu vaccine vs. NMO vs. MS etiology…. Infectious cause favored given fever, elevated WBC in serum and CSF." *Id.* at 56.

On November 29, 2016, Petitioner had a "vasovagal event" or diaphoresis[10] and diffuse weakness following a hot shower; he did not fall but required a wheelchair to get back to bed. Ex. 4 at 678.

On November 30, 2016, the infectious disease consult stopped acyclovir and switched azithromycin to doxycycline. Ex. 4 at 64. The consult added that it was "Likely 2/2 viral etiology vs. Mycoplasma despite conflicting titers." *Id.* at 67.

On December 1, 2016, the infectious disease consult concluded that Petitioner did not need doxycycline as his mycoplasma PCR was negative. Ex. 4 at 59.

On December 2, 2016, Petitioner was seen by a neurologist, reporting improvement with his symptoms; he was negative for the enterovirus and was having normal bowel movements. Ex. 4 at 684. On physical examination, Petitioner was largely normal, with the exception of decreased sensation to light tough in his bilateral lower extremities. *Id.* at 685. The neurologist noted that an "infectious cause favored given fever, elevated WBC in serum" but flu vaccine and NMO etiology were still noted. *Id.* at 687.

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[10] Sweating. DORLAND'S, www.dorlandsonline.com/dorland/definition?id=13776&searchterm=diaphoresis (last visited April 5, 2024).

Petitioner showed continued improvement on December 3, 2016 and was scheduled to be released after completion of IVMP (methylprednisone). Ex. 4 at 692.

Petitioner was discharged from BJC on December 4, 2016. A summary of Petitioner's stay at BJC as follows:

> There was a concern for transverse myelitis of infectious or immune-mediated etiology.
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> At the time of admission, he was continued on ceftriaxone and acyclovir and was started [on] vancomycin. Ceftriaxone and vancomycin were discontinued on 11/26 as CSF and blood cultures at the outside hospital showed no growth. On 11/28, the patient was febrile (38.7), and infectious workup (KUB, CXR, CBC, UA) was unrevealing. On the same day, serum mycoplasma IgM and IgG results came back equivocal. Patient was started on azithromycin, which was later changed to doxycycline for better CNS penetration in consultation with infectious disease team. CSF mycoplasma PCR came back negative and at this point doxycycline was discontinued and IV methylprednisone was started. He received a total of 5g methylprednisone over the span of 5 days. At the time of discharge, patient was voiding and defecating without difficulty, he reported resolution of headache and pain, and improvement of balance and strength.
>
> He was started on Gabapentin 300 TID for nerve pain. This was uptitrated to 900 TID during the hospitalization. We will plan to taper his gabapentin as an outpatient.

Ex. 4 at 697.

On December 9, 2016, Petitioner returned to Dr. Wade for a follow-up for his transverse myelitis. Ex. 2 at 7-8. Petitioner reported that he still felt weak but had improved, particularly with his bowel and bladder function. *Id.* at 7.

On June 19, 2017, Petitioner was seen by Dr. Larry Dobbs for a growth on the roof of his mouth. Ex. 2 at 5-6. In the history of present illness, it was noted that "About one half years ago he developed Guillain-Barr [sic] syndrome after getting influenza vaccination and now has complete recovery." *Id.* at 5.

Petitioner returned to his PCP Dr. Wade on July 25, 2016 for low back and leg aches and nausea. Ex. 2 at 3-4. Petitioner reported that he had a sinus infection, body aches, and weakness that was getting worse but no numbness. *Id.* at 3.

On November 30, 2017, Petitioner saw Dr. Justin Colanese for acute left knee pain and numbness in his toes. Ex. 9 at 1-3. Dr. Colanese noted Petitioner's past history of transverse myelitis following a flu shot, specifically noting that

> he was paralyzed from the waist down, and had no sensation in his legs at that point time. He was treated with steroids and recovered very well…. In about March 2017, the sensation finally return[ed] to his feet, and he states his feet were normal until several weeks ago. He has been having numbness at the tips of all 5 toes. No numbness anywhere else.

Id. at 1. Petitioner was diagnosed with patellar tendinitis of the left knee. *Id.* at 2. The etiology of his toe numbness was "most likely related to his transverse myelitis." *Id.*

No other medical records relevant to my determination on entitlement have been filed.

IV. Petitioners' Affidavits and Testimony

A. Petitioner, Hatim Salah

1. Affidavit

In his affidavit, Petitioner averred that prior to his October 21, 2016, flu vaccination, he was in generally good health and did not suffer from any medical conditions. Ex. 11 ("Pet. Aff.") at 1. He stated that at the time of his admission to Memorial Hospital on November 23, 2016, he was experiencing "loss of appetite, muscle pain in [his] lower back and bilateral lower extremities, difficulty urinating, and numbness in [his] feet." *Id.* He was transferred to Barnes Jewish Hospital on November 24 and discharged on December 4 having been diagnosed with TM. *Id.* at 2.

Petitioner averred that from the time of his discharge from the hospital through December 2018, he experienced weakness in his legs and lower back, fatigue, numbness in his feet and toes, difficulty urinating, loss of balance, difficulty walking, weight loss, and muscle atrophy. Pet. Aff. at 2. Prior to his TM, Petitioner enjoyed participating in sports and his inability to do so caused him to become depressed. *Id.* At the time he signed his affidavit, he was not functioning athletically at his prior level. *Id.* He also had difficulty functioning at his job as a police officer. *Id.*

Petitioner recalled experiencing numbness in his feet and toes while travelling with his wife on their honeymoon in November 2018. Pet. Aff. at 2.

2. Testimony

At the entitlement hearing, Petitioner testified that he has been a police officer with the Belleville, Illinois, police department for six-and-one-half years. Tr. at 8. When he completed his police academy training in 2016, he began working nights and would play basketball at the YMCA in the morning after a 12-hour shift. *Id.* at 8-9. He testified that in the months prior to his October 21, 2016, flu vaccination, he was in the best shape of his life. *Id.* at 9. He had received the flu vaccine prior to this and had no adverse reaction. *Id.* at 10.

Petitioner received the flu vaccine on October 21, 2016, at his PCP's office. Tr. at 10. He began feeling unwell "approximately a week and a half, two weeks" later. Tr. at 11. While playing basketball after a night shift, he described his symptoms as follows:

> I was playing, as I always did my entire life, and I noticed that like I would try to – this was the first sign I felt like something was wrong, where I would go to move or I would go to turn, and like my body wouldn't react quickly…I genuinely remember saying out loud, as I was leaving, something's wrong with me, like I don't know why I can't move well right now.

Id. Petitioner stated that he "started progressively feeling worse." *Id.* He began feeling severe aching in his legs and lower back and "hypersensitivity" in his skin. *Id.* He remembered calling his captain and saying, "I believe I have the flu." *Id.* at 12. After "four or five days" of not working Petitioner was still not improving, and in fact was "getting progressively worse." *Id.* At this time (mid-November 2016), Petitioner called his PCP and was seen the same day. *Id.* He complained of severe low back ache, body aches, leg ache, and loss of appetite. *Id.* Petitioner testified that his PCP administered "two steroid shots, one in each buttock," and possibly an IV. *Id.* at 13. Petitioner experienced some relief from his symptoms for about three days. *Id.* He reported going back to work and feeling like he was "crashing," and that his skin was "on fire". *Id.* He had difficulty standing up and was unable to urinate. *Id.* He experienced back pain and body aches so severe that he had trouble walking up the steps in his home. *Id.* at 13-14.

Petitioner saw his PCP again, who referred him to the emergency room due to his inability to urinate. Tr. at 14. He reported to the emergency room at Memorial Hospital and was admitted. *Id.* After some testing, hospital staff informed Petitioner that he would be transferred to Barnes Jewish Hospital, roughly 40 minutes away. *Id.* at 14-15. At the time of his admission at BJC, Petitioner felt paralyzed below the waist and had to be catheterized three to four times per day. *Id.* at 15-16. He was unable to bathe or use the restroom unassisted. *Id.* at 16.

During his admission, Petitioner was told that he may never fully recover or be able to work as a police officer again. Tr. at 16-17. He testified that he asked one of his providers whether his condition could have been caused by the flu vaccine, and he responded that it "seem[ed] likely." *Id.* at 17.

Petitioner testified that, at the time of his discharge from Barnes Jewish Hospital in December 2016, he was still experiencing severe low back pain, muscle aches in his legs, and weakness. Tr. at 18. He was unable to walk up the stairs in his home without assistance. *Id.* His mother was caring for him during this time. *Id.* at 18-19. Petitioner attended physical therapy ("PT") until he lost his insurance due to his inability to work as a police officer. *Id.* at 19. Petitioner returned to his PCP in January 2017 after having been out of work for two months and reported that he was not feeling better. *Id.* at 19-20. He received medical clearance to go back to work because he needed to have health insurance. *Id.* at 20. In spite of having no feeling in his feet, Petitioner returned to work as a police officer in February 2017, albeit on light duty. *Id.* He was still experiencing low back pain, loss of appetite, and depression. *Id.* at 20-21.

Over the following few months, Petitioner continued to experience numbness in his toes and feet and severe fatigue. Tr. at 21-22. He testified that the foot and toe numbness persisted until at least March 2018, noting that he underwent the physical fitness test for employment in the

Belleville police department at that time with no feeling in his feet. *Id.* at 22. He also continued to experience difficulty urinating until mid-2018. *Id.* at 23.

Petitioner testified that he and his wife first met in early 2017 and that they were married on November 11, 2017. Tr. at 23. He stated that his condition has affected their relationship, causing him embarrassment and discomfort. *Id.* He was experiencing back pain, leg aches, difficulty urinating, and fatigue while they were on their honeymoon in November 2017. *Id.* at 24-25.

Petitioner stated that at the time of his testimony, he was no longer experiencing numbness, but he continued to have severe low back pain "regularly." Tr. at 26. He sees a chiropractor and uses a TENS unit. *Id.* He stated that he has not been the same since having TM. *Id.* Prior to receiving the flu vaccine in 2016, Petitioner testified that he never experienced difficulty with urination, extreme fatigue, extreme weakness in his legs or lower back, lower back injury, extreme weight loss, or difficulty walking or going up stairs. *Id.* at 26-27. Since having TM, Petitioner stated that he has not returned to his pre-injury baseline. *Id.* at 28.

On cross-examination, Petitioner stated that his symptoms were constant in the early months of his TM, and that they began to fluctuate with time. Tr. at 30. He did not recall telling his PCP in March 2017 that the numbness in his feet and toes had resolved. *Id.* at 30-31. He testified that he does not know why a note to that effect would be in the record of this visit because persistent numbness was one of his complaints at the appointment. *Id.* at 31.

Petitioner testified that he did not seek medical treatment for his ongoing symptoms after November 2017 due to feeling ashamed of his limitations and not wanting to complain. Tr. at 33.

B. Petitioner's Wife, Sherin Salah

1. Affidavit

In her affidavit, Petitioner's wife, Sherin Salah ("Ms. Salah"), stated that she and Petitioner began dating in December 2016. ECF No. 63 at 1.[11] From that time until their marriage in November 2017, she observed Petitioner experience pain in his back and legs, loss of feeling in his feet, difficulty urinating, and depression. *Id.*

Ms. Salah stated that during their honeymoon in November 2017, Petitioner complained of daily numbness in his feet and toes, as well as back pain and fatigue. *Id.* at 2. She recalled Petitioner falling asleep in the airport and awakening feeling disoriented when it was time to board the plane. *Id.*

Ms. Salah also stated that Petitioner took a fitness examination in March 2018 for his job as a police officer and that he told her that he was unable to feel his feet during the entire examination. *Id.*

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[11] Petitioner did not associate an exhibit number with this document.

2. Testimony

Ms. Salah testified that she and Petitioner were married on November 11, 2017. Tr. at 37. They met in December 2016. *Id.* Ms. Salah lived in Chicago at the time, and she and Petitioner communicated by phone and video chat daily, with monthly in-person visits. *Id.* at 38. She relocated to Belleville, Illinois, in November 2017. *Id.* at 39.

Ms. Salah testified that, around the time of the couple's engagement in April 2017, Petitioner "was not in a good state of mind." Tr. at 40. He was sad and depressed about his inability to play basketball. *Id.* During their honeymoon in November 2017, Petitioner was "extremely fatigued," and had no feeling in his feet. *Id.* He fell asleep in the airport during a layover and Ms. Salah had difficulty waking him up when it was time to board the flight. *Id.* at 41.

Ms. Salah testified that Petitioner had no feeling in his feet at the time of his physical examination for employment as a police officer in March 2018. Tr. at 42. She stated that at the time of her testimony, Petitioner continued to experience back pain. *Id.* at 43.

V. Expert Opinions

A. Petitioner's Expert: David Simpson, M.D.

1. Qualifications

Dr. Simpson received his bachelor's degree in psychology at the State University of New York ("SUNY") – Stony Brook in 1975 and his medical degree at SUNY – Buffalo in 1979. Ex. 22 ("Simpson CV") at 1. He completed his residency in neurology in 1983 and a fellowship in clinical neurophysiology in 1984. *Id.* He currently serves as professor of neurology and sees patients at Mount Sinai Medical Center in New York City. *Id.* at 2. Dr. Simpson is board certified in psychiatry and neurology with subspecialties in clinical neurophysiology and neuromuscular medicine. Tr. at 51. He is the author of 250 peer-reviewed articles and nearly 100 book chapters. Simpson CV at 11-37. I recognized him as an expert in neurology, neuropathy, and clinical neurophysiology. Tr. at 57.

2. Expert Reports and Testimony

Dr. Simpson provided three expert reports and testified at the entitlement hearing. Exs. 10 ("First Simpson Rep."), 12 ("Second Simpson Rep."), 23 ("Third Simpson Rep.").

To begin with, Dr. Simpson opined that Petitioner's diagnosis of TM is "unequivocal" based on the findings of his treating physicians. First Simpson Rep. at 4. He stated that the acute presentation of TM is characterized by "rapidly progressing lower extremity weakness and sensory impairment, associated with saddle anesthesia, [and] bladder and bowel dysfunction." *Id.* He opined that Petitioner exhibited all of these symptoms. *Id.*

Dr. Simpson stated his belief that the flu vaccine Petitioner received caused him to develop TM. Tr. at 12. Dr. Simpson opined that there are several biological mechanisms by which a vaccine

can cause neurologic illness, including molecular mimicry, neurotoxic effect, immune complex formation, and loss of self-tolerance. First Simpson Rep. at 4. He added that he is unable to opine as to which of these mechanisms caused Petitioner's TM without "specific proof," but opined that molecular mimicry is the most likely. Second Simpson Rep. at 2; Tr. at 64. He cited medical literature supporting his theory that various vaccinations, including flu, can cause TM. First Simpson Rep. at 5.

Dr. Simpson opined that Petitioner was neurologically asymptomatic prior to the allegedly causal flu vaccination. First Simpson Rep. at 5; Tr. at 60. He noted that after "an extensive diagnostic evaluation," Petitioner's infectious disease specialists were unable to identify a specific infectious cause of his TM, leading them to recommend discontinuing his course of empirical antibiotics. *Id.* at 5-6; *see also* Tr. at 75. At the hearing, Dr. Simpson testified that Petitioner's treating physicians, "including the infectious disease consultants, excluded an infectious cause" for Petitioner's TM.[12] Tr. at 61. Dr. Simpson opined that "influenza vaccine remains as the only identifiable cause of [Petitioner's] TM." First Simpson Rep. at 6; *see also* Tr. at 65.

Dr. Simpson opined that Petitioner's condition improved both subjectively and objectively after treatment with high-dose corticosteroids. First Simpson Rep. at 6. He opined that, given the degree of damage to Petitioner's spinal cord, it is unsurprising that Petitioner's residual neurological and functional deficits persisted. *Id.* He opined that "it is quite common for patients with chronic neurological diseases to have waxing and waning symptoms over time," and that the fluctuating lower extremity symptoms Petitioner reported are consistent with TM sequelae. Second Simpson Rep. at 2. He testified that the numbness in Petitioner's toes that was documented on March 2017 was due to his TM and not some other illness or condition. Tr. at 67 (citing Ex. 9 at 1-2).

Dr. Simpson opined that the timing of onset of Petitioner's TM is consistent with the 2012 Institute of Medicine's ("IOM's") conclusion that up to 42 days after vaccination is medically appropriate for vaccine-induced immune response. First Simpson Rep. at 6; citing Stratton et al., Committee to Review Adverse Effects of Vaccines, Institute of Medicine, eds., *Adverse Effects of Vaccines: Evidence and Causality,* Washington (DC): National Academies Press (2012) (filed as Ex. 21). He testified that Petitioner's statements in his affidavit are consistent with Dr. Simpson's conclusion that the sequelae of Petitioner's TM lasted longer than six months. Tr. at 68. He opined that the severity of Petitioner's symptoms and the extent of his spinal cord pathology make "persistent and long-lasting symptoms," including extreme fatigue or difficulty with urination, likely. *Id.*

Dr. Simpson opined that Dr. Price's theory that Petitioner's TM had a parainfectious etiology was "entirely speculative and based on no confirmatory data." Second Simpson Rep. at 1; *see also* Tr. at 69. He noted Dr. Price's statement that 15 to 30 percent of TM cases are idiopathic and added that, "in the absence of an identified infectious etiology in this case, then idiopathic TM is [Petitioner's] alternative diagnosis." *Id.* at 2. In his testimony, he clarified that cases in which TM "develops out of the blue, and the work-up is entirely negative for any identified cause,

[12] This statement is not accurate. *See* Ex. 4 at 75, 76; Ex. 4 at 67; Ex. 4 at 692; Tr. at 82-87.

autoimmune, infection, vaccine and otherwise, then that falls into the idiopathic category." Tr. at 91.

On questioning by the Court, Dr. Simpson testified that the evidence that Petitioner had fever for several days early in his disease course is "certainly…a notable part of the history." Tr. at 70. He noted that, based on Petitioner's fever and elevated white blood cell count in his CSF, Petitioner's treating physicians were right to suspect an infection. *Id.* Dr. Simpson opined that Petitioner's fever, elevated white blood cell count, neck pain, and headache were the result of the "general inflammatory response to his illness," and cytokine production in particular, as opposed to an infection. *Id.* at 70-71. He opined that a fever in the absence of an infection is well-reported in cases of TM. *Id.* at 71-72. He added that inflammation and systemic symptoms such as myalgia, muscle pain, and flu-like symptoms can be a response to TM. *Id.* at 72-73. He opined that it is reasonable to conclude that Petitioner's TM was caused by the flu vaccine in the absence of an identified infectious cause. *Id.* at 73.

On cross-examination, Dr. Simpson acknowledged that Petitioner's treating physicians continued to suspect that his condition had a viral etiology even after extensive investigation failed to identify a specific infection. *Id.* at 83-85. He disagreed with this opinion and opined that it was speculative to suspect a viral etiology after the workup Petitioner received failed to reveal a specific infection. *Id.* at 87. He acknowledged that testing looks at specific infections and that it is possible that Petitioner had an infection that was not tested for. *Id.* at 89.

B. Respondent's Expert: Raymond Price, M.D.

1. Qualifications

Dr. Price received his bachelor's degree in biochemistry from the University of North Carolina in 2000, and his medical degree at the University of Pennsylvania in 2004. Ex. B ("Price CV") at 1. He completed his residency in neurology in 2008 and a fellowship in clinical neurophysiology in 2010. *Id.* He is board certified in neurology, neuromuscular medicine, and electrodiagnostic medicine. Tr. at 107. He is currently an associate professor of neurology at the University of Pennsylvania and a clinical neurologist in the University of Pennsylvania Health System. *Id.*; Price CV at 1. He is the author of 20 peer-reviewed publications and 38 book chapters. Price CV at 5-6. I recognized Dr. Price as an expert in neurology. Tr. at 110.

2. Expert Reports and Testimony

Dr. Price submitted two expert reports in this matter and testified at the entitlement hearing. Exs. A ("First Price Rep."), F ("Second Price Rep.").

Dr. Price opined that etiologies of TM fall into several categories, including parainfectious, paraneoplastic, drug/toxin-induced, system autoimmune disorders (*e.g.*, lupus), acquired demyelinating disorders (*e.g.*, multiple sclerosis or neuromyelitis optica). First Price Rep. at 5. He stated that parainfectious TM "has been described with numerous viral, bacterial, fungal, and parasitic infections." *Id.* He opined that molecular mimicry is not a proven mechanism by which

the flu vaccine can cause TM. Tr. at 125-26. He opined that patients with parainfectious TM tend not to have oligoclonal bands in their CSF. *Id.* at 127-28, 153.

Dr. Price opined that Petitioner's November 2016 symptoms including myalgias, fever, decreased appetite, rigors, and nausea "are suggestive of a concurrent infectious syndrome, more specifically a viral syndrome." First Price Rep. at 5. He opined that parainfection is the most likely etiology of Petitioner's TM. *Id.* He opined that infectious processes typically start one to two days before symptom onset. Tr. at 145. Based on this assumption, he testified that he believed that Petitioner's infection began between November 10 and 16, 2016. *Id.* He noted that the symptoms Petitioner exhibited are not included in the detailed description of the clinical presentation of TM found in Court exhibit 1003. Second Price Rep. at 4 (citing Frohman & Wingerchuk, *Transverse Myelitis*, 363 N ENGL J MED 6, 564-72 (2010) (filed as Court Ex. 1003) (hereinafter "Frohman & Wingerchuk")). He also disagreed with Dr. Simpson's opinion that Petitioner's fever was not related to an infection, but he acknowledged that a chronic systemic inflammatory reaction could cause a fever in some cases of TM. Tr. at 129-30, 146.

Dr. Price noted that Petitioner tested negative for a wide array of infections, and that his test results for Mycoplasma were inconclusive. First Price Rep. at 5. He opined that infectious etiology can be very difficult to identify and noted that approximately 10 years prior to the onset of his TM, Petitioner presented with a fever of unknown origin that was later attributed to Epstein-Barr virus. *Id.* at 5-6; Tr. at 138. He opined that while the list of infections for which Petitioner tested negative may appear comprehensive, the list is actually "a relatively small subset of the common infectious etiologies." First Price Rep. at 6; *see also* Tr. at 133-34 (noting that Petitioner was tested for 20-30 organisms while there are thousands that can cause infection). He opined that Petitioner's TM most likely had a parainfectious etiology "even in the absence of definitive identification of the infectious organism." *Id.* He added that failure to identify a particular infectious cause may result in "incorrect attribution to a temporally associated event such as vaccination, despite repeated high-quality evidence failing to demonstrate an increased rate of [TM]" compared to patients who have not been recently vaccinated. Second Price Rep. at 6. Dr. Price added that Petitioner's etiology would be presumptively infectious according to one of the articles cited by Frohman and Wingerchuk. *Id.* at 4 (citing Pidcock).

Dr. Price stated that Petitioner developed "myalgia, fatigue, and a temperature on 11/14/16." First Price Rep. at 6. He opined that Petitioner's "first clear neurologic symptoms of low back pain and allodynia develop on 11/22/16." *Id.* He cited medical literature finding no association between TM and immunization within two to 42 days. *Id.* (citing Baxter). He also noted that Court exhibit 1001 found no increased risk of developing central nervous system demyelinating disorders within three years after vaccination. Second Price Rep. at 2 (citing Annette Langer-Gould et al., *Vaccines and the Risk of Multiple Sclerosis and Other Central Nervous System Demyelinating Diseases*, 71 JAMA NEUROL 1506 (2014) (filed as Court Ex. 1001) (hereinafter "Langer-Gould")). He acknowledged that Langer-Gould found an increased rate of central nervous system demyelination in patients under the age of 50 within 30 days of vaccination. *Id.* (citing Langer-Gould). However, he opined that this was a subgroup analysis that "does not provide scientific evidence of a relationship between vaccination and [TM]." *Id.* at 3. He argued that, by contrast, Baxter, which was "focused on the relationship between [TM] and vaccination,

would be consider[ed] higher quality scientific evidence than the subgroup analysis by Langer-Gould." *Id.*

Dr. Price criticized Dr. Simpson's reliance on case studies and case series to support his opinion that the flu vaccine can cause TM. First Price Rep. at 7; Tr. at 120-23. He noted that Court exhibit 1002 is a collection of case reports and opined that case reports "are not meant to be used as epidemiologic data since novel case reports are primarily published and additional case reports of the same phenomenon are less likely to be published." Second Price Rep. at 2. He criticized Frohman and Wingerchuk for misleadingly aggregating the percentage of TM cases that are postinfectious with those that are post-vaccination. *Id.* at 5 (citing Frohman & Wingerchuk). He cited literature pointing out that "extensive data continue to overwhelmingly show that vaccinations are safe and are not associated with an increased incidence of neurologic complications." *Id.*; citing Kaplin et al., *Diagnosis and Management of Acute Myelopathies*, 11 THE NEUROLOGIST 1, 2-18 (2005) (filed as Ex. H) (hereinafter "Kaplin").

On questioning by the Court, Dr. Price opined that Petitioner's myalgias that began around mid-November 2016 were not the start of his TM. Tr. at 160. He opined that symptoms such as stiff neck, headache, and foot numbness "would be the crux of when the [TM] started." *Id.* at 163. He added that low back pain could also be a symptom of TM, but could also be caused by elevated white blood cell count in CSF. *Id.*

Dr. Price opined that there are multiple hypotheses as to the mechanism by which a viral infection can cause TM. Tr. at 164. One possibility is that the virus itself is in the CSF and triggers an immune response there. *Id.* He stated that another possibility is that parainfectious TM results from molecular mimicry. *Id.* He opined that in a case of parainfectious TM, it would be possible for the infection and the TM to begin at the same time. *Id.* at 166-67.

Dr. Price opined that Petitioner "has made an excellent recovery" from his TM. First Price Rep. at 7. He disagreed with the opinion of Petitioner's orthopedist that the numbness Petitioner experienced in his toes in November 2017 was related to his TM. *Id.* He opined that TM is a monophasic syndrome and that he would not expect Petitioner to make "a complete recovery" by March of 2017 and develop new symptoms of TM in November 2017. *Id.*; *see also* Tr. at 113. He opined that "there are no documented residual clinical abnormalities related to his [TM]." First Price Rep. at 8. He also acknowledged that he did not have an alternative explanation for Petitioner's November 2017 toe numbness and opined that it could have been the result of his TM. Tr. at 114, 117. Dr. Price opined that the disorientation that Petitioner described in his testimony is not typical of TM sequelae, but the fatigue could have been related to his TM or to depression resulting from his illness. Tr. at 117-18.

Dr. Price disagreed with the proposition that, because the flu vaccine has been known to cause Guillain-Barré syndrome, a peripheral nervous system demyelinating disease, it must also be able to cause TM, a central nervous system demyelinating disease. Tr. at 112. He explained that the peripheral and central nervous systems are myelinated by different kinds of cells with different protein expressions. *Id.* He stated that vaccination has not been proven to be a cause of TM. *Id.*

VI. Applicable Law

A. Petitioner's Burden

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

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

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

Petitioner may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1325-26 (2007)). However, special masters are "entitled to require some indicia of reliability to support the assertion of the expert witness." *Boatmon*, 941 F.3d at 1360 (*quoting Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010)). Special Masters, despite their expertise, are not empowered by statute to conclusively resolve what are complex scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Hum. Servs.*, 121 Fed. Cl. 230, 245 (2015), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017); *see also Hock v. Sec'y of Health & Hum. Servs.*, No. 17-168V, 2020 U.S. Claims LEXIS 2202 at *52 (Fed. Cl. Spec. Mstr. Sept. 30, 2020).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause-and-effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed

as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

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

B. Law Governing Analysis of Fact Evidence

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

Medical records created contemporaneously with the events they describe are generally trustworthy because they "contain information supplied to or by health professionals to facilitate

diagnosis and treatment of medical conditions," where "accuracy has an extra premium." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378 (Fed. Cir. 2021) citing *Cucuras*, 993 F.2d at 1528. This presumption is based on the linked proposition that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11-685V, 2013 WL 1880825 at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) *mot. for rev. denied*, 142 Fed. Cl. 247, 251-52 (2019), *vacated on other grounds and remanded*, 809 Fed. Appx. 843 (Fed. Cir. Apr. 7, 2020).

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475 at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony -- especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; see also *Murphy v. Sec'y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")). The Federal Circuit has "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby*, 997 F.4d at 1383 (explaining that a patient may not report every ailment, or a physician may enter information incorrectly or not record everything he or she observes).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475 at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

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

a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. Analysis of Expert Testimony

Establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of her claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (*citing Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

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

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

D. Consideration of Medical Literature

Although this decision discusses some but not all of the medical literature in detail, I reviewed and considered all of the medical records and literature submitted in this matter. *See Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally

presume that a special master considered the relevant record evidence even though [s]he does not explicitly reference such evidence in h[er] decision."); *Simanski v. Sec'y of Health & Hum. Servs.*, 115 Fed. Cl. 407, 436 (2014) ("[A] Special Master is 'not required to discuss every piece of evidence or testimony in her decision.'" (citation omitted)), *aff'd*, 601 F. App'x 982 (Fed. Cir. 2015).

VII. Analysis

Because Petitioner does not allege an injury listed on the Vaccine Injury Table, his claim is classified as "off-Table." As noted above, to prevail on an "off-Table" claim, Petitioner must prove by preponderant evidence that he suffered an injury and that this injury was caused by the vaccination at issue. *See Capizzano*, 440 F.3d at 1320.

A. *Althen* Prongs One and Three

While Dr. Simpson has articulated a theory describing how the flu vaccine can cause TM and the timeframe that is medically acceptable, I need not reach those questions. My factual findings, discussed in the next section, that Petitioner's viral infection was the more likely than not cause of his condition, make analysis of either his causal theory or the timing of his condition with respect to vaccination unnecessary. *See*, *e.g.*, *Hibbard v. Sec'y of Health & Hum. Servs.*, 698 F.3d 1355, 1365 (Fed. Cir. 2012); *Holmes v. Sec'y of Health & Hum. Servs.*, 115 Fed. Cl. 469, 488 (2014); *Vaughan v. Sec'y of Health & Hum. Servs.,* 107 Fed. Cl. 212, 222 (2012). Accordingly, in my analysis of *Althen* prong two, I have assumed, but have not decided that Petitioner has established a medical theory causally linking the flu vaccine to TM and that he has established receipt of the flu vaccine within a timeframe for which it is medically acceptable to infer causation.

B. *Althen* Prong Two

Under *Althen's* second prong, a petitioner must "prove a logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Althen*, 418 F.3d at 1278. The sequence of cause and effect must be "'logical' and legally probable, not medically or scientifically certain." *Id.* A petitioner is not required to show "epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." *Id.* (omitting internal citations). *Capizzano*, 440 F.3d at 1325. Instead, circumstantial evidence and reliable medical opinions may be sufficient to satisfy the second *Althen* prong.

1. Factual Determination: Onset of TM

Petitioner argued that he began to develop symptoms of TM one-and-one-half to two weeks after receipt of his flu vaccine. *See* Pet'r's Post-Hearing Brief at 8-9 (stating "The sequence of events, with neurological symptoms beginning within one-and-a-half to two weeks following the flu vaccination, followed by progressive neurological signs of TM, with consistent cerebrospinal fluid (CSF) and spinal MRI findings, demonstrate it is more likely than not that Petitioner suffered from TM caused by the flu vaccine."). Although Petitioner contended that he did not have a viral infection, he emphasized that his TM began before any purported infection. *Id.* at 10. Petitioner

based his position regarding TM onset on his testimony at the entitlement hearing, where he described his symptoms while playing basketball:

> I was playing, as I always did my entire life, and I noticed that like I would try to – this was the first sign I felt like something was wrong, where I would go to move or I would go to turn, and like my body wouldn't react quickly…I genuinely remember saying out loud, as I was leaving, something's wrong with me, like I don't know why I can't move well right now.

Tr. at 11. There is no notation in any of the contemporaneous medical records which describes this difficulty with movement recounted in Petitioner's testimony.

Petitioner further testified that he continued to feel worse and that when he visited Dr. Wade in mid-November, he reported "severe lower back aching, leg aching, body aches. I wasn't eating." Tr. at 12-13. However, the accounts that Petitioner conveyed that he was experiencing leg pain and back pain to Dr. Wade at the November 16, 2016 medical appointment are inconsistent with the contemporaneous medical records. There is no mention of these symptoms in the medical records from November 16 or November 17, 2016. *See* Ex. I at 83-84.

In order to overcome the presumption that contemporaneous written medical records are accurate, testimony must be "consistent, clear, cogent, and compelling." *Blutstein*, 1998 WL 408611, at *5. Because of this presumption, "special masters in this Program have traditionally declined to credit later testimony over contemporaneous records." *Sturdivant v. Sec'y of Health & Hum. Servs.,* No. 07-788V, 2016 WL 552529, at *15 (Fed. Cl. Spec. Mstr. Jan. 21, 2016). *See, e.g., Stevens v. Sec'y of Health & Hum. Servs*., No. 90–221V, 1990 WL 608693, at *3 (Fed. Cl. Spec. Mstr. Dec. 21, 1990); *see also Vergara v. Sec'y of Health & Hum. Servs*., No. 08–882V, 2014 WL 2795491, at *4 (Fed. Cl. Spec. Mstr. Jul. 17, 2014) ("Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recorded in later medical histories, affidavits, or trial testimony."); *see also Cucuras*, 993 F.2d at 1528 (noting that "the Supreme Court counsels that oral testimony in conflict with contemporaneous documentary evidence deserves little weight"). *Kirby*, 997 F.4d at 1383 (explaining that a patient may not report every ailment, or a physician may enter information incorrectly or not record everything he or she observes). In this case, I credit the information documented in the contemporary medical records.

During his visit with Dr. Wade, on November 23, 2016, Petitioner described that he "was feeling good after the last treatment but now hurts all over and states that he is numb everywhere." Ex. I at 81. Dr. Wade further noted that Petitioner was experiencing constipation and decreased urine output. *Id.*

After his admission to Banes Jewish Hospital, a November 25, 2016 neurology consultation documented that on November 22, 2016, Petitioner experienced "pronounced pain in the lower back and bilateral lower extremities, He also experienced allodynia ("pain when drying with a towel") of the back and paresthesia ("pins and needles") of the lower extremities." Ex. 4 at 53.

Dr. Simpson testified that Petitioner's presentation constituted a "single illness and a unified presentation" and that this was "part and parcel of the progressive illness that went from systemic symptoms, including fever, to the onset of the neurological symptoms which was numbness, weakness, sphincter loss, and so forth." Tr. at 102-03.

Dr. Price disagreed, and opined that Petitioner experienced the "first clear neurologic symptoms of low back pain and allodynia … on 11/22/16" and that this constituted the onset of Petitioner's TM. First Price Rep. at 6. He testified that myalgias (muscle aches) are not a typical symptom of transverse myelitis. Tr. at 160.

I find Dr. Price's interpretation is persuasive. First, I note that myalgias, fever, decreased appetite, rigors, and nausea are not described by the medical literature as signs and symptoms of TM. *See* Frohman and Wingerchuk; Beh.

Further, if Petitioner's TM began one-and-one-half to two weeks after vaccination (when his shift ended at 0600 one morning directly after which he played basketball), that would put TM onset between approximately October 31 and November 4, 2016. The diagnostic criteria for TM require that the progression to nadir of clinical deficits occur between four hours and 21 days after symptom onset. Frohman & Wingerchuk at 565 (Table 1). Petitioner reached nadir of his condition sometime during his admission at BJC, likely between November 25 and November 26, 2016.[13] This timeline places the onset to nadir of Petitioner's clinical deficits outside of the diagnostic criteria, further reducing the likelihood that Petitioner began to experience the onset of his condition one-and-one-half to two weeks after vaccination, and that Petitioner's symptoms constituted one disease course, as described by Dr. Simpson.

Based on the above, I credit Dr. Price's opinion that Petitioner's symptoms of low back pain, allodynia, and paresthesia that he began to experience on November 22, 2016 constituted the onset of his condition.

2. Factual Determination: The Existence and Onset of a Viral Infection

Petitioner's expert, Dr. Simpson contended that because no infectious cause was discovered after testing, it is "speculative" to conclude that Petitioner had a viral infection. Tr. at 69. When I asked him about Petitioner's fever, he opined that this constituted a "general inflammatory response to his [TM]." *Id.* at 70.

Dr. Price disagreed, opining that Petitioner's November 2016 symptoms including myalgias, fever, decreased appetite, rigors, and nausea "are suggestive of a concurrent infectious syndrome, more specifically a viral syndrome." First Price Rep. at 5. Dr. Price further observed

[13] Petitioner testified regarding his inability to move his legs while he was at BJC (which was between 11/24/16 and 12/4/16). *See* Tr. at 15-16. Although it is unclear in the medical records when this occurred, it was not when he was first admitted. The record documents "slight weakness of LLE" and that he "moves all extremities" on admission. Ex. 4 at 70, 639. He strength was documented as 4+/5 on 11/25/16, and on 11/26/16. Ex. 4 at 55, 663. By 11/28/16, Petitioner reported improved strength and was assessed as 5/5 motor strength. Ex. 4 at 668. He experienced urinary retention on 11/25/16 and 11/26/16, but was "voiding without difficulty on 11/30/16. Ex. 4 at 954, 955, 964.

that Petitioner's "persistent fever, his peripheral leukocytosis … suggest a systemic infection and not an isolated process to the central nervous system." Tr. at 131.

Petitioner's contemporaneous medical records provide strong support for the existence of a viral infection. During his appointment with Dr. Wade on November 16, 2016, Petitioner described chills, hot flashes, shortness of breath, body aches, and chest tightness. Ex. I at 84. His temperature was 100.5˚F. *Id.* Based on this presentation, Dr. Wade diagnosed him with a viral syndrome. *Id.* When Petitioner returned to Dr. Wade the next day, the record documents that Petitioner had also been experiencing nausea.[14] *Id.* at 83. Dr. Wade reiterated the viral syndrome diagnosis on November 17, 2016. *Id.*

Petitioner was tested for a panel of viruses and all testing returned negative. *See* Ex. 4 at 65-67. Dr. Price acknowledged the negative results, but reiterated his opinion that Petitioner did have a viral infection. He testified that "the clinical manifestations strongly suggest an infection, and the absence of a positive test shows the limitations on how many viruses we test for on a routine basis." Tr. at 134.

This opinion is consistent with the views of Petitioner's treating physicians, who consistently documented that Petitioner had a viral illness and that it was the likely cause of his condition. While at Memorial Hospital on November 24, 2016, Dr. Filipova assessed Petitioner with a fever "likely secondary to viral syndrome." Ex. 3 at 30. At a neurology consultation on November 25, 2016, Dr. Lee diagnosed Petitioner with TM, stating "Consider transverse myelitis of infectious vs. flu vaccine vs. NMO vs. MS etiology…. Infectious cause favored given fever, elevated WBC in serum and CSF." Ex. 4 at 56. After Petitioner's testing for infectious etiologies returned negative, Petitioner had an infectious disease consultation on November 29, 2016 where Dr. George Kyei stated, "Given LP [lumbar puncture] findings with elevated nucs [nucleated cells] as well as the relatively rapid onset of symptoms, suspect an underlying infection instead of an autoimmune process. … Most likely a resolving viral etiology." Ex. 4 at 75. The attending physician's additional comments add, "Given CSF pleocytosis likely 2/2 viral etiology." *Id.* at 76. Another infectious disease consult on November 30, 2016 assessed "Likely … viral etiology vs. Mycoplasma despite conflicting titers." Ex. 4 at 67. On December 3, 2017, one day before he was discharged from the hospital, the medical record notes "Infectious cause favored given fever, elevated WBC in serum." Ex. 4 at 692. Petitioner's medical records do not document that any of his treating physicians attributed his condition to the flu vaccine.[15]

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[14] Records from BJC note Petitioner's history of nausea and vomiting. Ex. 4 at 615.

[15] Although several of Petitioner's treating physicians note that he received a flu vaccine, they did not opine that the vaccine caused his condition. *See e.g.* Ex. 4 at 53 (Dr. Lee documented that Petitioner received a flu vaccine); Ex. 4 at 56 (Dr. Dionne wrote ""Consider transverse myelitis of infectious vs. flu vaccine vs. NMO vs. MS etiology…"). Dr. Wade also signed a letter dated 6/14/17 where he wrote, "My patient may never receive the flu vaccine secondary to guillain-barre syndrome per Dr. Wade." Ex. 5 at 3. While I have considered this letter, I do not find it to be persuasive. Dr. Wade references the wrong disease, and further, does not articulate 1) that he believes the vaccine caused Petitioner's condition, or 2) how that occurred.

In weighing evidence, special masters are expected to consider the views of treating doctors. *Capizzano*, 440 F.3d at 1326. The views of treating doctors often persuasive because the doctors have direct experience with the patient whom they are diagnosing. *See McCulloch v. Sec'y of Health & Hum. Servs.*, No. 09-293V, 2015 WL 3640610, at *20 (Fed. Cl. Spec. Mstr. May 22, 2015). I find the views of Petitioner's treating doctors to be persuasive, and conclude that he did have a viral infection.

Dr. Wade diagnosed Petitioner with a viral syndrome on November 16, 2016 and noted that Petitioner "returns to the office with cc of fever, chills, body aches and weakness that has been present over the past two days and is getting worse." Ex. I at 84. This contemporaneous medical record is especially persuasive because it is the first time Petitioner sought treatment for his illness. The record establishes that Petitioner first developed signs and symptoms of his viral infection on approximately November 14, 2016, eight days before he developed his first signs and symptoms of TM.

The existence of a viral infection is significant because the medical literature states that TM has an infectious etiology in a high percentage of cases. Agmon-Levin describes that "up to 40% of TM cases are associated with a preceding infectious illness, mostly within a month of TM onset." Agmon-Levin at 1199. According to Agmon-Levin, in one study of 33 TM patients, 46% had a preceding infection. *Id.*, citing Jeffery et al., *Transverse myelitis Retrospective analysis of 33 cases, with differentiation of cases associated with multiple sclerosis and parainfectious events*, 50 ARCH NEUROL 532-35 (1993) (this article was not filed as an exhibit). Kaplin et al. note that in "30% to 60% of idiopathic TM cases, there is an antecedent respiratory, GI, or systemic illness." Kaplin at 4. G. Fenichel states that "[a]pproximately 30% of patients at all ages report a preceding systemic viral illness." Gerald M. Fenichel, *Neurological Complications of Immunization*, 12 ANN NEUROL 119-28, 122 (1982) (filed as Ex. 16).

I acknowledge that Petitioner is not required to eliminate other potential causes of TM in order to be entitled to compensation in the Vaccine Program. *See Walther v. Sec'y of Health & Hum. Servs.*, 485 F.3d 1146, 1149-52 (Fed. Cir. 2007) (concluding a petitioner does not bear the burden of eliminating alternative independent potential causes). However, I find it appropriate to consider other possible sources of injury in making a determination pursuant to *Althen* prong two. *See Stone v. Sec'y of Health & Hum. Servs.*, 676 F.3d 1373, 1379-80 (Fed. Cir. 2012); *see also Winkler v. Sec'y of Health & Hum. Servs.*, 88 F.4th 958, 963 (Fed. Cir. 2023), *pet. for panel rehearing and rehearing en banc denied*, No. 22-1960 (Mar. 28, 2024). Petitioner's viral illness is a likely source of his injury.

Given the fact that Petitioner developed symptoms of a viral infection eight days before the onset of TM, I conclude the timing of Petitioner's illness persuasively connects this viral condition with his development of TM. Pidcock et al. studied 47 children with acute TM and, in the 47% who experienced an infectious illness prior to their TM, found that the mean time between antecedent infection and onset of neurological symptoms was 11 days with a standard deviation of 10 days. Pidcock at 1476. Special masters who have assessed this issue have come to the same conclusion. *Morris ex rel. Morris v. Sec'y of Health & Hum. Servs.*, No. 99-412V, 2002 WL 31965739, at *18 (Fed. Cl. Spec. Mstr. Dec. 18, 2002) ("Medical literature is highly supportive of a relationship between viral infections, even concurrent ones, but certainly ones occurring within

a few days of onset of TM, being the cause of TM."); *mot. for rev. denied*, 57 Fed. Cl. 383 (2003); *see also White v. Sec'y of Health & Hum. Servs.*, No. 20-1319V, 2023 WL 4204568, at *18 (Fed. Cl. Spec. Mstr. June 2, 2023) (opining that an infection was more likely causal than vaccination when the infection was closer to the onset of disease than vaccination); *mot. for rev. denied*, 168 Fed. Cl. 660 (2023); *appeal docketed*, No. 2024-1372 (Fed. Cir. Jan. 23, 2024). The existence of this other source of injury, a viral infection, weakens the persuasiveness of Petitioner's prong two showing in that it reduces the likelihood of the vaccine's causal role.

In summary, there is preponderant evidence that Petitioner suffered from a viral infection whose symptoms began eight days before the onset of his TM. Viral infections are a known cause of TM. Further, Petitioner's treating physicians attributed his TM to his viral infection. Accordingly, I find that Petitioner has failed to present preponderant evidence in support of the second *Althen* prong.

VIII. CONCLUSION

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

IT IS SO ORDERED.

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

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