In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 14-851V
(to be published)

J.S.,	*	
	*	
	*	Filed: April 9, 2018
Petitioner,	*	
	*	Entitlement; Transverse Myelitis ("TM"); Influenza ("flu") Vaccine; Onset; Polyneuropathy; Bystander Activation
v.	*	
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	

Ronald Craig Homer, Conway, Homer, P.C., Boston, MA, for Petitioner.

Mallori Browne Openchowski, U.S. Dep't of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On September 15, 2014, J.S. filed this action seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program"[2]). Petition ("Pet.") (ECF No. 1). Petitioner alleges that he developed transverse myelitis ("TM") as a result of the influenza ("flu") vaccine he received on September 23, 2011. *See generally* Petition ("Pet.") at 1.

[1] This Ruling will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Ruling will be available to anyone with access to the internet**. As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the published Ruling's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire Ruling will be available in its current form. *Id.*

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

A hearing in this matter was held on September 28, 2017. After consideration of the record and testimony provided at hearing, I find that Petitioner is entitled to a compensation award, for the reasons set forth in greater detail below.

I. Factual Background

A. *Medical History Prior to Vaccination*

Petitioner (who was 41 years old at the time of vaccination) had several preexisting health conditions prior to his receipt of the flu vaccine in September 2011, including hypertension, kidney stones, polycythemia vera[3], and obesity. Exhibit ("Ex.") 1 at 4; Ex. 3 at 22. Of particular relevance herein is the fact that in the month preceding the vaccination, J.S. underwent anesthesia for two different procedures.

First, on August 9, 2011, J.S. underwent a ureteroscopy[4] to remove a large kidney stone. Ex. 4 at 53-55. Second, just two weeks later (on August 22, 2011) Petitioner had a laparoscopic umbilical hernia repair on a bulge that had been present on his umbilicus for two years. Ex. 3 at 15-17, 25-27. The preoperative anesthesiologist notes from the latter procedure indicated that Petitioner was at that time reporting bilateral paresthesias in his legs below his knees just prior to surgery. Ex. 6 at 39. The day after, on August 23, 2011, J.S. called his surgeon, Dr. Dustin Robinson, at University Physicians and Surgeons in Pilgrim, Kentucky reporting that the numbness he had been feeling "for a while" below his knees had worsened, and that his ankles were now swollen. Ex. 3 at 14. Dr. Robinson instructed J.S. to go to the emergency room ("ER"). *Id*.

Petitioner appeared in the ER at Highlands Regional Medical Center ("Highlands") in Prestonburg, Kentucky later that night. Ex. 4 at 93. The records from this visit contain varying reports on how long J.S. had been experiencing numbness. The original intake note from the ER stated that J.S. began experiencing the numbness that morning, and noted that there had been no prior episodes. *Id*. Notes taken during his lab work, however, suggested that he had been experiencing numbness since his hernia repair. *Id*. at 100.

The evaluation J.S. received at Highlands was quite extensive. J.S. presented with normal vital signs (with the exception of a low blood pressure reading of 116 over 60) and the initial

[3] Polycythemia vera is a condition characterized by the overproduction of red blood cells. Transcript ("Tr.") at 48. It can thicken the blood, slowing its flow, and can result in complications such as blood clots, which can in turn lead to a heart attack or stroke. https://www.mayoclinic.org/diseases-conditions/polycythemia-vera/.../syc-20355850 (last visited April 2, 2018).

[4] A ureteroscopy involves examination of the ureter with a fiberoptic endoscope. *Dorland's Illustrated Medical Dictionary* 2007 (32 ed. 2012) (hereinafter "*Dorland's*").

impression of his treaters was that his symptoms could be attributed to coronary artery disease, hypertension, and/or his recent surgery. Ex. 4 at 93-94. Petitioner then underwent a number of different tests—CT[5] scans of the head and lumbar spine, a complete blood count ("CBC"), a comprehensive metabolic panel ("CMP"), a prothrombin time test ("PT") that measured how long it took his blood to clot, an EKG,[6] and several other blood tests used to determine if the numbness he was experiencing related to his heart.[7] *Id*. at 88-90. The results of the blood work seemed largely unremarkable, with the exception of some levels being slightly elevated or low.

The imaging, however, indicated slightly more serious problems. While the CT scan of Petitioner's brain was normal, an August 23, 2011 CT (performed without contrast) of his lumbar spine suggested the existence of "mild multilevel degenerative disc and degenerative joint disease." Ex. 4 at 101-102. J.S. was discharged the same day with a diagnosis of hypotension and dehydration. His discharge notes indicate that his condition had improved, and he was instructed to return to his primary care physician the next day. *Id*. at 96.

J.S. called his physician two days later (on August 25, 2011) around two in the afternoon, indicating that he was again experiencing tingling in his legs and groin and expressed the desire to speak to a nurse. Ex. 3 at 13. About two hours later, however, he reported that he was doing better. *Id*. Four days later, on August 29, 2011, J.S. called his physician again, stating that he had noticed a bulge around his incision site, but no complaints of tingling were reported. *Id*. at 12. An appointment with Dr. Robinson was scheduled, and J.S. saw him on August 30, 2011. *Id.* There was no indication at this visit that J.S. was experiencing tingling or paresthesia. *Id*. at 9. Rather, the evaluation showed that "his energy was returning toward normal" and that he could return to work (on light duty-no lifting more than 25 pounds) in two weeks, with a follow-up visit in four weeks (September 8, 2011). *Id*. at 9-10.

Two weeks later, on September 13, 2011 (10 days prior to vaccination), J.S. saw a nurse practitioner, Robin A. Sanger, at the Massey Clinic in Williamson, West Virginia reporting that he was once again experiencing "lower extremity tingling and fatigue with walking." Ex. 1 at 4. He underwent another CMP and CBC with a diagnosis of hypertension. *Id*. at 6.

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[5] A computed tomography (CT) scan employs an emergent x-ray beam measured by a scintillation counter, with the results recorded and processed by a computer for reconstruction display. *Dorland's* at 1935. CT scans are useful when a disease of the central nervous system is implicated and degenerative abnormalities can be identified. *Mosby's Manual of Diagnostic and Laboratory Tests* 1026 (5th ed. 2014) (hereinafter "*Mosby's"*). A CT scan is generally preferable to an MRI during the initial trauma evaluation and the identification of subarachnoid (hemorrhage) bleeding. *Id*.

[6] An EKG is an electrocardiogram, which is a "graphic representation of the electrical impulses that stimulate the heart to contract." *Mosby's* at 544. It is primarily used to identify irregular heart rhythms. *Id*. at 546.

[7] CK-MB test measures those variants in the blood as a cardiac marker to help diagnose a myocardial infarction. Ex. 4 at 89. The Tropinin ("Trop") test measures the troponin levels in the blood because those proteins are released if the heart is in distress, such as in a heart attack. *Id*. at 90.

B. *Medical History after Vaccination*

Petitioner received the trivalent flu vaccine on September 23, 2011, at Comprehensive Health Solutions in Williamson, West Virginia. Ex. 17 at 1. The records do not indicate that a physical exam was performed at this visit. Six days later, on September 29, 2011, he went back to the Massey Clinic with continued reports of bilateral leg pain and numbness and trouble walking, which he related to his late-August umbilical hernia surgery. Ex. 1 at 1. The results of his September 13th CMP and CBC were not yet available, but the nurse ordered additional studies to measure nerve conduction, plus an arterial doppler. *Id*. at 3. J.S. was diagnosed with somatic dysfunction—a generic term used to describe altered function of related components of the body system. *Id*.

That same night (September 29, 2011), J.S. was taken by ambulance to Three Rivers Medical Clinic ("TRMC"), in Louisa, Kentucky, after falling as a result of numbness in his legs. Ex. 15 at 8. The physicians at TRMC did not perform any additional blood work or imaging, but concluded that J.S. had weakness of the legs from a "possible neuropathy." Ex. 16 at 82. They treated him with a corticosteroid shot, and he was discharged that night by wheelchair as he still could not walk. *Id*. at 85-86. J.S. was instructed to follow-up with his primary care physician the next day for a referral to a neurologist. *Id*.

Before he could see his primary care physician, J.S. called the paramedics early on the morning of September 30, 2011 (less than 12 hours after his discharge). Ex. 15 at 1. Petitioner reported that he was still experiencing numbness and tingling in both legs and he could not walk. *Id*. at 3. He was taken to Williamson Appalachian Regional Hospital ("WARH") in Williamson, Kentucky. The doctors at WARH ordered another CBC, CMP, and EKG. Ex. 12 at 6. J.S. was transferred to King's Daughters Medical Center ("KDMC") in Ashland, Kentucky for further evaluation. *See generally* Ex. 12; Ex. 8. He was admitted to KDMC on September 30, 2011, and was discharged to a rehabilitation center on October 11, 2011. Ex. 8 at 248.

Petitioner's initial evaluation on September 30, 2011, by Dr. Kirubel Tefera, stated that his physicians were considering as part of the differential diagnosis Guillain-Barré syndrome ("GBS"), a central nervous system disorder, and/or an acute polyneuropathy. Ex. 8 at 243. To get a more precise diagnosis, Dr. Pramit Bhasin was engaged for a neurological consultation on October 1, 2011. Dr. Bhasin provided a detailed summary of J.S.'s current condition, which stated in part "[o]n Sunday, September 25, 2011 he felt some weakness in his feet with some associated numbness and tingling that was intermittent. By Thursday, September 29, 2011 he felt weakness in his legs so profound that he was using a cane for assistance in order to ambulate safely." *Id*. at

257. Dr. Bhasin ordered diagnostic testing, including an MRI[8] of the thoracic spine, because he was unsure if J.S. was suffering from a neurologic or spinal injury. *Id*. at 258, 426-28. Dr. Bhasin, however, noted that because J.S. displayed deep tendon reflexes, a demyelinating inflammatory polyneuropathy was unlikely. *Id*. Similarly, J.S. had control of his bowel and bladder, making a thoracic spine injury questionable. *Id*. at 258. Dr. Bhasin specifically noted that a "risk factor at present appears to be the flu shot." *Id*. at 262.

Dr. Bhasin J.S.'s daily progress and his condition. On October 2, 2011, while much of the lab work was still pending, Dr. Bhasin noted that he could elicit from Petitioner no ankle jerks. Ex. 6 at 263. Dr. Bhasin now stated that "I suspect Transverse Myelitis. Whether or not this is an initial harbinger of a demyelinating illness i.e. MS-Time will tell. This is certainly not a second episode." *Id*. (emphasis added). The radiologist interpreting the MRI results offered a corroborative opinion:

> [e]xtensive signal abnormality throughout the spinal cord in the thoracic spine most advanced from the T7/T8 level extending caudally to the conus where the cord is expanded and with abnormal fluid sensitive signal centrally involving more than two-thirds of the spinal cord and with areas of patchy enhancement . . . [t]his is most concerning for acute idiopathic transverse myelitis . . . multiple sclerosis less likely . . . [t]his does not have the typical imaging findings of Guillain-Barré Syndrome.

Ex. 8 at 427-28.

At KDMC, on October 6, 2011, J.S. underwent a nerve conduction study which found absent bilateral sensory sural responses, "bilateral tibial and peroneal CMAP's had normal distal latencies, amplitude, and conduction velocities, and bilateral peroneal and right tibial "F" wave latencies [to be] normal or borderline . . . [t]here was no evidence of any temporal dispersion or conduction blocks in the wave forms that were obtained." Ex. 8 at 260. The impression was that the results were "under the broad limits of normal." *Id*. The interpretation of an EMG[9] further noted:

> [t]here is no overwhelming evidence of an acute inflammatory demyelinating polyneuropathy (slow conduction velocities, conduction blocks, evidence of temporal

[8] Magnetic Resonance Imaging (MRI) is a diagnostic scanning tool that places the patient in a magnetic field rather than exposing him to radiofrequency signals in a traditional x-ray. *Mosby's* at 1106-07. An MRI provides several benefits over CT scans, such as providing better contrast between normal and pathologic tissue as well as not being obscured by bone artifacts. *Id*. at 1107.

[9] An EMG, or electromyography, test is a diagnostic method that measures the response to electrical stimulation of muscle nerves. *Dorland's* at 602.

> dispersion). The absence of sensory sural responses and the prolonged left tibial "F" wave latency is of unclear significance and in the appropriate clinical context could be suggestive of an early or evolving acute inflammatory demyelinating polyneuropathy.

Ex. 8 at 260.

An MRI of Petitioner's brain, a repeat MRI of the thoracic spine, and spinal tap were also performed. Ex. 8 at 248. The repeat MRI on October 5th noted no significant changes since the October 2nd MRI, and confirmed that TM was likely the proper diagnosis. *Id*. at 422. It was also noted that onset "was abrupt 5 days ago with gradually worsening course." *Id*. at 251. J.S. had since received rehabilitation care but is still unable to walk and remains wheelchair bound. *Id*.

II. Expert Opinions

A. *Dr. Norman Latov*

Dr. Latov authored two reports and testified at the entitlement hearing on Petitioner's behalf. *See* Expert Report, dated June 29, 2015, filed as Ex. 33 (ECF No. 19) ("First Latov Rep."); Supplemental Expert Report, dated May 26, 2016, filed as Ex. 35 (ECF No. 28) ("Second Latov Rep."); Transcript ("Tr.") at 4-89. Dr. Latov opined that Petitioner's TM was caused by the flu vaccine, either through the mechanism of molecular mimicry or via bystander activation. First Latov Rep. at 5.

Dr. Latov is a board-certified neurologist currently employed as a physician at Weill Medical College of Cornell University. Latov First Rep. at 1; Curriculum Vitae of Dr. Latov, dated June 29, 2015, filed as Ex. 34 (ECF No. 19-4) ("Latov CV"). He attended medical school and received a Ph.D. at the University of Pennsylvania after completing his bachelor's degree at Columbia College. Latov CV at 1. In addition to his teaching responsibilities at Cornell, Dr. Latov sees patients about three times per week. *Id*.; Tr. at 7. Although Dr. Latov treats patients with TM about once a month, the majority of his patients have a peripheral neuropathy. Tr. at 7. Prior to his current role at Cornell, Dr. Latov directed the hospital's neuroimmunology lab. Tr. at 5. Dr. Latov has published approximately 200 articles on the subjects of his expertise. First Latov Rep. at 1; Latov CV at 4-21.

Dr. Latov began by addressing J.S.'s pre-vaccination condition, maintaining that Petitioner did not have TM before receipt of the flu vaccine. He characterized any prior leg weakness or numbness Petitioner had experienced as most likely due to a reaction to anesthesia or positioning during Petitioner's prior surgeries, and therefore a compressive neuropathy. Tr. at 8-9. He deemed significant the fact that Petitioner was experiencing these symptoms below the knee, supporting the conclusion that the symptoms were "distal disturbances" resulting from compression of the

nerves from surgery, rather than the early onset of TM. *Id*. at 39. In addition, Dr. Latov described those incidences as "remitting rather than progressive, which is not consistent with a progressive transverse myelitis." Second Latov Rep. at 1. He provided record support for this contention, citing a note from Dr. Robinson indicating that Petitioner had reported that his weakness had improved. *Id*.; Ex. 3 at 13.

Dr. Latov contrasted the lack of evidence of myelitis present in Petitioner's August 23rd pre-vaccination CT against a later, post-vaccination MRI (on October 2, 2011) that showed extensive myelitis. Second Latov Rep. at 2. Although Dr. Latov recognized that a CT is inherently less sensitive than an MRI, the spinal cord swelling that the MRI revealed should *also* have been picked up to some degree by the earlier CT regardless – and the fact that it was not suggested to him that Petitioner's myelitis could not have begun before the vaccination. Tr. at 43-45; Ex. 8 at 426-28; Ex. 4 at 101. Dr. Latov also relied on the post-vaccination EMG, which did not confirm the existence of an ongoing demyelinating neuropathy, and instead suggested to him that Petitioner had most likely experienced a mild compressive or distal polyneuropathy prior to vaccination. Tr. at 45, 47.[10]

With this factual underpinning, Dr. Latov posited that molecular mimicry was the biologic mechanism most likely responsible for the development of Petitioner's TM following his flu vaccination. Dr. Latov described molecular mimicry as occurring when an antigen present in a vaccine (or an infectious agent) causes the body to mount an immune response against self-structures, because the antigen has a similar protein sequence and/or structure to one present in tissue in the body (in this case, in the spinal cord). First Latov Rep. at 5; Tr. at 21. That "homology" in protein sequence or structure causes the immune system to mistakenly attack the human tissue rather than the foreign antigen, which then causes disease. Tr. at 21. *See* N. Agmon-Levin, et al., *Transverse Myelitis and Vaccines: A Multi-Analysis*, 18 Lupus 1198, 1198-99 (2009), filed as Ex. 33, Tab A (ECF No. 19-1) ("Agmon-Levin") (finding an association between TM and the flu vaccine via molecular mimicry); Tr. at 16.

In support, Dr. Latov cited several pieces of medical literature that studied cross-reactivity in animal models and showed that infection or vaccination could cause different types of inflammatory neuropathies. *See e.g.*, C.M. Caporale, et al., *Experimental Axonopathy Induced by Immunization with Campylobacter Jejuni Lipopolysaccharide from a Patient with Guillain-Barre*

[10] Dr. Latov also proposed that Petitioner's polycythemia vera might have predisposed him to develop a neuropathy akin to what he actually experienced. Tr. at 48; Second Latov Rep. at 2-3; M. Mihalj, et al., *Sensomotor Axonal Peripheral Neuropathy as a First Complication of Polycythemia Rubra Vera: A Report of 3 Cases*, 14 American J. Case Report 385-87 (2013), filed as Ex. 35, Tab F (ECF No. 28-1). Dr. Gelfand later contested this argument, admitting that polycythemia vera is a known cause of polyneuropathies (Tr. at 136), but maintaining that the literature cited by Dr. Latov to support that point involved more severe neuropathies than the one present in this case. *Id*. The record ultimately does not support Dr. Latov's proposal -- no treaters ever concluded that polycythemia vera had any relationship to Petitioner's symptoms -- but my resolution of this case does not turn on this point in any event.

Syndrome, 174 J. Neuroimmunology 12 (2006), filed as Ex. 33, Tab D (ECF No. 19-1); H.J. Willison, *Glycoconjugates and Neuroimmunological Diseases*, 9 Advanced Neurobiology 543 (2014), filed as Ex. 33, Tab Y (ECF No. 19-3). He also referenced a study finding that the anti-rabies vaccine induced GBS, myelitis, and acute disseminated encephalomyelitis via molecular mimicry. *See* E. Appelbaum & J. Nelson, *Neurological Complications Following Antirabies Vaccination*, 151 J. Am. Medical Ass'n 3:188 (1953), filed as Ex. 33, Tab C (ECF No. 19-1).

As an alternative causal mechanism, Dr. Latov proposed bystander activation, which occurs when immune system cells that are suppressed, or anergic (and thus "bystanding"), are stimulated to react by an existing/ongoing immune response, thereby allowing that existing dysregulation of the immune response to continue or expand. First Latov Rep. at 5. He cited examples of this mechanism present in animal models designed to replicate multiple sclerosis ("MS"). *See, e.g.*, A. Nogai, et al., *Lipopolysaccharide Injection Induces Relapses of Experimental Autoimmune Encephalomyelitis in Nontransgenic Mice via Bystander Activation of Autoreactive CD4+ Cells*, 175 J. Immunology 2:959 (2005) ("Nogai"), filed as Ex. 33, Tab N (ECF No. 19-2); P. Soulas, et al., *Autoantigen, Innate Immunity, and T Cells Cooperate to Break B Cell Tolerance During Bacterial Infection*, 115 J. Clinical Investigation 8:2257 (2005), filed as Ex. 33, Tab U (ECF No. 19-3) ("Soulas"); J. Goverman, et al., *Transgenic Mice that Express a Myelin Basic Protein-specific T Cell Receptor Develop Spontaneous Autoimmunity*, 72 Cell 4:551, filed as Ex. 33, Tab I (ECF No. 19-1) ("Goverman"). Common to each of these articles was the concept that existing inactive immune cells could (due to some other ongoing immunologic pathogenic process) contribute to and/or initiate an autoimmune response (which could in some instances be mediated by cytokines). *See, e.g.,* Goverman at 558 ("an infectious agent or an environmental factor could provoke changes in cytokine levels, responsiveness to cytokines . . . that then activate an autoimmune response").

Dr. Latov emphasized his overall belief that Petitioner's pre-vaccination symptoms were unrelated to his TM. Tr. at 54. However, if Dr. Latov adopted the suggestion that Petitioner's leg weakness and numbness prior to vaccination were evidence of pre-existing TM, then he proposed that the flu vaccine likely exacerbated Petitioner's TM, through the mechanism of bystander activation and increased permeability of the blood-spinal cord barrier caused by inflammation. First Latov Rep. at 5-6. Dr. Latov supported this contention with studies that have shown increases in relapse of MS symptoms, or comparable neuropathic conditions, following vaccination. *See e.g.*, M. Farez & J. Correale, *Yellow Fever Vaccination and Increased Relapse Rate in Travelers with Multiple Sclerosis*, , 68 Archives of Neurology 1267 (2011), filed as Ex. 33, Tab H (ECF No. 19-1); J.D. Pollard & G. Selby, *Relapsing Neuropathy due to Tetanus Toxoid. Report of a Case*, 13 J. Neurological Science 113-25 (1978), filed as Ex. 33, Tab R (ECF No. 19-2).

Dr. Latov also addressed what he would expect the disease course of TM to be had it been significantly aggravated by vaccination. Tr. 85-86. He stated that TM has a limited course, so if it

began about a month prior to vaccination following one of Petitioner's surgeries, Dr. Latov thought it would have run its course by the time Petitioner was vaccinated. *Id*. As a result, essentially any worsening in the condition that was observed post-vaccination would be evidence to him that the vaccine was the cause of it, in light of the overall timeframe of Petitioner's different symptoms. *Id*.

Regardless of whether Petitioner's TM was the product of, or was exacerbated by, the flu vaccine, Dr. Latov opined that the timing of onset/worsening—around two days after the vaccination — was medically acceptable. In a study of GBS and the flu vaccine, the authors found that the increased risk period for disease began a few days after vaccination and then lasted for about five weeks. First Latov Rep. at 6; L.B. Schonberger, et al. *Guillain-Barre Syndrome Following Vaccination in the National Immunization Program, United States*, 110 American J. Epidemiology 105-23 (1979), filed as Ex. 33, Tab S (ECF No. 19-1) ("Schonberger"). Two days was therefore in his view reasonable.

B. *Dr. Jeffrey Gelfand*

Respondent presented his own neurologist expert, Jeffrey Gelfand, M.D., who authored two reports and testified at hearing. *See* Expert Report, dated Feb. 10, 2016, filed as Ex. A (ECF No. 24-1) ("First Gelfand Rep."); Supplemental Expert Report, dated Jan. 19, 2017, filed as Ex. B (ECF No. 33-1)("Second Gelfand Rep."); Tr. at 90-193. Dr. Gelfand opined that Petitioner's vaccination was not the cause of his TM, but rather that Petitioner's TM was idiopathic in origin, and that it pre-dated his vaccination. Tr. at 95; First Gelfand Rep. at 9, 12.

Dr. Gelfand is a board-certified neurologist who received his medical degree from Harvard University after attending Princeton University for his undergraduate education. *See* Curriculum Vitae of Dr. Gelfand, dated Feb. 10, 2016, filed as Ex. A, Tab 1 (ECF No. 24-2) ("Gelfand CV"); Tr. at 90. He completed a residency and fellowship at the University of California, San Francisco (UCSF). Gelfand CV at 1; Tr. at 90. Currently, Dr. Gelfand serves as an assistant professor of clinical neurology at UCSF, and his duties include being an attending physician, directing the fellowship training program, and serving as a clinical researcher and medical educator. Tr. at 91. He sees patients about three days a week, and of those patients he estimated he had seen hundreds with myelitis or spinal cord inflammation. Tr. at 92. As his CV indicates, Dr. Gelfand has published around 30 articles focusing on neurological diseases such as sarcoidosis, autoimmune encephalitis, and MS. Gelfand CV at 9-12; Tr. at 93.

Like Dr. Latov, Dr. Gelfand began by addressing Petitioner's chronological progression of symptoms and those that he believed were TM. In his clinical experience, a waxing and waning of symptoms is consistent with TM, especially in those patients that first experience sensory complaints. Tr. at 159. Some of Dr. Gelfand's TM patients had experienced mild sensory

complaints from days to several weeks before the condition significantly worsened. *Id*. at 159-61. Petitioner's gradual worsening, from before his vaccination until he was admitted to the emergency room in late September, was therefore in Dr. Gelfand's opinion consistent with a process that likely began the month before. First Gelfand Rep. at 13; Tr. at 106.

The numbness Petitioner experienced from his knees down after his August 22nd surgery, and the EMG showing no evidence of polyneuropathy, further bolstered his opinion of ongoing TM prior to vaccination. Second Gelfand Rep. at 12. Dr. Gelfand conceded that Dr. Latov's argument (that Petitioner was experiencing an independent polyneuropathy before vaccination, rather than initial TM symptoms) was reasonable, but he thought that it was less likely given documentation in the medical records that Petitioner had displayed ankle reflexes to Dr. Bhasin (something that would be atypical in a distal neuropathy). Second Gelfand Rep. at 1; Tr. at 134-35. Dr. Gelfand also attempted to rebut the view that a compressive neuropathy related to surgery could explain Petitioner's pre-vaccination symptoms, referencing the EMG study to support his view (although he allowed that it could be interpreted consistent with Dr. Latov's opinion). Tr. at 135-36.

Dr. Gelfand specifically addressed distinctions in different imaging tests performed pre- and post-vaccination. He admitted that a CT myelogram (where the spinal cord is injected with dye) can be used in the diagnosis of TM, but rejected the idea that the kind of CT scan Petitioner received in late August (a CT of the lumbar spine) was the same, or was sufficient to show cord swelling or anything else relevant to revealing onset of TM. Tr. at 150. Thus, in his view Petitioner could have had TM at the time the CT was taken even if the scan did not disclose it. *Id*. He nevertheless acknowledged that the abnormalities revealed on Petitioner's October 2, 2011 MRI were distinguishably "severe" and "bad"—in comparison to the less-alarming CT results. *Id*. at 151.

Assuming that Petitioner began having symptoms of TM prior to vaccination, Dr. Gelfand stated that he could not find anything in medical literature supporting the conclusion that a vaccine could worsen an existing myelitis. First Gelfand Rep. at 12; Second Gelfand Rep. at 3-5. And he viewed the two-day interval between vaccination and worsening to be too soon to make the worsening attributable to vaccination. *Id*. Citing Petitioner's own literature, Dr. Gelfand posited that an adverse event following vaccination even within seven days is considered a rare event, precluding a causal relationship. *See* Agmon-Levin at 1201; First Gelfand Rep. at 13. He found additional case reports that postulated an association between vaccination and myelitis, but the onset of symptoms in such instances was no shorter than five days. First Gelfand Rep. at 14; M. Viera, et al., *Transverse Myelitis with Brown-Sequard Syndrome after H1N1 Immunization*, 70 Arquivos de Neuro-Psiquiatria 7: 555 (2012), filed as Ex. A, Tab 13 (ECF No. 26-12); L. Gui, et al., *Acute Transverse Myelitis Following Vaccination Against H1N1 Influenza: A Case Report*, 4

Int'l J. Clinical and Experimental Pathology 3:312-14 (2011), filed as Ex. A, Tab 14 (ECF No. 26-13).

Dr. Gelfand also disputed more generally Petitioner's contention that the flu vaccine could cause TM or similar demyelinating neuropathies. A study of nearly a quarter million pregnant women (75,906 vaccinated with the flu vaccine, 147,992 unvaccinated) revealed no incident cases of acute TM. First Gelfand Rep. at 14; J. Nordin, et al., *Maternal Safety of Trivalent Inactivated Influenza Vaccine in Pregnant Women*, 121 Obstetrics and Gynecology 3: 519-25 (2013), filed as Ex. A, Tab 15 (ECF No. 26-14).

III. Procedural Background

This Petition was initiated on September 15, 2014. Pet. at 1. Within six months, the parties filed a joint statement of completion, and Respondent filed his Rule 4(c) report on March 16, 2015. Thereafter the parties endeavored to obtain and file expert reports, a process that continued until November 16, 2016. During that time, I scheduled the matter for hearing to be held on September 28, 2017, through September 29, 2017. *See* Prehearing Order, dated July 19, 2016 (ECF No. 31). As stated previously, the hearing was held as scheduled.

IV. Applicable Law

A. Petitioner's Overall Burden in Vaccine Program Cases

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury" – *i.e.*, an injury falling within the Vaccine Injury Table – corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[11] In this case, Petitioner does not assert a Table claim.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's

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

existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

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

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015) ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017). But this does not negate or reduce a petitioner's ultimate burden to establish

his overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).[12]

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human 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"); *Snyder v. Sec'y of Health & Human Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct – that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record – including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Dept. 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 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

[12] Although decisions like *Contreras* suggest that the burden of proof required to satisfy the first *Althen* prong is less stringent than the other two, there is ample contrary authority for the more straightforward proposition that when considering the first prong, the same preponderance standard used overall is also applied when evaluating if a reliable and plausible causal theory has been established. *Broekelschen v. Sec'y of Health & Human Servs*., 618 F.3d 1339, 1350 (Fed. Cir. 2010).

understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human 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 & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human 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. Standards Applicable to Significant Aggravation Claim

In this matter, besides arguing that the flu vaccine caused his TM, Petitioner also offers a parallel theory that the flu vaccine significantly aggravated his pre-existing TM. Where a petitioner so alleges, the *Althen* test is expanded, and the petitioner has additional evidentiary burdens to satisfy. *See generally Loving v. Sec'y of Health & Human Servs*., 86 Fed. Cl. 135, 144 (2009). In *Loving*, the Court of Federal Claims combined the *Althen* test with the test from *Whitecotton v. Sec'y of Health & Human Servs*., 81 F.3d 1099, 1107 (Fed. Cir. 1996), which related to on-Table significant aggravation cases. The resultant "significant aggravation" test has six components, which are:

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a 'significant aggravation' of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving, 86 Fed. Cl. at 144; *see also W.C. v. Sec'y of Health & Human Servs*., 704 F.3d 1352, 1357 (Fed. Cir. 2013) (holding that "the *Loving* case provides the correct framework for evaluating off-table significant aggravation claims"). In effect, the last three prongs of the Loving test correspond to the three *Althen* prongs.

C. Law Governing Analysis of Fact Evidence

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury,

condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Human Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms.").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human 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 & Human Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, 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 & Human 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 & Human 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 & Human Servs*., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human 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.

D. Analysis of Expert Testimony

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Human 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 & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Human 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 for a (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence

that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs*., 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742-45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Human Servs*., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 91997)); *see also Isaac v. Sec'y of Health & Human Servs*., No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 Fed. App'x 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Human Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

E. Consideration of Medical Literature

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

ANALYSIS

I. Overview of TM

TM is an inflammatory condition causing damage to the spinal cord, which can produce neurological deficits with sensory loss in the extremities. Tr. at 15. It is understood to be mediated by pathogens that cause demyelination. *See* Agmon-Levin at 1198-99. Acute TM is so characterized because of its abrupt onset of motor and autonomic dysfunction. *Id*. at 1199. Diagnosis of the condition typically comes after inflammation is shown on a spinal MRI or derived from CSF analysis. Tr. at 15. TM is often autoimmune in origin, although it is not exclusively so (for example, it can be caused by a direct viral infection). *Transverse Myelitis*, Mayo Clinic website (https://www.mayoclinic.org/diseases-conditions/transverse-myelitis/symptoms-causes/syc-20354726) (last accessed on April 2, 2018).

In the Program, petitioners have successfully established that a number of different vaccines (including the flu vaccine) were causally connected to their subsequent development of TM. *See, e.g., Schmidt v. Sec'y of Health & Human Servs.,* No. 07-20V, 2009 WL 5196169 (Fed. Cl. Spec. Mstr. Dec. 17, 2009) (influenza vaccine and TM); *Hargrove v. Sec'y of Health & Human Servs.,* No. 05-0694, 2009 WL 1220986 (Fed. Cl. Spec. Mstr. Apr. 14, 2009) (Diphtheria-tetanus-acellular pertussis vaccine and TM); *Raymo v. Sec'y of Health & Human Servs.,* No. 11-0654V, 2014 WL 1092274 (Fed. Cl. Spec. Mstr. Feb. 24, 2014) (tetanus diphtheria-acellular-pertussis vaccine and TM); *Whitener v. Sec'y of Health & Human Servs.,* No. 06-0411V, 2009 WL 3007380 (Fed. Cl. Spec. Mstr. Sept. 2, 2009) (petitioner developed a peripheral neuropathic autoimmune illness – GBS with aspects of TM - about a month after receiving the meningococcal vaccine); *but see Caves v. Sec'y of Health & Human Servs.,* 100 Fed. Cl. 119 (2011) (upholding special master's determination that petitioner had not met her burden in establishing that the flu vaccine can cause TM; expert's opinion was conclusory, and failed to support theory with reliable scientific bases), *aff'd,* 463 Fed. App'x 932 (Fed. Cir. 2012).

II. Petitioner Has Carried His Burden of Proof on his Direct Causation Claim[13]

The parties do not dispute that J.S. was correctly diagnosed with TM after he received the flu vaccine. Rather, they disagree as to whether his TM *was related* at all to his vaccination, and also dispute the extent to which Petitioner's pre-vaccination symptoms were connected to his later TM.

[13] Because I find that Petitioner has met his burden proving a direct causation claim, I will not address the alternative theory of significant aggravation as it is moot.

A. *Althen* Prong One

Petitioner's general theory—that the flu vaccine could cause TM—is consistent with other successful causation theories frequently proposed in Program cases. *See, e.g., Schmidt,* 2009 WL 5196169; *Land v. Sec'y of Health & Human Servs.,* No. 12-474V, 2014 WL 2488705 (Fed. Cl. Spec. Mstr. May 13, 2014); *Raymo, 2*014 WL 1092274, at *1. While these decisions do not bind me, I take note of them and their sound analyses.

In the present case, Dr. Latov's causation opinion was bulwarked with literature suggesting that the flu vaccine has been associated in some case study reports with TM. *See, e.g.,* Agmon-Levin at 1199-1201. Dr. Latov further cited to specific literature that has found an association between the flu vaccine and demyelinating conditions generally. *See, e.g.,* W. Huynh, et al., *Post-vaccination Encephalomyelitis: Literature Review and Illustrative Case*, 15 J. Clinical Neuroscience 1315 (2008) (literature review of primary inflammatory demyelinating disorders—for which acute TM is one—finding that post infectious and post-vaccine encephalomyelitis occur in three-quarters of cases). And to support his contention that increased permeability of the blood brain barrier caused by inflammatory cytokines could cause TM, Dr. Latov referenced literature that found that inflammatory monocytes were induced two days after flu vaccination. *See* S. Mohanty, et al., *Prolonged Proinflammatory Cytokine Production in Monocytes Modulated by Interleukin 10 After Influenza Vaccination in Older Adults*, 211 J. Infectious Disease 1174 (2005) ("Mohanty").

Dr. Latov also proposed several biologic mechanisms—molecular mimicry, bystander activation, and permeability of the blood brain barrier caused by inflammatory cytokines– by which the flu vaccine could precipitate an autoimmune response such as TM. Tr. at 12. Other Program cases have deemed such mechanisms scientifically reliable in evaluating causes of autoimmune-mediated demyelinating illnesses. *Raymo,* 2014 WL 1092274, at *21 ("[a]lthough the precise biological mechanism has not been determined, molecular mimicry and bystander activation theories are biologically probable" explanations for how autoimmune TM occurs).

Overall, I find Petitioner's theory persuasive and reliable from a medical and scientific standpoint – based both upon the testimony and literature offered herein, and also taking into account the prior persuasive and well-reasoned decisions from other, factually-similar Program cases.[14] Nor has Respondent adequately rebutted it. Accordingly, I find that Petitioner has met the first *Althen* prong.

[14] I acknowledge that there are persuasive cases in which the flu vaccine was *not* shown by preponderant evidence to cause TM. *See, e.g., Caves,* 100 Fed. Cl. at 133-36. But in the Vaccine Program, variance in outcomes based upon analysis of an individual claimant's success in establishing his burden of proof in a particular case is deemed acceptable. *Whitecotton*, 81 F.3d at1108 ("Congress desired the special masters to have very wide discretion with respect to the evidence they would consider and the weight to be assigned that evidence"); *Sharpnack v. Sec'y of Health & Human Servs*., 27 Fed. Cl. 457, 461 (1993) ("variations in the analysis of the special masters are within

B. *Althen* Prong Two

1. *Petitioner's Pre-Vaccination Symptoms Were Distinct from his Subsequently-Diagnosed TM*

After a thorough review of the medical records and opinions of Drs. Latov and Gelfand, I find that the record best supports the conclusion that Petitioner's pre-vaccination symptoms were more likely than not unrelated to his later-diagnosed TM, even though they seem comparable. The numbness and weakness Petitioner experienced prior to vaccination reasonably appears associated with his hernia repair surgery on August 23, 2011. As Dr. Latov explained, it is not uncommon for patients who have undergone surgery to complain of tingling and weakness, given their positioning during surgery and the anesthesia involved. Tr. at 8-9. This can cause a compressive neuropathy. *Id*. In addition, it appears that after the vaccination, when Petitioner sought treatment for his leg numbness, his treaters included in the differential diagnosis explanations for his symptoms that might have supported linking his pre-vaccination symptoms as also demyelinating in character, but ultimately found that TM was the more accurate diagnosis, abandoning the initial suspicion that he had experienced GBS or a similar kind of demyelinating peripheral neuropathy.

Testing performed on Petitioner both before and after receipt of the flu vaccine further bulwarks the conclusion that his pre-vaccination symptoms did not reflect the beginning of his TM. First, the EMG study performed after vaccination (which could have confirmed the extent to which Petitioner's pre-vaccination symptoms were the product of a demyelinating condition) only suggested the existence of a mild polyneuropathy. Tr. at 48; Ex. 8 at 260; Second Latov Rep. at 2-3. Second, the CT scan he received prior to vaccination showed no signs of TM, while his MRI less than a week after vaccination indicated that he had severe abnormalities in his spinal cord. Ex. 8 at 426-28. Even though (as both experts admitted) a CT scan would inherently be less precise and might therefore not be able to detect TM early on, it did not produce alarming readings – as opposed to the post-vaccination MRI scans, which showed particularly severe damage. From this, it can be inferred (if faintly) that the injury detected at the time of the MRI had occurred closer in time to the second scans, and had not been progressively developing since before vaccination.

The course of Petitioner's symptoms further undermines the conclusion that Petitioner's TM began before vaccination. As Dr. Latov noted, the initial tingling and weakness Petitioner was experiencing was remitting in nature, and his symptoms had largely waned by the time of vaccination – something he credibly posited was not characteristic of TM given its progressive quality. The later testing performed on Petitioner never resulted in any connection of the pre-vaccination symptoms with his TM – nor did the test results establish earlier peripheral

Program standards."). Individual cases turn on the facts presented therein – and *in this case* Petitioner successfully established the first *Althen* prong.

demyelination or something directly linked. And there is record evidence of treaters associating Petitioner's TM to the flu vaccine he had received.

Dr. Gelfand attempted to rebut each of these points through his own, counter-reading of the medical record. Although he made many reasonable assertions about how much certainty could be attached to Dr. Latov's record interpretation, he also on several occasions allowed for the fact that Petitioner's arguments had evidentiary plausibility, given the record and in light of his own expertise with neuropathic illnesses. In particular, he agreed that Petitioner's post-vaccination symptoms were notably distinct, and abruptly worse, when compared to the more vague complaints he raised before vaccination – suggesting they did not link up with his earlier symptoms. Tr. at 151 (noting the "aggressive" character of Petitioner's myelitis based on post-vaccination scans and testing results).

Given the above, I find that the record adequately supports the conclusion that it is more likely than not that Petitioner's pre-vaccination symptoms were unrelated to his later-diagnosed TM. In so finding, I am *not* concluding that Petitioner has overwhelmingly carried the day on this matter. Both experts expressed reliable, informed interpretations of the medical records, and I do not find that one was especially more persuasive than the other. There is certainly more than a scintilla of evidence in this case supporting Respondent's position that the pre-vaccination neurologic symptoms Petitioner experienced *were* connected to his later-diagnosed TM (and the fact that treaters never diagnosed him with a peripheral neuropathy could be read to support Respondent's reading of the medical history). But there is *just* enough evidence here favoring Petitioner's interpretation of the record to find the preponderance test satisfied. This determination is consistent with the Federal Circuit's admonition that close cases be decided in favor of petitioners. *Althen*, 418 F.3d at 1280.

2. *Petitioner's TM is Consistent with Dr. Latov's Theory of Causation*

Outside of the onset issue in this case, both parties agreed that Petitioner suffered from TM. There is also no dispute that Petitioner received the flu vaccine on September 23, 2011. As the medical records indicate, Petitioner began to experience intermittent leg weakness and tingling beginning around September 25, 2011. These post-vaccination symptoms proved to be progressive (consistent with TM's expected course), and by September 30, 2011, Petitioner had difficulty walking and was taken by the paramedics to the emergency room. Ex. 15 at 1. By the time an MRI was performed, on October 2, 2011, Petitioner displayed severe abnormalities around his spinal cord. Ex. 8 at 426-28. Dr. Latov testified that Petitioner's clinical course was consistent with vaccine-induced TM, and many of Petitioner's treaters took note of his recent vaccination as a relevant risk factor. First Latov Rep. at 6; Ex. 8 at 256-58, 262-63, 373-75, 426.

Having found that Petitioner's TM-related symptoms began after vaccination, many of Respondent's arguments against finding a causal association (to the extent they rely on the pre-vaccination symptoms as linked) fall away. In addition, in challenging the sufficiency of Petitioner's "did cause" showing, Respondent seems to rely on the prong one contention that TM cannot be caused by the flu vaccine, rather than pointing to specific evidence why it did not occur *in this instance*. Other than the earlier symptoms, Respondent points to little that would undermine Petitioner's "did cause" showing.

I therefore conclude that Petitioner provided sufficient preponderant evidence to meet his *Althen* Two burden. He established a logical sequence of cause and effect from vaccine to injury that is supported by the evidentiary record.

C. *Althen* Prong Three

The medical records indicate that Petitioner began experiencing some weakness and numbness on September 25, 2013 - two days after his vaccination. As already noted, it is not entirely clear if those symptoms were attributable to post-surgery issues, a different kind of polyneuropathy, or if they were the actual beginning of his TM - but my finding that the post-vaccination symptoms were more likely than not distinguishable and separate obviates the need for further comparison of the two periods. This still leaves, however, the question of whether the timeframe for onset of these post-vaccination symptoms was medically acceptable.

As both experts recognized, two or three days is a very short onset period. Respondent also offered some reliable evidence supporting the conclusion that such a timeframe is too short for the occurrence of an autoimmune process. Petitioner, by contrast, offered only Schonberger, an item of literature involving a demyelinating condition of the peripheral neuropathy rather than of the spinal cord. Neither expert possessed deep experience researching or otherwise dealing with immunological matters (although both were competent enough overall in medical subjects to testify intelligibly on the subject). Other special masters have found in TM cases that a short onset is medically acceptable, although usually the timeframe in question is longer than in this case. *See, e.g., Raymo* 2014 WL 1092274, at *23 (TM caused by vaccination (Tdap, Hep A, Meningococcal, HPV) with a three to four-day onset); *Land,* 2014 WL 2488705, at *5-6 (onset about three days was appropriate in a TM/flu vaccine case); *but see Crosby v. Sec'y of Health & Human Servs.,* No. 08-799, 2012 WL 13036266, at *1 (Fed. Cl. Spec. Mstr. June 20, 2012) (24 hours was too short of a period between vaccination (DTaP) and onset of TM).

This does not mean, however, that nothing in the record supports Petitioner's contention that the timeframe in question was medically appropriate. In particular, a short time period under the circumstances of this case can be found medically acceptable if considered in conjunction with one of Petitioner's proposed mechanisms, bystander activation (in which an ongoing immunologic

response is broadened by a subsequent stimulus, resulting in a breaking of immune tolerance and producing an autoimmune response). *See* Nogai at 959 (full immunologic activation requires co-stimulation from another molecule—such as from infection or a preexisting, ongoing immune response). As Petitioner's medical history demonstrates, ten days passed from his last visit to a doctor to obtain treatment for his pre-vaccination neuropathic symptoms to the date he received the vaccine – and it is reasonable to infer that the immune response mounted in connection with his pre-vaccination symptoms (whatever their derivation) could still have been ongoing or not fully resolved in this period, even though Petitioner was not complaining of symptoms at the time of vaccination. From this, it can be reasonably concluded (concurrent with Petitioner's causation theory) that the vaccine incited an autoimmune reaction in a fairly short period of time via bystander activation – building on the existing efforts of his immune system due to the additional immunologic stimulation provided by the vaccine.

This *Althen* prong, like the second (as it pertained to differentiating the pre-vaccination symptoms from those afterward) presents a very close case. In other circumstances (for example, where a claimant had no neuropathic symptoms whatsoever before administration of the relevant vaccine, and/or no prior illness that could be deemed to have sparked the immunologic response necessary for the bystander mechanism to be plausible), such a short onset might well be fatal to an entitlement claim.[15] But the timeframe at issue herein is consistent with Petitioner's proposed mechanism – which in turn gains credence from the fact that Petitioner's immune system was at that time likely still dealing with the distal polyneuropathy he had experienced after his surgical procedures. In addition, Petitioner's arguments were not rebutted effectively by Respondent's more generalized assertions about the overall lack of association between the flu vaccine and similar demyelinating conditions.

Under such circumstances, it is appropriate to find that Petitioner has met his preponderant burden with respect to timeframe – if barely.

CONCLUSION

Petitioner has established a prima facie case by proving each of the *Althen* prongs by a preponderance of the evidence, and is therefore entitled to compensation under the Vaccine Program. In order to guide the parties through the damages phase of the action, a separate damages order will issue.

[15] I therefore expressly do *not* find that a two-day onset of TM following the flu vaccine should always be considered medically acceptable in all future cases.

IT IS SO ORDERED.

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