In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 16-633V
Filed: April 28, 2023

MELISSA LARSON, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	TO BE PUBLISHED Guillain-Barré syndrome (GBS); Influenza Vaccine; Decision on Entitlement

John F. McHugh, Law Office of John McHugh, LLC, New York, NY, for Petitioner
Alexa Roggenkamp, U.S. Department of Justice, Washington, DC, for Respondent

DECISION ON ENTITLEMENT[1]

Oler, Special Master:

On May 27, 2016, Melissa Larson ("Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program[2] alleging that she suffered from fibromyalgia as result of the influenza ("flu") vaccination she received on November 6, 2013. Pet. at 1, ECF No. 1. Without amending her petition, Petitioner subsequently asserted that the flu vaccination she received caused her to develop Guillain-Barré syndrome ("GBS"). Pet'r's Pre-Hearing Brief, ECF

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

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) ("Vaccine Act" or "the Act"). Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

No. 91 at 1-2, 8; Tr. at 177. For the reasons set forth below, I find that Petitioner has not preponderantly demonstrated that she had GBS. Accordingly, her petition is dismissed.

I. Procedural History

Petitioner filed her petition on May 27, 2016. ECF No. 1 ("Pet."). Petitioner filed medical records on June 15, 2016, September 29, 2016, and October 25, 2016. ECF Nos. 8, 9, 17, 19. Respondent filed his Rule 4(c) report recommending against compensation on January 12, 2017. ECF No. 23.

The parties filed expert reports from Dr. Dimitrios Karussis (Ex. 15), Dr. Yehuda Shoenfeld (Ex. 31), and Dr. Timothy Vartanian (Ex. A).

On September 18, 2019, I posed three questions to the parties' experts. ECF No. 60. Petitioner engaged Dr. Marcel Kinsbourne as an expert after her attempts to contact Dr. Karussis were unsuccessful. ECF No. 67. Dr. Shoenfeld responded to my questions on December 12, 2019. Ex. 74 ("Shoenfeld Answers"). Dr. Kinsbourne responded to my questions on December 13, 2019. Ex. 90 ("Kinsbourne Answers"). Dr. Vartanian responded to my questions on December 19, 2019. Ex. C ("Vartanian Answers").

I held an entitlement hearing on November 8, 2021, where I heard testimony from Petitioner and from Drs. Shoenfeld, Kinsbourne, and Vartanian. *See* Minute Entry dated November 8, 2021. The parties filed post-hearing briefs over the following six months. Pet'r's Post-Hearing Brief, ECF No. 104; Resp't's Post-Hearing Brief, ECF No. 107; Pet'r's Reply Brief, ECF No. 108. On May 26, 2022, the parties filed a joint status report confirming that the record was complete for a decision on entitlement. ECF No. 109. This matter is now ripe for adjudication.

II. Medical History

Prior to November 2013, Petitioner was generally in good health. Petitioner suffered from mild asthma for which she took albuterol as needed. Ex. 9 at 41. She also experienced anxiety and panic attacks, for which she had been prescribed Xanax and Belviq. *Id.*; Ex. 3a at 26.

On November 6, 2013, Petitioner, then aged 36 years, received the allegedly causal flu vaccine at Aurora Healthcare, where she worked as a respiratory therapist. Ex. 2 at 2; Tr. at 8.

Forty-one days later, on December 17, 2013, Petitioner saw Julia Johnson, DO, in the emergency room reporting that she had begun experiencing sharp pain in her lower back the previous evening while sitting on her bed playing with her 18-month-old child. Ex. 3a at 25. Petitioner denied numbness, tingling, and other symptoms. *Id.* Examination revealed "decreased range of motion, tenderness, pain and spasm" with "no bony tenderness" in her lumbar spine. *Id.* at 28. Dr. Johnson diagnosed lumbosacral joint sprain and prescribed diazepam, ibuprofen, and Percocet. *Id.* at 29.

On December 18, 2013, Petitioner followed up with Shashi Bhushan, MD, her regular physician. Ex. 9 at 44. Petitioner reported continuing lower back pain, but denied trauma, radiating

pain, and bowel and urinary incontinence. *Id.* at 45. Petitioner's strength and reflexes were normal. *Id.* Dr. Bhushan noted that Petitioner experienced pain on flexion and extension and was "unable to be on the examination table." *Id.* Dr. Bhushan diagnosed Petitioner with low back pain likely resulting from musculoskeletal strain, administered a Solu-Medrol injection, and prescribed prednisone, diclofenac, and Flexeril. *Id.*

When her back pain did not improve, Petitioner saw Dr. Bhushan again on December 20, 2013. Dr. Bhushan ordered an MRI, which took place that same day. Ex. 9 at 47; Ex. 3a at 10. The MRI revealed minimal anterolisthesis[3] on Petitioner's L4 and L5 vertebrae, with normal alignment in the rest of her lumbar spine. *Id.* The MRI also revealed mild to moderate disc protrusion at L4 and L5, desiccation of the disc between L4 and L5, and narrowing of the spinal canal. *Id.*

Petitioner saw Dr. Bhushan again on December 24, 2013, complaining that her back pain was "excruciating" and "7/10 in intensity". Ex. 9 at 48. Petitioner denied tiredness, headache, focal weakness, and sensory changes. *Id.* Dr. Bhushan referred Petitioner to a neurosurgeon. *Id.* at 49.

On December 27, 2013, Petitioner saw neurologist John Pidgeon, MD, reporting that she felt "numb and weak all over" and that, two to three days prior to her visit, she had begun experiencing generalized paresthesias. Ex. 4 at 5. She also reported facial drooping on both sides, shortness of breath during the night, difficulty swallowing, and progressively worsening weakness. *Id.* During her appointment, Petitioner had difficulty rising from a sitting to a standing position and was unable to raise her arms above shoulder level. *Id.* Dr. Pidgeon noted that Petitioner exhibited facial diplegia,[4] symmetric 1+ reflexes, full extraocular movements, dysarthria,[5] and 4-/5 strength bilaterally in her neck and upper extremities. *Id.* at 6. Dr. Pidgeon expressed concern that Petitioner may have GBS and noted that this "could be a reaction to the flu shot that she received." *Id.* He referred Petitioner back to the emergency room out of concern that her condition might worsen, necessitating a ventilator. *Id.*

In the emergency room that same day, Petitioner saw Thulasiraman Ravichandran, MD, reporting that she felt like she had pins and needles from her feet to her lower chest and that she felt numbness and tingling in both hands. Ex. 5a at 77. Petitioner reported difficulty breathing, slurred speech, and a feeling that her body was heavy ("like jell-O"). *Id.* Dr. Ravichandran noted that Petitioner exhibited no facial weakness and no plegia and that her reflexes were symmetrical and "quite brisk." *Id.* He referred Petitioner to the Neuro ICU for close monitoring for acute GBS

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[3] Anterolisthesis (also known as spondylolisthesis) is "forward displacement (olisthy) of one vertebra over another, usually of the fifth lumbar over the body of the sacrum, or of the fourth lumbar over the fifth, usually due to a developmental defect in the pars interarticularis." DORLAND'S MEDICAL DICTIONARY ONLINE (hereinafter "DORLAND'S"), https://www.dorlandsonline.com/dorland/definition?id=46742 (last visited on Apr. 19, 2023).

[4] Diplegia is "paralysis affecting like parts on both sides of the body." DORLAND'S, https://www.dorlandsonline.com/dorland/definition?id=14328 (last visited on Apr. 19, 2023).

[5] Dysarthria is "a speech disorder consisting of imperfect articulation due to loss of muscular control after damage to the central or peripheral nervous system." DORLAND'S, https://www.dorlandsonline.com/dorland/definition?id=15144 (last visited on Apr. 19, 2023).

and ordered an electromyography nerve conduction study and a spinal tap. *Id.* at 78. Petitioner underwent an MRI of her cervical spine, which revealed a "[s]mall right paracentral disc protrusion" at C5-C6 and a "subtle increased enhancement on the surface of the lower thoracic spinal cord and conus," possibly representing an inflammatory or infectious process. Ex. 5b at 98-99. Petitioner also underwent an MRI of her brain, which was unremarkable. *Id.* at 100. Analysis of her cerebrospinal fluid (CSF) showed slightly elevated protein (57 mg/dL, where the reference range is 15-45 mg/dL). Ex. 5c at 24. The nerve conduction study was not performed until March 2014 because Petitioner improved rapidly and there was no one available to perform the test during her hospital stay. Ex. 5a at 70, 78; Ex. 5e at 33.

Petitioner saw Dr. Ravichandran the next day, December 28, 2013. Ex. 5a at 75. He noted that Petitioner was "much improved," that her reflexes were brisk, and that she showed no facial diplegia. *Id.* Based on her condition, Dr. Ravichandran determined not to begin IVIG treatment or plasmapheresis unless her condition began to deteriorate. *Id.* at 76.

That same day, Petitioner had an infectious disease consultation with Francisco Aguilar, MD. Ex. 5a at 79. Petitioner reported four or five days of diaphoresis[6] but denied fever and chills. *Id.* at 80. Dr. Aguilar noted that Petitioner had had multiple episodes of stomach flu in October and November 2013. *Id.* Dr. Aguilar's examination revealed some weakness in Petitioner's extremities, symmetrical reflexes, and no signs of respiratory failure. *Id.* Dr. Aguilar's impression was that the "presumptive diagnosis [was] possible [GBS]." *Id.* at 81. Influenza A and B assays on December 19, 2013, were negative. *Id.* Petitioner tested negative for Epstein-Barr virus, cytomegalovirus, toxoplasmosis, tuberculosis, myasthenia gravis, enterovirus, Lyme, HIV, antinuclear antibody, campylobacter jejuni ("c. jejuni") IgG, and West Nile virus. *Id.* at 53-68.

On December 29, 2013, Petitioner saw Dr. Ravichandran again, who noted that Petitioner's numbness was resolving and was then mostly in her feet. Ex. 5a at 94. Petitioner was able to walk without tachycardia or dysautonomia. *Id.* Petitioner exhibited normal range of motion in her shoulders and legs and showed no facial symptoms. *Id.* Dr. Ravichandran noted that Petitioner had a urinary tract infection at the time of this visit and that her symptoms were "related to post-flu shot demyelinating neuropathy." *Id.* at 95.

Petitioner was discharged from the hospital on December 31, 2013. Ex. 5a at 69-70. Her condition had improved "fairly rapidly," and IVIG and plasma exchange were never administered. *Id.* at 70. Petitioner's diagnosis at the time of discharge was generalized weakness and possible GBS. *Id.* at 69.

On January 6, 2014, Petitioner saw Dr. Pidgeon for a follow-up, complaining of uncomfortable pins and needles sensations, paraphasic errors,[7] and weakness. Ex. 4 at 11.

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[6] Diaphoresis is "sweating, sometimes specifically that induced artificially." DORLAND'S, https://www.dorlandsonline.com /dorland/definition?id=13776 (last visited on Apr. 19, 2023).

[7] Paraphasia is "a type of dysphasia in which a person uses wrong words or uses words in wrong and senseless combinations." DORLAND'S, https://www.dorlandsonline.com/dorland/definition?id=36908 (last visited on Apr. 20, 2023).

Petitioner exhibited facial diplegia but was not dysarthric and was able to walk without difficulty. *Id.* She exhibited brisk reflexes in all her extremities. *Id.* Dr. Pidgeon noted that it would be unusual for a patient with GBS to have brisk reflexes, especially given that Petitioner's MRI showed a possible change in signal in the thoracic spinal cord. *Id.*

On January 23, 2014, Petitioner saw Dr. Pidgeon again, at which time Dr. Pidgeon's diagnosis was GBS. Ex. 4 at 16. Petitioner complained of ongoing fatigue that was preventing her from returning to her job, as well as paresthesias. *Id.* at 15-16. Another MRI of Petitioner's thoracic spine revealed that the previously identified abnormality was likely benign. *Id.* at 17. Dr. Pidgeon noted that Petitioner still exhibited facial diplegia, but that it had improved since her last visit. *Id.* He also noted 4+ out of 5 reflexes in all of Petitioner's extremities. *Id.*

On February 25, 2014, Petitioner followed up with Dr. Pidgeon. Ex. 4 at 19-23. Dr. Pidgeon noted that Petitioner was undergoing physical therapy three times per week and daily occupational therapy, as well as aqua therapy. *Id.* at 22. Petitioner reported that Gabapentin was helping with the discomfort related to her paresthesias and that she was also using a TENS unit to manage her pain. *Id.* On examination, Petitioner exhibited more facial animation and increased arm strength and was not dysarthric. *Id.*

On February 28, 2014, Petitioner saw Kenneth Bortin, MD, for a cardiology consultation. Ex. 3a at 103-06. Petitioner complained of tachycardia and chest pain over "the past several weeks" and noted that sharp discomfort in her chest was usually positional and associated with a rapid heartbeat. *Id.* at 103. Petitioner denied dizziness, syncope, blurred and double vision, and dyspepsia.[8] *Id.* at 103-04. Petitioner's blood pressure at this visit was 110 over 80 and her pulse was 110. *Id.* at 105. The examination of Petitioner and her recent EKG were both normal. *Id.* at 106. Dr. Bortin diagnosed Petitioner with "[a]typical chest pain and tachycardia in the setting of a recent viral syndrome/[GBS]." *Id.*

On March 14, 2014, Petitioner was admitted to intensive care for generalized progressive weakness. Ex. 5e at 6. Petitioner complained of generalized weakness, a "jell-O" feeling, numbness, and tingling. *Id.* at 7. Analysis of Petitioner's CSF revealed minimally elevated proteins, possibly indicating the presence of chronic inflammatory process. *Id.*; *Id.* at 20. Wilson Cueva, MD, expressed doubt that petitioner had GBS and described her examination as "pretty benign," noting that she did have hyperreflexia. *Id.* at 4-5. Dr. Cueva posited that Petitioner could be suffering from a chronic inflammatory process or ongoing inflammatory condition. *Id.* at 5. He remarked that while Petitioner may have had GBS in December 2013, he did not believe that she had GBS at the time of his examination in March 2014. *Id.*

Petitioner's symptoms improved without resort to IVIG or plasmapheresis. Ex. 5e at 10. Petitioner was transferred out of intensive care on March 15, 2014, and her neurological examination on March 16, 2014, was "essentially normal." *Id.* at 19. Additional CSF studies were negative. *Id.* at 20. Dr. Cueva noted that the bulging in Petitioner's L5 disc might explain the mild chronic inflammatory changes in her CSF. *Id.* Dr. Cuerva observed that Petitioner may have been

[8] Dyspepsia is "impairment of the power or function of digestion; usually applied to epigastric discomfort following meals." DORLAND'S, https://www.dorlandsonline.com/dorland/definition?id=15263 (last visited on Apr. 20, 2023).

experiencing worsening of her residual slight generalized weakness secondary to a systemic process (upper respiratory infection). *Id.* Dr. Cuerva approved Petitioner to be discharged home. *Id.*

On March 17, 2014, Petitioner saw Elizabeth Marriott, MD, for a neurology consultation. Ex. 5e at 26-28. Dr. Marriott noted that Petitioner had a mild to moderate upper respiratory infection "for the past few days." *Id*. at 26. Examination revealed that Petitioner's reflexes and motor strength were intact and her sensory and cerebellar examinations were normal. *Id.* at 28. Dr. Marriott noted that the etiology of Petitioner's symptoms was not clear, but that her condition was "[c]linically inconsistent with recurrent inflammatory neuropathy." *Id.*

On March 18, 2014, Petitioner underwent EMG and NCS, which showed no electrophysiological evidence of L2-S1 acute/active radiculopathy, lumbosacral plexopathy, myopathy, entrapment neuropathy, or peripheral polyneuropathy of the bilateral lower extremity. Ex. 5e at 33. Based on Petitioner's normal EMG, increased reflexes, and only minimal elevation in CSF protein, Dr. Marriott's diagnosis was subjective weakness and paresthesias. *Id.* at 33-34. Dr. Marriott noted that Petitioner's symptoms may have resulted from a subclinical process and referred Petitioner for outpatient follow-up. *Id.* at 34.

Petitioner returned to her primary care provider, Dr. Bhushan, on April 16, 2014, complaining of an unsteady gait, forgetfulness, and weakness in her legs. Ex. 9 at 53. Dr. Bhushan diagnosed neurological symptoms and opined that Petitioner's symptoms were likely somatoform. *Id.*

On April 22, 2014, Petitioner saw occupational health specialist Christopher Kolimas, MD, for a fit for duty/disability evaluation. Ex. 4 at 33. Petitioner indicated that her condition had started to improve since her hospitalization in March 2014. *Id.* at 35. She reported symptoms including facial twitching; diminished sensation in her face, left arm, and left leg; heaviness and weakness in all extremities; dysarthria; difficulty speaking, including choosing words; double vision; weakness in both hands (more severe on the left side than the right); trouble walking on uneven surfaces and stairs; and weakness and paresthesias in her legs such that she was unable to walk or stand for more than 10 minutes. *Id.* Petitioner reported that she was unable to do household chores for more than a few minutes at a time or drive for more than 15 minutes at a time. *Id*. at 36. She also reported that she had trouble performing calculations and with fine motor skills. *Id.* Dr. Kolimas noted that Petitioner's speech was slow and that she had difficulty finding and articulating words. *Id.* at 37. Petitioner was able to stand up from a seated position without assistance, but she walked with a limp and had trouble walking on her heels, exhibiting more weakness on her left side. *Id.* She was able to squat and rise, but struggled with rapid alternating movements, more slowly on the left side than the right. *Id.* Dr. Kolimas noted mild weakness distally involving ankle dorsiflexion and grip strength which was more severe on Petitioner's left side. *Id.* at 38. Petitioner's reflexes were brisk. *Id.* Notes from other providers indicated that Petitioner experienced persistent bilateral upper extremity weakness and incoordination and had difficulty completing everyday tasks. *Id.* at 40. Dr. Kolimas concluded that Petitioner was unable to perform many of her job functions as a respiratory therapist. *Id.* at 42.

On May 19, 2014, Petitioner saw neurologist Barend Lotz, MD, for a neuromuscular consultation. Ex. 11 at 2-7. Dr. Lotz noted that at first, he had difficulty obtaining an accurate history from Petitioner. *Id.* at 4. Petitioner indicated that her legs had become "completely paralyzed" in December 2013 and that she experienced new arm weakness about a week later. *Id.* Dr. Lotz noted that Petitioner's records showed that she had never lost reflexes, that her CSF protein had been slightly elevated with no pleocytosis,[9] that her EMG was normal, and that degenerative changes in her L5-S1 may have explained her back pain. *Id.* Dr. Lotz noted that Petitioner did not display any weakness in either her arms or legs and was able to walk on her heels and toes without difficulty. *Id.* He further noted that Petitioner claimed she could not move her toes up or down, but that on exam, "she could do this completely normally." *Id.* Petitioner did exhibit a limping gait "for unknown reasons," but reported that she was not in pain. *Id.* at 5. Dr. Lotz's diagnosis was a conversion reaction simulating weakness in the left leg. *Id.* Dr. Lotz wrote the following in the medical record:

> I spent a lot of time explaining to the patient and her husband that she does not have Guillain-Barre or Guillain-Barre-like disease. If there was such a disease, it would have started within 10 days of vaccination because that is when the antibodies are produced. Her EMG study would have been abnormal. She would have lost her reflexes, so there is no evidence that she had that. Therefore, I cannot tell them why she had this disease with paralysis of the arms and legs.

Id.

On June 19, 2014, Petitioner saw Rose Dotson, MD, for a neuromuscular consultation. Ex. 6a at 8-25. Dr. Dotson reviewed Petitioner's medical records and diagnosed her with subjective generalized muscle weakness, "give way". *Id.* at 8, 24. She noted that Petitioner's previous diagnosis of GBS was made "clinically" in spite of there being "no convincing CSF finding" and no EMG performed at the time of diagnosis. *Id.* at 24. Dr. Dotson's specific assessments appear as follows in the medical record:

ASSESSMENT AND PLAN:

1. **Generalized muscle weakness, subjective, give way; negative EMG-NCS previously, reported worsening per hx; previously dx'd clinically with GBS and no convincing CSF finding; no EMG performed at time of dx; subsequent worsening with negative exam, EMG-NCS and CSF findings for dx of GBS**
2. Paresthesias, negative EMG-NCS previously
3. Neuropathic pain, reported benefit with gabapentin
4. Fatigue, no fatigability on exam
5. Dysautonomia, per hx; negative exam
6. Tachycardia, unspecified
7. Orthostatic lightheadedness, no OH or significant orthostatic lightheadedness
8. Vitamin D deficiency
9. Subjective visual disturbance, unspecified; evaluated by ophthalmology
10. Gait abnormality, nonphysiologic

Id.

[9] Pleocytosis is "presence of a greater than normal number of cells in the cerebrospinal fluid." DORLAND'S, https://www.dorlandsonline.com/dorland/definition?id=39556 (last visited on Apr. 20, 2023).

On July 7, 2014, Petitioner underwent a nerve conduction study which yielded normal results and no evidence of neuropathic or myopathic process. Ex. 6a at 34.

On August 17, 2014, Petitioner saw Dr. Dotson for a follow up. Ex. 6a at 68-69. Petitioner complained of tachycardia, generalized weakness, fatigue, orthostatic lightheadedness, paresthesias, and myalgia. *Id.* at 68. Dr. Dotson noted that Petitioner's previous diagnosis of GBS had been made "without objective evidence." *Id.* Petitioner underwent a tilt table test with "mildly abnormal" results. Ex. 6b at 4. Her neurological examination was normal. *Id.* at 2. Dr. Dotson's assessment was unspecified tachycardia. *Id.* at 5. When Petitioner returned the following day, Dr. Dotson diagnosed her with small fiber neuropathy per clinical examination and neuropathic pain. *Id.* at 18.

On August 18, 2014, Petitioner underwent a sweat test. Ex. 6b at 15. The results showed normal volume at all sites with lower relative volume on Petitioner's forearm. *Id.*

Petitioner returned to see Dr. Dotson on October 6, 2014, complaining that her pain had increased and that fatigue was making it difficult to perform household tasks. Ex. 6b at 51. She also complained of trouble falling and staying asleep and of cognitive slowing and brain fog. *Id.* On examination, Petitioner exhibited 14 out of 18 fibromyalgia tender points. *Id.* at 53. Petitioner's autoantibody profile was negative and skin biopsies from her left leg were both normal. *Id.* at 54-57. Dr. Dotson diagnosed Petitioner with fibromyalgia with widespread pain, tender points, sleep disturbance, and cognitive symptoms. *Id.* at 57. Dr. Dotson noted that there was no objective support for her prior clinical diagnosis of small fiber neuropathy, and that the prior diagnosis was in question in light of the findings supporting fibromyalgia. *Id.*

On November 24, 2013, Petitioner saw Mary Yellick, APNP, reporting that her symptoms had worsened since the end of October 2014. Ex. 6c at 10. Petitioner complained of fatigue, pain, trouble falling and staying asleep, and brain fog. *Id.* Petitioner's physical examination was unchanged. *Id.* at 10-17. NP Yellick continued Petitioner's prior diagnosis of fibromyalgia. *Id.* at 17.

On December 10, 2014, Petitioner reported to the emergency room complaining of a headache, facial numbness on the left side, and weakness in her left arm and left leg. Ex. 3b at 97. The emergency physician noted that Petitioner's history was significant for GBS and fibromyalgia and that she was seeing a neurologist for a "mystery diagnosis." *Id.* Petitioner spoke very slowly and complained of facial paresthesias. *Id.* at 99. The record notes no focal neurologic deficits. *Id.* Petitioner's heart rate was 77 bpm and her head CT was normal. *Id.* at 99-100. Petitioner was advised to follow up with Dr. Dotson. *Id.* at 101.

On December 18, 2014, Petitioner saw Farzan Mahmood, MD, for a rheumatology consultation. Ex. 9 at 56-58. Dr. Mahmood's assessment was chronic pain and fatigue likely due to fibromyalgia. *Id.* at 58. He noted that Petitioner also had dysautonomia "which is commonly seen with fibromyalgia." *Id.* In January 2015, Petitioner began taking Savella, which helped somewhat. Ex. 9 at 59. Petitioner continued to receive treatments over the following months and Dr. Mahmood cleared her to return to work part time in March 2016. Ex. 10a at 100.

Petitioner applied for worker's compensation for her alleged vaccine injury in December 2013 or early January 2014. Ex. 96 at 38 (showing that the insurer had received her claim prior to January 8, 2014). Neurologist Brian A. Chapman, MD, reviewed her case on behalf of the insurer and opined that "[a]t this time, no clear diagnosis can be made of Guillain-Barre syndrome." *Id.* at 54. Accordingly, Petitioner's claim for worker's compensation was denied on March 31, 2014. *Id.* at 51. Petitioner also applied for long term disability benefits through her employer, which were approved on April 17, 2014. *Id.* at 4. In support of her claim for disability benefits, Petitioner supplied medical records documenting her inability to work due to her symptoms, particularly fatigue, weakness, cognitive issues, and pain. *Id.* at 24.

No further medical records pertinent to this analysis have been filed.

III. Expert Reports and Testimony

A. Petitioner's Expert – Dimitrios Karussis, MD, PhD

1. Qualifications

Dr. Karussis received his medical degree at Aristotelion University in Greece in 1986 and his PhD in neuroimmunology at Hebrew University in Israel in 1993. Ex. 16 ("Karussis CV") at 2. He is board certified in neurology in the European Union and in clinical neurology and neurology in Israel. *Id.* at 3. He has been a member of the neurology faculty at Hebrew University since 1997 and was promoted to full professor in 2014. *Id.* Dr. Karussis has been the Director of the Neuroimmunology Unit at Haddassah University Hospital since 2014 and has been the Head of the Hadassah MS Centre since 2007. Karussis Rep. at 2.

Dr. Karussis's research interests include topics in neuroimmunology, particularly MS. Karussis CV at 5-6. He has been a principal investigator in 28 clinical trials related to MS since the early 1990's. *Id.* at 7-9. He also teaches courses in neurology and advises graduate students at Hebrew University. *Id.* at 9-11. He is the author of five book chapters and more than 100 peer-reviewed journal articles in neuroimmunology and neurology, with a particular focus on MS. *Id.* at 11-28.

2. Expert Report

Dr. Karussis authored one expert report in this case. Ex. 15 ("Karussis Rep."). In his report, he opined that GBS is Petitioner's correct diagnosis based on her medical records. *Id.* at 11. He opined that, while Petitioner did not exhibit elevated protein in her CSF, reduced nerve conduction velocity on EMG, or loss of deep tendon reflexes, these findings may be absent or "not prominent" in the early stages of GBS. *Id.* at 9-10. He further opined that the symptoms Petitioner reported, including paresthesias, numbness, general weakness, pain in the lower back and extremities, and facial diplegia "represent the most typical/classical presentations of GBS." *Id.* at 10. Dr. Karussis stated that the change in Petitioner's diagnosis from GBS to fibromyalgia in 2014 was "puzzling" and "not based on any new findings." *Id.* He also posited that diffuse muscle pain and autonomic instability, both of which Petitioner experienced, are common to both conditions and might have caused confusion of the two. *Id*.

Dr. Karussis acknowledged that "this is certainly not a very typical case of GBS," but nevertheless maintained that GBS rather than fibromyalgia was the most likely diagnosis. Karussis Rep. at 11. He opined that Petitioner's lack of neurological symptoms prior to December 2013 makes fibromyalgia less likely because "it would be very peculiar that all these symptoms started 'by chance' after the vaccination and without any association with it." *Id.*

Dr. Karussis concluded his report by summarizing the link between the H1N1 flu vaccination and an increased incidence of GBS cases (an additional 1.6 GBS cases for every 1,000,000 people vaccinated). Karussis Rep. at 12. He opined that this data combined with the timing of the onset of Petitioner's condition "is very supportive of a causative association." *Id.*

B. Petitioner's Expert – Yehuda Shoenfeld, MD, FRCP

1. Qualifications

Dr. Shoenfeld received his medical degree at Hebrew University in Israel in 1972. Ex. 32 ("Shoenfeld CV") at 3. He completed his post graduate studies in internal medicine at Tel-Aviv University in 1978. *Id.* He presently holds the Laura Schwarz-Kipp Chair for Research of Autoimmune Diseases at Tel-Aviv University and is the Head of the Zabludowicz Center for Autoimmune Diseases at Sheba Medical Center, also at Tel-Aviv University. *Id.* His responsibilities as an emeritus professor include teaching medical students and advising graduate students. Shoenfeld Rep. at 2. He also sees patients two days per week. Tr. at 93.

Dr. Shoenfeld's research interests include cancer and autoimmunity, as well as autoimmune diseases. Shoenfeld CV at 26-141. Dr. Shoenfeld is the author of 62 books, 158 book chapters, and 1,982 peer-reviewed journal articles. *Id.* at 23-141. I recognized him as an expert in the field of autoimmunity. Tr. at 77-78.

2. Expert Report

Dr. Shoenfeld authored one expert report in this case. Ex. 31 ("Shoenfeld Rep."). In it, he concluded that Petitioner's medical history and the medical literature "support the diagnosis of [GBS] accompanied by fibromyalgia and chronic fatigue," and that the flu vaccine most likely caused Petitioner's condition by means of molecular mimicry. *Id.* at 22.

Dr. Shoenfeld noted that the symptoms Petitioner reported were numerous and varying in intensity over a period of months. *Id.* at 17-18. He opined that "such a constellation of symptoms is almost mostly [sic] a snapshot of [GBS]." *Id.* at 18. Dr. Shoenfeld also noted that one of the components of the flu vaccine administered in 2013 and 2014 "shares numerous peptide sequences with 22 human proteins involved in myelin, (de)myelination, and/or axonal neuropathies." *Id.* He added that "the mathematical probability of a pentapeptide occurring at random in two proteins may be calculated as about 20^{-5} or 1 in 3,200,000." *Id.* He posited that the vaccine could have caused Petitioner's GBS by means of molecular mimicry. *Id.*

Dr. Shoenfeld also addressed Petitioner's fibromyalgia diagnosis at length. He noted that Petitioner's medical records indicate abnormal titers for striational antibodies. Shoenfeld Rep. at

19. He cited medical literature supporting his theory that "major antigenic targets of striational antibodies" include titin, Ryanodine receptor, and Kv1.4. *Id.* at 19-20. He opined that molecular mimicry may have induced Petitioner's striational antibodies to attack these three self-antigens, resulting in progressive weakness, myalgia, and chronic pain, respectively. *Id.* at 20. Dr. Shoenfeld also noted that a component of the flu vaccine shares two peptide chains with "the human membrane magnesium transporter 1, isoform 2." *Id.* at 21. He opined that molecular mimicry could cause immune attack on the magnesium transporter, resulting in an "altered level of cellular magnesium, a condition that has been repeatedly associated with fibromyalgia, asthma, and chronic fatigue syndrome." *Id.*

3. Response to My Questions

Prior to the entitlement hearing, I posed three questions to the parties' experts. ECF No. 60. First, I asked when they believe Petitioner developed GBS. Dr. Shoenfeld responded that Petitioner's GBS developed "somewhere between December 6, 2013 – December 27, 2013" based on the sharp, shooting pain Petitioner reported that eventually spread throughout her body. Shoenfeld Answers at 1.

Second, I asked when each expert believes Petitioner developed fibromyalgia. ECF No. 60. Dr. Shoenfeld responded that this occurred "most probably between December 28, 2013 and January 7, 2014." noting that Petitioner's discharge diagnosis after her December 29-31, 2013 hospital stay was generalized weakness. Shoenfeld Answers at 2. He posited that Petitioner's facial diplegia and slurred speech may have been early manifestations of fibromyalgia. *Id.*

Third, I asked whether each expert believes that the conditions of GBS and fibromyalgia are related. ECF No. 60. In response, Dr. Shoenfeld cited to medical literature supporting his theory that the flu vaccine triggered different autoantibodies that attacked different parts of Petitioner's nervous system (i.e., large nerves, causing GBS, and small fibers, causing fibromyalgia). Shoenfeld Answers at 2-3.

4. Testimony

Having reviewed the Petitioner's medical records, Dr. Shoenfeld testified that he believes that Petitioner suffered from overlapping GBS and fibromyalgia. Tr. at 78. He explained that autoimmune diseases are induced in people who are genetically prone to them, meaning that they "have a very aggressive immune system." *Id.* Dr. Shoenfeld testified that women in their child-bearing years are prone to developing autoimmune diseases and that 83% of immune disease cases are in this group. *Id.* He opined that Petitioner developed GBS, "a classical autoimmune disease," four to six weeks after vaccination. *Id.* at 79. He also opined that, with regard to timing of onset, "there are no rules…Sometimes it may be three weeks. Sometimes it may be even seven weeks...40 days or 42 days, this is an average." *Id.*

Dr. Shoenfeld testified that it is common for a patient with one autoimmune disease to develop more of them. Tr. at 80. He noted that fibromyalgia is an autoimmune disease. *Id.* He also noted that Petitioner suffered from tachycardia, which indicates that her autonomic nervous system

was activated. *Id.* at 82. Dr. Shoenfeld opined that tachycardia and small fiber neuropathy are objective signs of autoimmune disease. *Id.* at 84.

Dr. Shoenfeld addressed the fact that Petitioner's original diagnosis of GBS was later changed to fibromyalgia by positing that she developed first the one and then the other. Tr. at 86. He opined that "[m]any of the cases of [GBS] will eventually follow with fibromyalgia." *Id.* He further posited that it was the flu vaccine, by means of molecular mimicry, that triggered the parallel autoimmune attack on both large nerves and small fibers that led Petitioner to develop GBS and fibromyalgia in a "natural progression." *Id.* at 91.

On cross-examination, Dr. Shoenfeld acknowledged that, while he has seen many patients with GBS and fibromyalgia over the course of his career, he has recently begun seeing patients only two days per week rather than full-time. Tr. at 93. Dr. Shoenfeld also acknowledged that, based on Petitioner's CSF protein analysis, nerve conduction studies, and deep tendon reflex exams, Drs. Lotz, Dotson, and Cueva declined to diagnose Petitioner with GBS. *Id.* at 103-04. He nevertheless maintained that Petitioner had GBS because abnormal findings as to these diagnostic tests are not required to diagnose GBS. *Id.* at 101. He also noted that Petitioner had elevated albumin in her CSF that may indicate GBS and that was not explained by any other diagnosis. *Id.* at 102.

To conclude, Dr. Shoenfeld reiterated his theory that the flu vaccine, by means of molecular mimicry, hyperstimulated Petitioner's immune system, thereby inducing an autoimmune reaction. Tr. at 106. As a result, he opined, Petitioner's immune system attacked the cells of her central and peripheral nervous systems, her small fibers, and the GPCR receptors of her autonomic nervous system. *Id.* Initially, Petitioner exhibited the signs and symptoms of GBS, and by a single continuing process of molecular mimicry, Petitioner recovered from GBS and developed parallel fibromyalgia, from which she still suffers today. *Id.* at 106-08.

C. Petitioner's Expert - Marcel Kinsbourne, MD

1. Qualifications

Dr. Marcel Kinsbourne is board certified in pediatrics. Ex. 91 ("Kinsbourne CV") at 2. He received his medical degree at Oxford University in England in 1955, and he has been licensed to practice medicine in North Carolina since 1967. *Id.* at 1-2. From 1967 to 1974, Dr. Kinsbourne served as an associate professor in pediatrics and neurology and a senior research associate at Duke University Medical Center before holding a series of academic positions, including professorships in pediatrics, neurology, and psychology. *Id.* at 2. His clinical experience includes serving as a senior staff physician in Ontario, Canada, from 1974–1980, and a clinical associate in neurology at Massachusetts General Hospital from 1981–1991, although (as noted in other cases) many years have passed since he regularly saw patients. *Pope v. Sec'y of Health & Hum. Servs.*, No. 14–078V, 2017 WL 2460503, at *8 (Fed. Cl. Spec. Mstr. May 1, 2017). He has not personally studied the immunologic issues raised by theories claiming vaccine causation and lacks specialization in the field of peripheral neuropathies (although his general neurologic expertise rendered him competent to discuss such matters). Dr. Kinsbourne has testified as an expert witness in the Vaccine Program since the Program began, but his clinical practice ended in the mid-1990's. Tr. at 40. I recognized

Dr. Kinsbourne as an expert in neurology. *Id.*

2. Response to My Questions

Dr. Kinsbourne responded to the three questions that I posed to the parties' experts. First, I asked when each expert believes Petitioner developed GBS. ECF No. 60. Dr. Kinsbourne responded that Petitioner developed GBS on December 16, 2013. Kinsbourne Answers at 1. He opined that Petitioner's severe lower back ache was the onset of her GBS. *Id.* He cited medical literature finding that "[p]ain signals the onset of GBS in about one third of cases." *Id*.

Second, I asked when each expert believes Petitioner developed fibromyalgia. ECF No. 60. He responded that he does not believe that she ever developed fibromyalgia. Kinsbourne Answers at 1. He noted that diagnostic criteria exist for fibromyalgia, but that none of Petitioner's providers ever applied them. *Id.* He opined that generalized pain and weakness are not enough to support a diagnosis of fibromyalgia. *Id.*

Finally, I asked whether each expert believes that GBS and fibromyalgia are related. ECF No. 60. Dr. Kinsbourne replied that he does not. Kinsbourne Answers at 1. He noted that pain and weakness are symptoms of both conditions, and that both may involve small fiber damage. *Id.* at 1-2. He opined that he knew of no evidence to suggest that these conditions are related, "let alone that they might substitute for one another in the course of an illness or even both occur at much the same time." *Id.* at 2.

3. Testimony

Dr. Kinsbourne testified at the entitlement hearing on November 8, 2021. He began his testimony by noting that he had reviewed Dr. Karussis's expert report and agreed with the latter's opinion. Tr. at 37. He later clarified that he believes that Petitioner has GBS and that the flu vaccine triggered her condition. *Id.* at 51.

Dr. Kinsbourne opined that Petitioner's GBS had begun with the severe lower back pain she reported in December 2013, and that this is "a really common way [for GBS] to begin." Tr. at 40-41. He also noted that Petitioner's reported feelings of having cinder blocks hanging from her limbs occurred close in time to the low back pain, and that the weakness and low back pain that she described are "a very typical onset symptomatically for [GBS]." *Id.* at 41.

Dr. Kinsbourne opined that facial diplegia is "uniquely found in [GBS] in this particular context" and "occurs in more than half of all GBS cases." Tr. at 41. He stated that he knew of "no other alternative explanation, no other disease, that would have the kind of acute onset of weakness, including weakness of the face; no alternative to GBS as a diagnosis for what happened to her." *Id.*

Dr. Kinsbourne testified that the timing of the onset of Petitioner's condition at 40 days after vaccination was within acceptable limits for medically establishing causation. Tr. at 42.

Dr. Kinsbourne opined that Petitioner alleges a pain syndrome. Tr. at 44. He noted that the

pain in Petitioner's back and legs led to her exhibiting an antalgic gait, meaning that she unconsciously modified the way she walked in order to minimize pain. *Id.* Dr. Kinsbourne opined that the bulging disc in Petitioner's spine would not explain the pain or weakness that she experienced. *Id.*

Dr. Kinsbourne next addressed the medical records indicating that Petitioner suffered from an unidentified gastrointestinal illness in November 2013 just before Thanksgiving. Tr. at 45. He noted that there is a known association between c. jejuni infection and the development of GBS. *Id.* He noted that Petitioner was not treated for this illness, and so was not tested for c. jejuni until she was admitted to the hospital in December 2013, at which time the test was negative. *Id.* He opined that, while it is not impossible that c. jejuni caused Petitioner's GBS, the record contains insufficient evidence to say that this is what occurred. *Id.*

Dr. Kinsbourne next addressed the change in Petitioner's diagnosis from GBS to fibromyalgia. He referred to this as an "unusual course of events" and opined that Petitioner had "a really rather straightforward, though mild, GBS onset" and that fibromyalgia "is really not that kind of disease at all." Tr. at 46. He did acknowledge that the change in diagnosis is understandable to an extent because Petitioner never lost her reflexes. *Id.* Dr. Kinsbourne noted that loss of reflexes affects "the great majority of people with GBS." *Id.* He cited medical literature finding that about 10 percent of patients with GBS do not lose their reflexes, and that some even have exaggerated reflexes. *Id.* at 47; Yuki, et al., *Guillain-Barré syndrome associated with normal or exaggerated tendon reflexes*, 259 J. NEUROL. 1181-90 (2012) (filed as Ex. 19) ("Yuki"). He opined that "there was no affirmative evidence for fibromyalgia" in the record. Tr. at 47. Dr. Kinsbourne posited that the burning pain that Petitioner reported in her legs was caused by small nerve fiber damage caused by GBS. *Id.* at 47-48. He noted that about half of GBS cases involve small fiber damage, and many have it for a long period of time. *Id.* at 48. Dr. Kinsbourne noted that Petitioner's skin biopsy did not show small fiber damage, but nevertheless opined that she suffered small fiber damage because "you can only biopsy one or two points in the skin, not the skin of the whole body." *Id.* at 49.

Dr. Kinsbourne testified that the duration of pain that Petitioner reported, approximately three years, is not unusual in GBS cases. Tr. at 49. He noted that the course of GBS involves an acute autoimmune attack followed by a period of residual symptoms, and that the length of time involved "varies enormously from person to person." *Id.* He testified that chronic inflammatory demyelinating polyneuropathy ("CIDP") is thought to be a chronic version of GBS and that he does not believe that Petitioner has CIDP. *Id.*

On cross-examination, Dr. Kinsbourne acknowledged that he is no longer seeing patients, and that during his time as a clinician, he saw many GBS patients, but no fibromyalgia patients. Tr. at 52-53.

Dr. Kinsbourne also disagreed with the conclusion that Petitioner's CSF analysis was normal. Tr. at 55. He opined that protein in "the CSF was elevated and it was elevated at the level that's very typical in fairly early GBS." *Id.* at 55-56. He reiterated his opinion that the fact that Petitioner never lost her reflexes "undermined [her providers'] confidence" in the GBS diagnosis because they were unaware of the literature suggesting that some GBS patients never lose their reflexes, and some indeed have exaggerated reflexes. *Id.* at 58; Yuki. Dr. Kinsbourne posited that

providers who diagnosed fibromyalgia but did not see Petitioner until after onset of her condition did not realize that the onset was inconsistent with fibromyalgia. *Id*. at 59. Rather, he opined that what appeared to be symptoms of fibromyalgia were in fact "residual injuries caused by the acute but mild and brief GBS attack." *Id.* at 59-60.

Dr. Kinsbourne went on to explain that his assessment of Petitioner's GBS case as "mild" was based in part on the fact that she recovered on her own without resort to IVIG or plasmapheresis. Tr. at 61.

With regard to diagnosis of GBS in general, Dr. Kinsbourne opined that CSF protein analysis, EMG, and deep tendon reflex exam are appropriate tests. Tr. at 68. He opined that, because there is variation according to the stage and severity of the disease, there is no specific protein level in the CSF that would indicate a patient does or does not have GBS. *Id.* He opined that the CSF is typically normal in the first week of the GBS disease process and that it typically rises in the second week. *Id.* He testified that Petitioner's CSF analysis was done on her admission to the hospital roughly 10 days after onset, and that the results were what he would have expected given the stage and severity of her case. *Id.*

Dr. Kinsbourne also stated that the fact that Petitioner's EMG was normal does not change his opinion that Petitioner had GBS. Tr. at 69. He opined that, because Petitioner had a mild case of GBS that did not require treatment, he did not find it surprising that the EMG was not diagnostic. *Id.* Dr. Kinsbourne explained that GBS onset can be sudden and that the acute autoimmune attack phase typically lasts about four weeks, after which the damage to the nervous system "can result in handicaps that last for years, as in this case." *Id.* at 70. Dr. Kinsbourne posited that Petitioner's EMG may have been normal because the acute autoimmune attack phase of the disease process had already subsided. *See id.* at 69.

Dr. Kinsbourne opined that it is possible that Petitioner had fibromyalgia at some point. Tr. at 71. He added that "[a]nyone could have it at any time" and that it is "a very common condition." *Id.* He emphasized that facial diplegia is very typical in cases of GBS and not at all consistent with fibromyalgia. *Id.* at 74. He went so far as to opine that facial diplegia is enough on its own to clinically diagnose GBS. *Id.* Based on the timeline of Petitioner's symptoms, Dr. Kinsbourne posited that the acute autoimmune attack phase of her GBS ended around the end of January or beginning of February 2014. *Id.* at 72.

Finally, Dr. Kinsbourne responded to Dr. Vartanian's testimony that Petitioner's initial headache was likely the result of an annular tear. Tr. at 172-74. He remarked that this explanation was "appealing," but was never investigated. *Id.* at 173-74. He concluded that it was possible, but that he maintained his opinion that the flu vaccine caused Petitioner's condition. *Id.* at 173.

D. Respondent's Expert – Timothy Vartanian, MD, PhD

1. Qualifications

Dr. Vartanian is a board-certified neurologist who subspecializes in the research and care of patients with inflammatory demyelinating diseases. Ex. B at 1 (hereinafter "Vartanian CV").

Dr. Vartanian taught at Harvard Medical School from 1992-2009 and is currently a professor of neurology and neuroscience at Weill Cornell Medical College of Cornell University. *Id*. at 2. He is the attending neurologist at New York Presbyterian Hospital; Chief Scientist at Neurogen Research Foundation; and Director of the Judith Jaffe Multiple Sclerosis Center at Beth Israel Deaconess Medical Center. *Id*. at 2-3,7. Dr. Vartanian has published over 60 peer-reviewed papers and is a peer editor for many publications, some of which include Journal of Cell Biology, Journal of Neuroscience, Brain, Developmental Neuroscience, and Annals of Neurology. *Id*. at 11-19.

I recognized Dr. Vartanian as expert in neurology, biochemistry, molecular biology and autoimmune demyelinating diseases. Tr. at 116.

2. Expert Report

In his expert report, Dr. Vartanian opined that "the clinical record does not support a diagnosis of GBS for multiple reasons." Ex. A ("Vartanian Rep.") at 12. He summarized his reasons as follows: (1) Petitioner's clinical presentation is not typical of GBS because she never lost her reflexes; (2) clinical features such as sensory level are unusual for GBS; (3) Petitioner's EMG and NCS were normal even when she was still symptomatic; (4) she had only mildly elevated protein in her CSF; (5) Dr. Dotson had opined that the GBS diagnosis was made without objective evidence. *Id.*

Dr. Vartanian noted that alternative diagnoses of fibromyalgia and small fiber neuropathy had been proposed. Vartanian Rep. at 12. He noted that "small fiber neuropathy is associated with chronic metabolic and inflammatory diseases." *Id.* He opined that "[t]here is no epidemiological association between distal small fiber neuropathy and influenza vaccination." *Id.* at 13.

Dr. Vartanian next responded to points made by Dr. Karussis in his expert report. Dr. Vartanian disagreed with Dr. Karussis's observation that Petitioner's medical records showed reduced nerve conduction velocity. Vartanian Rep. at 15. He argued instead that Petitioner's EMG/NCS was normal and was performed while she was symptomatic. *Id.*

Dr. Vartanian next responded to Dr. Karussis's observation that the change in diagnosis from GBS to fibromyalgia was "puzzling." Vartanian Rep. at 15-16. Dr. Vartanian observed that "[t]he diagnosis of fibromyalgia may or may not be supported but I can certainly see why it was proposed." *Id.* at 16.

Dr. Vartanian disagreed with Dr. Karussis's opinion that Petitioner's autonomic nervous system was involved in her condition. Vartanian Rep. at 16. He argued that "there was minimal autonomic dysfunction" and that "most of the testing was normal." *Id*.

Dr. Vartanian next responded to points made by Dr. Shoenfeld in his expert report. In response to Dr. Shoenfeld's observation that GBS is a demyelinating polyneuropathy, Dr. Vartanian noted that "[s]ome demyelinating polyneuropathies are included in the spectrum of GBS but not all demyelinating neuropathies are GBS." Vartanian Rep. at 17.

Dr. Vartanian next responded to Dr. Shoenfeld's comment that it was unclear why

Petitioner's providers changed her diagnosis from GBS to fibromyalgia. Vartanian Rep. at 17. Dr. Vartanian noted that the "consideration of fibromyalgia over GBS was based on clinical presentation, exam, and the absence of a significantly high elevation in CSF protein." *Id.*

Dr. Vartanian disagreed with Dr. Shoenfeld's opinion that components of the flu vaccine share several peptides with proteins in myelin, and that this substantiates Petitioner's GBS diagnosis. Vartanian Rep. at 20. Dr. Vartanian opined that this logic contains "two fundamental flaws." *Id.* First, he stated that given the large number of flu vaccine doses administered each year, we would expect to see a high incidence of vaccine-induced GBS if there were an immunologically significant number of shared epitopes. *Id.* Second, Dr. Vartanian noted "the idea that identity of five or six amino acids, sequential or non-sequential, with a putative antigen is sufficient evidence for a molecular mimic fails on biologic stringency." *Id.* He cited medical literature indicating that identity of short amino acid chains is merely a matter of chance. *Id.* at 21 (citing Silvanovich, et al., *The Value of Short Amino Acid Sequence Matches for Prediction of Protein Allergenicity*, 90(1) TOXICOLOGICAL SCI. 252-58 (2006) (filed as Ex. V)).

3. Response to My Questions

In response to the questions I posed to the parties' experts (ECF No. 60), Dr. Vartanian reiterated his opinion that Petitioner's clinical presentation does not support a diagnosis of GBS. Vartanian Answers at 1. He again noted that Petitioner's reflexes were brisk and intact, the presence of a sensory level, and normal EMG and NCS months after clinical onset all indicated that she did not have GBS. *Id.*

4. Testimony

Dr. Vartanian testified at the entitlement hearing on November 8, 2021. He began by opining that Petitioner did not have GBS. Tr. at 118. He went on to explain that the general approach to GBS diagnosis involves three criteria: (1) characteristic clinical presentation, (2) characteristic CSF findings, and (3) a characteristic EMG nerve conduction study. *Id.* He opined that none of these criteria are met in Petitioner's case. *Id.*

With regard to Petitioner's diagnosis of fibromyalgia, Dr. Vartanian testified that the record does not definitively establish that Petitioner had fibromyalgia, but that it is the most likely diagnosis because it is "the most fitting with her constellation of symptoms." Tr. at 118-19.

Dr. Vartanian opined that the sudden, acute low back pain Petitioner experienced on December 16, 2013, was in fact not related to her condition, be it GBS, fibromyalgia, or small fiber neuropathy. Tr. at 119-20. He noted that low back pain is not uncommon in cases of GBS, but that it is typically a "dull, aching pain" rather than an "acute, sharp, lancinating pain." *Id.* at 120. He also testified that Petitioner's pain onset occurred "in a characteristic setting for acute lower back pain [or] strain, which was physical activity." *Id*. Dr. Vartanian went on to note that Petitioner's December 20, 2013, MRI showed an annular tear in the L4-L5 disc, which he opined would explain the pain she experienced beginning on December 16. *Id.* at 120-21. Dr. Vartanian explained that the annulus is the thick, fibrous capsule surrounding the disc and that physical activity can cause the annulus to rupture and the disc to extrude. *Id.* at 121. Such a rupture and

extrusion can be extremely painful. *Id.* Dr. Vartanian opined that Petitioner's "clinical presentation was characteristic of a disc rupture, an annular tear." *Id.* at 122. He added that the MRI on December 20 was "fully diagnostic." *Id*. at 123.

Dr. Vartanian testified that in Petitioner's case initially, "the working diagnosis was GBS." Tr. at 124. He opined that "in medicine…this is extremely common…based on that constellation of symptoms and findings, there is a working diagnosis and maybe other alternative diagnoses…commonly called differential diagnoses." *Id.* He noted that GBS was never confirmed. *Id.* at 125.

Dr. Vartanian testified that it is significant that Petitioner never lost her reflexes. Tr. at 125. He added that loss of reflexes is characteristic, "almost pathognomonic," in most GBS cases. *Id.* He opined that "[t]he fact that reflexes remained present throughout her clinical course…is not consistent with the vast majority of GBS." *Id.* at 125-26.

Dr. Vartanian also opined that Petitioner's only minimally elevated CSF protein is significant. Tr. at 126. He explained that in GBS cases, CSF protein is typically normal or mildly elevated for the first week after onset and becomes "quite high" as the disease progresses, approaching 80-120. *Id.* He noted that Petitioner's CSF protein analysis was done when she was in "an active state of being symptomatic" and that the results were only mildly elevated. *Id.* at 127. Dr. Vartanian opined that disc rupture and enhancement of the meninges, both of which Petitioner experienced, can also cause slight elevation in CSF protein; he further highlighted that several of Petitioner's treating physicians remarked that the CSF protein was not significantly elevated such that it would support a GBS diagnosis. *Id.*

Dr. Vartanian next addressed Petitioner's EMG nerve conduction results. Tr. at 128. He opined that these "were completely normal at a time when she was extremely symptomatic." *Id.* He disagreed with Dr. Kinsbourne's opinion that Petitioner could have a normal EMG at this stage of her condition and still have GBS, saying that the results "necessarily need to be abnormal…if [GBS] was the explanation for her disease." *Id.* He later disagreed with Dr. Kinsbourne's theory that Petitioner's EMG results were normal because she had a mild case of GBS, pointing out that if her case were so mild as to be "clinically irrelevant," that would not explain why the symptoms she experienced were not mild. *Id.* at 148.

Dr. Vartanian also found the fact of Petitioner's improvement without resort to IVIG or plasmapheresis significant. Tr. at 128-29. He opined that GBS is a progressive illness that "tends to persist or progress in the absence of treatment." *Id.* at 128. He added that, while cases of spontaneous remission have been known, "no one would leave a bona fide case of GBS untreated in this modern era." *Id.* at 128-29. He reiterated his opinion that Petitioner did not have GBS, adding that "you wouldn't make a diagnosis of GBS if all of the criteria that the neurologic community uses to make a diagnosis of GBS are all normal." *Id.* at 129-30.

Dr. Vartanian did acknowledge that Petitioner's initial clinical presentation was concerning and that her treating physicians were right to suspect and test for GBS. Tr. at 130. He noted that "numerous neurologic experts…felt the diagnosis of GBS did not fit at all, and this is when other things were raised such as small fiber neuropathy and fibromyalgia." *Id.* at 131.

While maintaining his position that Petitioner did not have GBS, Dr. Vartanian declined to opine on what the correct diagnosis was. Tr. at 136. He noted that Petitioner had a gastrointestinal illness in November 2013. *Id.* at 137. Although her antibody test for c. jejuni in December of that year was negative, he noted that conventional tests for c. jejuni sometimes fail to detect it. *Id.* He testified that the two primary issues with implicating a vaccine as having caused a neurological illness are "plausible biologic evidence that that process actually exists in these patients, and relevant timing." *Id.* at 138. He stated that he was unaware of any epidemiological data associating the flu vaccine with fibromyalgia. *Id.* at 140.

Dr. Vartanian next addressed the issue of the timing of onset of Petitioner's condition. Tr. at 143-44. He was unequivocal in his opinion that the low back pain Petitioner experienced on December 16, 2013, was caused by the annular tear in her L4-L5 disc. *Id.* He added that the onset of symptoms of fibromyalgia was unclear from the record. *Id.* at 143. Maintaining his opinion that Petitioner did not have GBS, he opined that the onset of symptoms "that could potentially be related to GBS" was December 24-25, 2013, approximately 48 days after vaccination. *Id.* at 144. Dr. Vartanian opined that 48 days after vaccination is not an appropriate timeframe to support causation. *Id.* He remarked that vaccination is "a potent immune stimulus" and that the ensuing immune response is "fairly predictable in terms of the temporal course of antibody response. *Id.* at 144-45. He added that "most vaccines induce a relatively robust humeral response in two weeks," meaning that symptom onset should occur two to three weeks after vaccination. *Id.* at 145. He opined that the timing of onset of Petitioner's condition does not fit either GBS or fibromyalgia. *Id.* at 146.

Dr. Vartanian opined that the record as to Petitioner's facial diplegia was "perplexing" in that not all of Petitioner's providers made a note of it. Tr. at 148. He opined that he would not expect facial diplegia associated with GBS to be "transient," but in Petitioner's case, "it wasn't substantiated on subsequent exams." *Id.* He noted that demyelination severe enough to result in facial diplegia can take weeks or months to repair. *Id.* at 160. He later opined that Dr. Pidgeon's examination of Petitioner had been less than thorough and that Dr. Pidgeon had failed to describe Petitioner's facial diplegia in sufficient detail. *Id.* at 157. Dr. Vartanian reiterated his opinion that Petitioner did not have GBS, adding that if she did, he would suspect her prior infection, rather than the flu vaccine, as being causative. *Id.* at 155.

Dr. Vartanian acknowledged that the possibility of GBS evolving into fibromyalgia as Dr. Kinsbourne theorized is the subject of ongoing investigation. Tr. at 154 ("I'm not sure I would regard it as definitive or textbook…I don't really dispute it as a possibility."). He also acknowledged that there is medical literature documenting patients with GBS who experience burning, pain, and paresthesias. *Id.*

Dr. Vartanian expressed uncertainty as to one aspect of Petitioner's medical record. He opined that the evidence of meningeal or leptomeningeal enhancement of Petitioner's thoracic spinal cord had gone without any further evaluation. Tr. at 159. He opined that this omission was bothersome. *Id.*

Dr. Vartanian next explained how elevated protein in CSF can be an indicator of GBS. Tr. at 163. He explained that normally, the protein content of CSF is very low. *Id.* at 164. In GBS

patients, there is frequently damage to the barrier between the bloodstream and the spinal cord, causing protein, mainly albumin, to leak into and mix with CSF. *Id.* at 163-64. This can cause the level of protein in CSF to become "quite high." *Id.* at 164. He again noted that Petitioner's CSF protein was only minimally elevated, a finding that could be explained by the ruptured L4-L5 disc. *Id.*

Dr. Vartanian also noted that Petitioner had taken cyclobenzaprine, a muscle relaxer, and Savella, a selective serotonin reuptake inhibitor, as treatment for fibromyalgia, and had seen some improvement. Tr. at 167.

IV. Affidavit and Fact Testimony: Melissa Larson

A. Petitioner's Affidavit

Petitioner filed her affidavit on April 27, 2017. Ex. 14 ("Pet. Aff."). In it, Petitioner averred that she received the allegedly causal flu vaccine on November 6, 2013. *Id.* at 2. She stated that, on December 4, 2013, she "left work early because [she] was feeling hot, weak, and [she] was sweating." *Id.* She described the onset of back pain that was "not extremely painful" in the evening on December 16, 2013, and waking the next morning with more severe pain such that she reported to the emergency room later that day. *Id.* She stated that playing with her child in the evening of December 16 seemed to exacerbate her back pain. *Id.*

Petitioner next described the progression of her pain and other symptoms over the following days. Pet. Aff. at 3. She stated that she saw Dr. Bhushan on December 20 and was prescribed Percocet, prednisone, a muscle relaxer, and an anti-inflammatory. *Id.* She described worsening pain and weakness on December 20, and experienced trouble walking. *Id.* Petitioner averred that she developed worsening pain such that she was unable to get out of bed from December 20 to 23, and that the medication did not help. *Id.* She returned to Dr. Bhushan on December 24 due to her worsening pain. *Id.* Dr. Bhushan referred her to a neurologist. *Id.*

Petitioner stated that on December 25, 2013, she began to have difficulty breathing while trying to sleep. Pet. Aff. at 3. This feeling continued through the night and did not improve when she changed position. *Id.* Petitioner's pain continued the following day and she continued to feel hot and to have trouble breathing. *Id.* Petitioner stated that she saw a neurologist on December 27. *Id.* Her legs felt heavy and she had trouble standing, walking, moving her arms, and speaking. *Id.* She was sent to St. Luke's Hospital in Milwaukee. *Id.*

B. Petitioner's Testimony

Petitioner testified at the entitlement hearing on November 8, 2021. Petitioner was 36 years old and working as a respiratory therapist when she received the flu vaccine on November 6, 2013. Tr. at 8. Flu vaccination was a condition of her employment at Aurora Healthcare, and she received the vaccine at work. *Id.*

Petitioner testified that she first began experiencing problems on the evening of December 16, 2013. Tr. at 8. After a day and night of rest, Petitioner's pain had worsened and she reported

to the emergency room. *Id.* at 9. Petitioner's regular physician prescribed muscle relaxers and steroids, but the pain continued and was severe enough that Petitioner was unable to get into the shower unassisted. *Id.* at 9-10.

Between December 16 and 23, 2013, Petitioner felt her condition worsen. Tr. at 11. She described the muscle weakness she experienced, analogizing it to the sensation of having cinder blocks attached to each of her feet and of having foam mattress pads wrapped around each of her limbs. *Id.* She would also wake with a gasp in the middle of the night. *Id.* at 11-12.

In December 2013, Petitioner saw her regular physician, who ordered an MRI. Tr. at 12. The MRI revealed a bulging disc between L4 and L5. *Id.* She saw Dr. Pidgeon, a neurologist, on December 27, 2013. *Id.* Petitioner required assistance from her teenage son to get into the car and she felt like a person was sitting on her chest during the ride to Dr. Pidgeon's office. *Id.* 12-13. She described the sensation of her face drooping as feeling as though her face was made of wax. *Id.* at 13. Dr. Pidgeon recommended that she be transferred to the emergency room, which she was that same day. *Id.* at 14. She testified that her speech was slurred and described feeling like her body was made of Jell-O. *Id.* at 14-15. She also described feeling alternately hot and cold. *Id.* at 15.

Petitioner testified that prior to the onset of her condition, she was in perfect health and was able to work a 12-hour shift as a respiratory therapist with only minimal breaks. Tr. at 16. Roughly one month after her initial hospital admission, Petitioner began experiencing prickling or burning pain in the backs of her legs. *Id.* at 18. This prevented her from sitting or kneeling comfortably and lasted about one year. *Id.* During this time, heaviness in her arms also prevented her from being able to lift anything or fold laundry. *Id.* at 19.

Petitioner testified that she began to feel better around December 28, 2013. Tr. at 19. However, she had to take frequent rest breaks from whatever she was doing. *Id.* at 20. She was discharged from the hospital on December 31 because her condition plateaued, and her providers were no longer concerned about respiratory failure. *Id.* at 21. She was never put on a ventilator. *Id.*

In March 2014, Petitioner was readmitted to the hospital when her condition suddenly worsened after she attempted to clean her bathroom. Tr. at 21. She had pain in the backs of her legs, heaviness and weakness in her limbs, and drooping in her face. *Id.* at 22. The pain in her legs persisted until December 2015, when her condition generally began to improve. *Id.* at 23. Petitioner returned to work as a respiratory therapist in April 2016. *Id.*

Petitioner testified that, shortly after she received the flu vaccine in early November 2013, she and her family all came down with a stomach virus that lasted three to four days. Tr. at 24. Petitioner never had a fever during this time. *Id.* at 25.

During cross-examination, Petitioner confirmed that, on December 18, 2013, her only symptom was back pain. Tr. at 25. Petitioner disagreed with the medical record of her December 24, 2013, visit to her regular physician which states that Petitioner denied weakness, tiredness, and malaise at that visit. *Id.* at 25-26. She testified that she had the feeling of cinder blocks on her limbs

and "could not move" at that time. *Id.* at 26. Petitioner confirmed that she began feeling weak and numb all over approximately two to three days before she saw Dr. Pidgeon on December 27. *Id.* at 27. Petitioner confirmed that she never received IVIG or plasmapheresis. *Id.* at 28.

Petitioner testified that, while it is true that Drs. Cueva, Marriott, Lotz, and Dotson believed that she did not have GBS, none of these providers saw her during the "acute stage" of her illness. *Id.* at 29-30.

Petitioner testified that she was diagnosed with fibromyalgia in October 2014. Tr. at 30. Petitioner received treatment for fibromyalgia for two years, but testified that she was reluctant to take the medications she was prescribed because she did not want to be tired. *Id.* at 32.

V. Applicable Law

A. Petitioner's Burden

Under the Vaccine Act, a petitioner may prevail in one of two ways. First, a petitioner may demonstrate that she suffered a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the time period provided in the Table. § 11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); *see* § 13(a)(1)(B). Second, where the alleged injury is not listed in the Vaccine Injury Table, a petitioner may demonstrate that she suffered an "off-Table" injury. § 11(c)(1)(C)(ii).

For both Table and non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010); *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873* (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records of 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*. *Althen* requires that petitioner establish by preponderant evidence that the vaccinations he 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.

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

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Special Masters, despite their expertise, are not empowered by statute to conclusively resolve what are 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) ("[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 her overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs*., 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).

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, because 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"); *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing … that mandates that the testimony of a treating physician is sacrosanct -- that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record -- including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs*., 100 Fed. Cl. 742,

749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *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. denied after remand on other grounds*, 105 Fed. Cl. 353 (2012), *aff'd without op.,* 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.")).

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 his or 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"). The flexible use of the *Daubert* factors to evaluate persuasiveness and reliability of expert testimony has routinely been upheld. *See*, e.g., *Snyder*, 88 Fed. Cl. at 743. In this matter, (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). 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"); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. Consideration of Medical Literature

Finally, although this decision discusses some but not all of the medical literature in detail, I have 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).

VI. Analysis

Petitioner alleges that the flu vaccination she received on November 6, 2013, caused her to develop GBS. Petitioner argues that she is entitled to compensation based on a causation-in-fact analysis as opposed to a Table claim.[10] Pet. at 1; Pet'r's Pre-Hearing Brief at 2; Pet'r's Post-Hearing Brief at 2.

As a threshold matter, a petitioner must establish that she suffers from the condition for which she seeks compensation. *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1346 (Fed. Cir. 2010). "The function of a special master is not to 'diagnose' vaccine-related injuries, but instead to determine 'based on the record as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [petitioner]'s injury.'" *Andreu v. Sec'y of Health & Hum. Servs*., 569 F.3d 1367, 1382 (Fed. Cir. 2009) (quoting *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994)). "Although the Vaccine Act does not require absolute precision, it does require the petitioner to establish an injury -- the Act specifically creates a claim for compensation for 'vaccine-related injury or death.'" *Stillwell v. Sec'y of Health & Hum. Servs*., 118 Fed. Cl. 47, 56 (2014) (quoting 42.U.S.C. § 300aa-11(c)). Accordingly, the Federal Circuit has established that it is "appropriate for the special master to first determine what injury, if any, [is] supported by the evidence presented in the record" before applying a causation analysis pursuant to *Althen v. Secretary of Health & Hum. Services, 418 F.3d 1274 (Fed. Cir. 2005). Lombardi v. Sec'y of Health & Hum. Servs*., 656 F.3d 1343, 1351-53 (Fed. Cir. 2011). In this case, Petitioner has not demonstrated that she suffered from GBS.

A. Petitioner has not Established that GBS is her Correct Diagnosis

When determining whether a petitioner has adequately proven a demonstrable injury, special masters analyze the petitioner's complete medical records filed into the record. 42 U.S.C. § 300aa-11(c)(2). Medical records created contemporaneously with the events they describe are presumed to be accurate and complete such that they present all relevant information on a petitioner's health problems. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

As an initial matter, Petitioner's experts did not agree on her diagnosis. Dr. Karussis and Dr. Kinsbourne opined that Petitioner developed GBS in December 2013 and that her symptoms

[10] GBS was added to the Vaccine Injury Table in March of 2017. However, the Vaccine Act specifies that the version of the Table that exists at the time a petition is filed is the version of the Table that controls. 42 U.S.C. § 300aa-14(c)(4). Because this case was filed in 2016, there is no Table injury of GBS relative to this petition. Theoretically, Petitioner could have refiled this case on or after March 21, 2017, to take advantage of the addition of GBS to the Table. However, this was not done. In any event, even if Petitioner had refiled such that a Table Injury could be considered, this fact would not change my weighing of the evidence and my finding that Petitioner has not preponderantly demonstrated that she suffered GBS. For example, the QAI for GBS specifies that a petitioner must demonstrate their condition to have been monophasic in order to establish GBS as a Table Injury, and I conclude in section (VI)(A)(1) *infra* that this Petitioner's clinical presentation was not monophasic. 42 C.F.R. § 100.3.

in March 2014 were also attributable to GBS. They specifically testified that she did not have fibromyalgia. *See* Karussis Rep. at 5 (stating "it is not clear why fibromyalgia has been proposed to substitute the Guillain Barre syndrome diagnosis."); Tr. at 47 (Dr. Kinsbourne testifying that "there was no affirmative evidence for fibromyalgia that I could see in the record."). Dr. Shoenfeld stated that Petitioner's GBS in December 2013 progressed to fibromyalgia by a parallel autoimmune reaction to the flu vaccine. Tr. at 91. At the end of the hearing, I asked Petitioner's counsel to state what injury Petitioner was alleging. Counsel responded as follows:

> MR. MCHUGH: She's alleging Guillain-Barre syndrome and the aftermath of the two years of this burning sensation and the lack of energy that kept her from working. I guess it's actually two and a half years.
>
> THE COURT: Is she alleging fibromyalgia?
>
> MR. MCHUGH: No, she's alleging Guillain-Barre syndrome. Now, we understand--
>
> THE COURT: I understand that.
>
> MR. MCHUGH: Yeah. The symptoms -- we believe the symptoms of one become the other. So, yes, there are two schools of thought that fibromyalgia can follow it, or be part of it, but it's -- the literature seems to indicate that this kind of sequelae is seen in Guillain-Barre. So it really doesn't matter whether it's Guillain-Barre syndrome or fibromyalgia, it started with the vaccination and the initial attack of Guillain-Barre, which then may have converted to something else. …

Tr. at 177 (emphasis added). Because I have determined that Petitioner did not have GBS, I have not analyzed whether she developed fibromyalgia after and as a consequence of GBS.

According to Respondent's expert, Dr. Vartanian, a GBS diagnosis based on "clinical presentation, EMG/NCS findings, and CSF analysis." Vartanian Rep. at 11. Petitioner's expert, Dr. Kinsbourne, agreed. Tr. at 68. I now examine each of these in turn, as well as the opinions of Petitioner's treating physicians.

1. Clinical Presentation

First, Dr. Vartanian opined that Petitioner's medical records show that her initial GBS diagnosis was never confirmed. Tr. at 125. Dr. Vartanian noted in his expert report and during testimony that Petitioner's case is not typical of GBS, emphasizing in particular that Petitioner never lost her reflexes. Vartanian Rep. at 12; Tr. at 125. Petitioner's medical literature supports this contention. Fokke, et al., *Diagnosis of Guillain-Barré syndrome and validation of Brighton criteria*, 137 BRAIN 33-43 (2014) (filed as Ex. 17) ("Fokke") (noting that all of the study's 395 GBS patients developed hyporeflexia in the legs); Dimachkie & Barohn, *Guillain-Barré Syndrome and Variants*, 31(2) NEUROL. CLINICS 491-510 (2013) (filed as Ex. 22) ("Dimachkie & Barohn") (clinical features of GBS include hyporeflexia or areflexia "within the first few days, but this may be delayed by up to a week."). Petitioner presented evidence that some GBS patients do not lose

reflexes. Yuki found that 10% of patients in their study's cohort retained reflexes or exhibited exaggerated reflexes throughout their disease course. Yuki at 1181. Fokke noted that two patients in their cohort "had initial hyperreflexia in weak limbs," one of whom was areflexic the next day. Fokke at 37. I conclude that it is possible, though rare, for a patient to have GBS but not lose reflexes. The fact that Petitioner had exaggerated reflexes suggests that GBS is not her correct diagnosis.

Second, the medical literature characterizes GBS as a monophasic disorder.[11] Fokke at 40; Goodfellow & Willison, *Guillain-Barré syndrome: a century of progress*, 12 NATURE REVS.: NEUROL. 723-31, 724 (2016) (filed as Ex. 18) ("Goodfellow & Willison"). GBS is known to recur in a small minority of patients (2-5%) for reasons as yet unknown. Kuitwaard, et al., *Recurrent Guillain-Barré syndrome*, 80 J. NEUROL, NEUROSURGERY, & PSYCHIATRY 56-59, 56 (2009) (filed as Ex. 21) ("Kuitwaard"). Petitioner's condition was improving in early 2014 and then deteriorated again suddenly in March of that year when Petitioner had to be hospitalized for a second time. Tr. at 19-21. This, by definition, is not a monophasic disorder. The course of Petitioner's disease is inconsistent with GBS because Petitioner experienced two distinct episodes of clinical worsening.

Third, the experts disagree as to the significance of Petitioner's facial diplegia. Dr. Kinsbourne opined that facial diplegia is "uniquely found in [GBS] in this particular context" and that he knew of no alternative diagnosis that would explain the rapid onset of facial diplegia that Petitioner experienced. Tr. at 41. He also opined that facial diplegia is inconsistent with fibromyalgia. *Id.* at 74. Dr. Vartanian countered that Petitioner's facial diplegia was never completely described and that it appeared to come and go. Tr. at 148. This position is supported by Petitioner's medical records. (Compare Ex. 4 at 5, Petitioner's December 27, 2013 visit with Dr. Pidgeon where he noted facial diplegia with Ex. 5a at 77, an ER visit that same day where Dr. Ravichandran documented no facial weakness and "no plegia"). Dr. Vartanian opined that in a case of GBS, he would not expect facial diplegia to be "transient" in this way. *Id*. Dr. Vartanian's opinion is persuasive; furthermore, Petitioner did not provide evidence to rebut Dr. Vartanian's opinion on this issue.

Finally, I note that Petitioner's condition improved after each hospitalization without resort to plasmapheresis or IVIG, the two primary treatments for GBS. Tr. at 60, 70; Goodfellow & Willison at 727-28. Dr. Vartanian opined that, while spontaneous remission does occur in some cases, GBS is in general a progressive disorder that "tends to persist or progress in the absence of treatment." Tr. at 128-29. Fokke reported a mere 4% of the GBS patients in their cohort recovered without treatment. Fokke at 36. It is compelling, too, that Petitioner did undergo treatment for fibromyalgia, which caused her condition to improve. Tr. at 167.

Taking these four pieces of evidence together, I conclude that Petitioner's clinical presentation was not consistent with GBS.

2. CSF Analysis

Petitioner underwent a lumbar puncture on December 27, 2013, roughly ten days after the

[11] Monophasic means "having one phase or variation." DORLAND'S, https://www.dorlandsonline.com/dorland/definition?id=32043 (last visited Apr. 17, 2023).

onset of her back pain, and again on March 14, 2014, upon her readmission to the hospital. Ex. 5c at 24; Ex. 5e at 5. At both times, the concentration of protein in her CSF was slightly elevated (57 and 49 respectively). *Id*. Further CSF studies after March 14, 2014, were normal. Ex. 5e at 20. Dr. Kinsbourne opined that CSF is typically normal during the first week after GBS onset and rises in the second week. *Id*. at 68. Petitioner's medical literature supports this contention. Fokke at 6 (finding that patients were more likely to show elevated CSF protein as time progressed after symptom onset). He further opined that Petitioner's first CSF analysis showed elevated protein consistent with what he would expect early in the course of GBS. Tr. at 56. Dr. Vartanian agreed that CSF protein tends to rise in the second week after onset, but opined that it was significant that Petitioner's CSF protein was only slightly elevated even as the symptoms she was experiencing were severe. *Id*. at 127. Dr. Karussis described that Petitioner's CSF studies returned "negative findings." Karussis Rep. at 9.

Dr. Vartanian also compellingly explained that the annular tear in Petitioner's L4-L5 disc and the meningeal enhancement on her MRI could explain the slight elevation in her CSF protein. Tr. at 127. On March 14, 2014, Dr. Cueva also noted that the bulging disc issue may have caused Petitioner's CSF protein concentration to rise slightly. Ex. 5e at 20. Dr. Vartanian agreed with Petitioner's treating physicians that the protein level in her CSF was not sufficiently high to support a diagnosis of GBS. Tr. at 127.

I conclude that the increase in Petitioner's CSF protein is reasonably explained by her annular tear at L4-L5.

3. Nerve Conduction Study

Petitioner underwent nerve conduction testing on March 18, 2014, during her second hospital admission. Ex. 5e at 33. Dr. Marriott noted that the results were normal and that the etiology of Petitioner's symptoms was still unknown. *Id*. Dr. Kinsbourne stated that the fact that Petitioner's EMG was normal does not change his opinion that Petitioner had GBS. Tr. at 69. He opined that, because Petitioner had a mild case of GBS that resolved without IVIG or plasmapheresis, he did not find it surprising that the EMG was not diagnostic. *Id*. Dr. Vartanian disagreed, opining that, if GBS was the proper diagnosis, he would have expected abnormal EMG results given the severity of the symptoms Petitioner reported at that time. Tr. at 128.

Petitioner's own medical literature emphasizes the importance of EMG as a diagnostic tool for GBS. Dimachkie & Barohn at 495 ("When GBS is suspected, electrophysiologic studies are essential to confirm the diagnosis and exclude its mimics."); Fokke at 38 (finding that only 1% of GBS patients in the study's cohort had normal EMG results).

I find that Petitioner's EMG results are not consistent with a diagnosis of GBS.

4. Treating Physicians

When weighing evidence, special masters should consider the opinions of treating physicians. *Capizzano*, 440 F.3d at 1326. The opinions of treating physicians about the appropriate diagnosis are often persuasive because the physicians 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).

Petitioner's treating physicians considered a GBS diagnosis upon her initial presentation in December 2013. *See* Ex. 4 at 5 (medical record from December 27, 2013 where Dr. Pidgeon expressed his concern that Petitioner had GBS which could be a reaction to the flu shot); Ex. 5a at 81 (December 28, 2013 visit with Dr. Francisco Aguilar who noted that the "presumptive diagnosis is possible Guillain-Barre."); Ex. 5a at 94-95 (medical record from December 29, 2013, where Dr. Ravichandran noted that Petitioner's symptoms were clearly related to post-flu shot demyelinating neuropathy); Ex. 5a at 69-70 (discharge paperwork from December 31, 2013, indicating that Petitioner's diagnosis was generalized weakness and "possible" GBS).

Later in time, however, Petitioner's doctors began to disfavor a GBS diagnosis. On March 14, 2014, Dr. Cueva expressed doubt that Petitioner had GBS at that time and described her examination as "pretty benign." Ex. 5e at 4-5. During a visit on March 17, 2014, Dr. Marriott opined that Petitioner's condition was "[c]linically inconsistent with recurrent inflammatory neuropathy." *Id.* at 28. Dr. Bhushan believed Petitioner's symptoms were more likely to be somatoform in nature. Ex. 9 at 53. Dr. Lotz diagnosed Petitioner with "conversion reaction simulating weakness in the left leg." Ex. 11 at 4. He told Petitioner that she "does not have Guillain Barre or Guillain Barre-like disease." *Id.* In fact, Dr. Lotz told Petitioner "with certainty that she does not have a serious underlying neurologic disease." *Id.* In an examination on June 19, 2014, Dr. Dotson described that several of Petitioner's symptoms were "give way" and "nonphysiologic". She further opined on August 17, 2014, that Petitioner's prior GBS diagnosis was made "without objective evidence." Ex. 6a at 67.

Further, it is significant to the issue of diagnosis that Petitioner's treating physicians never chose to treat her with IVIG or plasmapheresis. Ex. 5a at 10, 70. Dr. Vartanian opined at the entitlement hearing that GBS is a progressive illness that "tends to persist or progress in the absence of treatment." *Id.* at 128. He added that, while cases of spontaneous remission have been known, "no one would leave a bona fide case of GBS untreated in this modern era." *Id.* at 128-29. I find that the majority of Petitioner's treating physicians did not believe that she had GBS. Furthermore, the fact that none of her doctors administered typical medical treatment for this condition further supports Respondent's position that GBS is not Petitioner's correct diagnosis.

The medical literature filed in this case indicates that GBS can be difficult to diagnose. Fokke refers to GBS as a "spectrum of neuropathic disorders that may differ in the underlying pathogenesis and clinical manifestations." Fokke at 34. GBS has no pathognomonic clinical characteristics, no known biomarkers, and a long list of conditions that may be clinically similar. *Id*. Petitioner and Respondent provided evidence that clinical presentation, CSF analysis, and EMG/NCS are the three indicators that support a diagnosis of GBS. Vartanian Rep. at 11; Tr. at 68. As shown above, Petitioner's medical records do not support a diagnosis of GBS with respect to any of these three domains. Dr. Vartanian testified that Petitioner's providers were right to suspect GBS at the time of symptom onset, but that later objective findings made it less likely. Tr. at 149.

Ultimately, if GBS was Petitioner's correct diagnosis, that would mean she is 1) among the

approximately 10% of patients who do not experience diminished reflexes (Yuki at 1181); 2) among the 2-5% of patients who do not have a monophasic course (Kuitwaard at 56); 3) among the 4% of GBS patients who recovered without treatment (Fokke at 36); and 4) among the approximately 1% of patients with normal EMG results (Fokke at 38). While the co-occurrence of all these clinical features is possible, I do not find it is more likely than not. Viewing the medical record as a whole in light of the expert testimony and medical literature, I find that Petitioner has not provided preponderant evidence that she had GBS.

Because Petitioner has not preponderantly established that she had GBS, further analysis is unnecessary. However, for the sake of completeness, I will briefly analyze the *Althen* prongs.

B. *Althen* Prong One

In the Vaccine Program, "to establish causation, the standard of proof is preponderance of evidence, not scientific certainty." *Langland v. Sec'y of Health & Hum. Servs.*, 109 Fed. Cl. 421, 441 (Fed Cir. 2013). Petitioner's burden under *Althen*'s first prong is to provide a medical theory causally connecting the vaccination and the injury. *Id.* This theory must be sound and reliable. *Boatmon*, 941 F.3d at 1359. For the reasons discussed in detail below, I find that Petitioner has provided a sound and reliable medical theory causally connecting the flu vaccine to GBS.

Petitioner correctly points out that the relationship between the flu vaccine and GBS is sufficiently compelling that Respondent added it to the Vaccine Program Table in 2017, thus triggering the presumption of causation in qualifying cases. "In placing GBS on the Vaccine Injury Table relative to the flu vaccine, respondent had already recognized a causal relationship between the flu vaccine and GBS under at least some circumstances." *Goforth v. Sec'y of Health & Hum. Servs*., No. 14-1128V, 2021 WL 6337672, at *33 (Fed. Cl. Spec. Mstr. Nov. 19, 2021) (citing National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 82 Fed. Reg. 6294-6301, 6295 (Jan. 19, 2017)).

Petitioner argues that she has satisfied prong one because "[t]he revised Table eliminates any question that influenza vaccine can cause GBS." Pet. Post-Hearing Br. at 10. As support for her claim that the flu vaccine can cause GBS, Petitioner cited medical literature and provided both expert reports and testimony from Dr. Shoenfeld. Dr. Shoenfeld's theory that similarity between peptide sequences in the flu vaccine and in nervous system proteins causes an autoimmune attack on the peripheral nervous system (i.e., molecular mimicry) is well established in the Vaccine Program. *See, e.g., Conte v. Sec'y of Health & Hum. Servs.*, No. 17-403V, 2020 WL 5743696, at *23 (Fed. Cl. Spec. Mstr. July 27, 2020); *Barone v. Sec'y of Health & Hum. Servs.*, No. 11-707V, 2014 WL 6834557, at *8 (Fed. Cl. Spec. Mstr. Nov. 12, 2014); *Stitt v. Sec'y of Health & Hum. Servs.*, No. 09-653V, 2013 WL 3356791, at *8 (Fed. Cl. Spec. Mstr. May 31, 2013).

Accordingly, I find that Petitioner has provided a sound and reliable medical theory causally linking the flu vaccine to GBS.

C. *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.

Prong two requires Petitioner to preponderantly show that the flu vaccine actually did cause her to develop GBS. While causation in flu vaccine/GBS cases is presumptive in certain instances, this does not reduce a petitioner's burden in an off-Table claim like this one. *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992) (quoting H.R. Rep. No. 908, 99th Cong., 2d Sess., pt. 1, at 15 (1986)). Congress was clear that "[s]imple similarity to conditions or time periods listed in the Table is not sufficient evidence of causation." *Id.*

As discussed above, I have found that Petitioner has not presented preponderant evidence that she had GBS at all. Accordingly, Petitioner cannot show that the flu vaccine caused her to develop GBS. Petitioner has not met her burden under *Althen* prong two.

D. *Althen* Prong Three

The timing prong contains two parts. First, a petitioner must establish the "timeframe for which it is medically acceptable to infer causation" and second, she must demonstrate that the onset of the disease occurred in this period. *Shapiro v. Sec'y of Health & Hum. Servs.,* 101 Fed. Cl. 532, 542-43 (2011), *recons. denied after remand on other grounds*, 105 Fed. Cl. 353 (2012), *aff'd without op.,* 503 F. App'x 952 (Fed. Cir. 2013).

There is no dispute that Petitioner received the flu vaccine on November 6, 2013. Ex. 2 at 2. Onset of the condition that Petitioner asserts is GBS is disputed, even among Petitioner's experts. Dr. Shoenfeld opined that Petitioner developed GBS "somewhere between December 6, 2013 – December 27, 2013," or 30 to 51 days after vaccination. Shoenfeld Answers at 1. Dr. Kinsbourne opined that Petitioner's GBS began with the severe lower back pain she experienced on December 16, 2013, 40 days after vaccination. Tr. at 40. On the other hand, Dr. Vartanian opined that the sudden, acute low back pain Petitioner experienced on December 16, 2013, was in fact not related to her condition, but instead to an annular tear. *Id.* at 119-20. Maintaining his opinion that Petitioner did not actually have GBS, he opined that the onset of symptoms "that could potentially be related to GBS" was December 24-25, 2013, approximately 48 days after vaccination. *Id.* at 144.

Petitioner's failure to show that she had GBS means (1) that the timeframe from which it is medically acceptable to infer that the vaccine caused GBS is moot; and (2) that Petitioner cannot show that she developed GBS within such a timeframe. Accordingly, Petitioner has not met her burden under *Althen* prong three.

VI. Conclusion

Upon careful evaluation of all the evidence submitted in this matter, including the medical records, the experts' opinions and medical literature, I conclude that Petitioner has not shown by preponderant evidence that she is entitled to compensation under the Vaccine Act. **Her petition is therefore DISMISSED. The clerk shall enter judgment accordingly.**[12]

IT IS SO ORDERED.

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

[12] 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.