In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: October 27, 2025

SAMUEL J. LABINE,	*	
	*	
Petitioner,	*	No. 17-1443V
	*	
v.	*	Special Master Young
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

David John Carney, Green & Schafle, LLC, Philadelphia, PA, for Petitioner.
Felicia Langel, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On October 5, 2017, Samuel J. LaBine ("Petitioner") filed a petition in the National Vaccine Injury Compensation Program (the Program").[2] The petition alleged that Petitioner received an influenza ("flu") vaccine on October 9, 2014, and "suffered from a Shoulder Injury Related to Vaccination ("SIRVA") in and to his left shoulder as a result of this vaccination including without limitation a brachial neuritis injury (specifically neurogenic thoracic outlet syndrome with brachial neuritis) which has required extensive medical treatment and surgery." Pet. at ¶ 1, ECF No. 1.

After carefully analyzing and weighing all the evidence and testimony presented in this case in accordance with the applicable legal standards,[3] I find that Petitioner has provided

[1] Because this Ruling 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 Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

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

[3] While I have reviewed all of the information filed in this case, only those filings and records that are most relevant to the Ruling will be discussed. *Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322,

preponderant evidence that the flu vaccine he received on October 9, 2014, caused him to suffer from brachial neuritis. Accordingly, Petitioner is entitled to compensation.

I. Procedural History

Petitioner filed his petition, medical records, and an affidavit on October 5, 2017. Pet.; Pet'r's Exs. 1–17, ECF Nos. 4–6. Additional medical records and an affidavit were filed on November 17, 2017, and January 17, 2018. Pet'r's Exs. 18–19, ECF Nos. 11, 13. Respondent filed his Rule 4(c) report, arguing against compensation, on May 18, 2018. Resp't's Rep., ECF No. 18.

I held a status conference on June 26, 2018, to discuss the evidence in the record at that time regarding the exact location of Petitioner's vaccination. ECF No. 23. Petitioner asserted that the evidence in the record was sufficient to find that Petitioner received his vaccination in his left shoulder and requested to file an expert report. *Id.*

On January 28, 2019, Petitioner filed an expert report from Justin Willer, M.D., and supporting medical literature. Pet'r's Exs. 20–31, ECF Nos. 27–29. Respondent filed an expert report from Mark Bromberg, M.D., Ph.D., and supporting medical literature on June 20, 2019. Resp't's Ex. A, Resp't's Exs. A, Tabs 1–8, ECF No. 37. Petitioner filed a supplemental expert report from Dr. Willer on August 12, 2019, and filed supporting medical literature on August 30, 2019. Pet'r's Exs. 32–36, ECF Nos. 40–41. On December 3, 2019, Respondent filed a supplemental expert report from Dr. Bromberg and additional medical literature. Resp't's Ex. C, Resp't's Exs. C, Tabs 1–3, ECF No. 45. Petitioner filed a second supplemental expert report from Dr. Willer on February 21, 2020. Pet'r's Ex. 37, ECF No. 49. On December 28, 2020, Petitioner filed an expert report from Marc Serota, M.D., and supporting medical literature. Pet'r's Exs. 39, 41(a)–41(l), ECF Nos. 60–61, 63. Respondent filed an expert report from Robert Fujinami, Ph.D., and supporting medical literature on April 30, 2021. Resp't's Ex. D, Resp't's Exs. D, Tabs 1–14, ECF Nos. 65–66.

I held a Rule 5 conference on August 30, 2022. ECF No. 69. I discussed my concerns in the case, including how Petitioner's medical theory is applicable to the facts of this case, pursuant to *Althen* prong two. *Id.* Petitioner requested sixty days to file a supplemental expert report addressing the *Althen* prongs, especially Petitioner's proposed biological mechanism, and its applicability to his diagnosis. *Id.*

On November 14, 2022, Petitioner filed a supplemental expert report from Dr. Serota and supporting medical literature. Pet'r's Exs. 42, 43(a)–41(l), ECF No. 70. On March 5, 2023, Respondent filed a supplemental expert report from Dr. Fujinami and supporting medical literature. Resp't's Ex. E, Resp't's Exs. E, Tabs 1–6, ECF No. 74.

1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision.") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.*, 527 F. App'x 875, 884 (Fed. Cir. 2013) ("Finding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered.").

Petitioner filed a pre-hearing brief and additional medical records on September 28, 2023. Pet'r's Exs. 44–49, ECF No. 76; Pet'r's Pre-Hearing Br., ECF No. 77. Respondent filed his pre-hearing brief on November 13, 2023. Resp't's Pre-Hearing Br., ECF No. 78. Petitioner filed additional medical records on November 30 and December 5, 2023. Pet'r's Exs. 50, 61, ECF Nos. 79, 90. Petitioner and Respondent filed additional medical literature on December 4, 2023. Pet'r's Exs. 51–60, ECF No. 86; Resp't's Exs. C, Tabs 4–5, ECF No. 82.

An entitlement hearing was held on December 11 and 12, 2023. Min. Entry, docketed Dec. 13, 2023. Petitioner subsequently requested the opportunity to file post-hearing briefs. ECF Nos. 94, 96. On April 16, 2024, I issued an order specifying what may be addressed in the post-hearing briefs. ECF No. 95. Petitioner initially filed a post-hearing brief on May 13, 2024. ECF No. 98. That brief was stricken from the record for failure to comply with my order regarding the scope of post-hearing briefs. See ECF No. 101. Petitioner filed a compliant post-hearing brief on June 28, 2024. Pet'r's Post-Hearing Br., ECF No. 102. Respondent filed his post-hearing brief on August 8, 2024. Resp't's Post-Hearing Br., ECF No. 104. Petitioner filed a post-hearing reply brief on September 9, 2024. Pet'r's Post-Hearing Reply., ECF No. 105. This matter is now ripe for adjudication.

II. Factual History

A. Relevant Medical Records[4]

Petitioner was a 19-year-old college student and a competitive golfer at his school when he received the subject flu vaccine in his left[5] deltoid at a walk-in flu clinic at St. John's University on October 9, 2014. Pet'r's Ex. 2 at 2. Prior to vaccination, Petitioner's medical history was significant for multiple musculoskeletal injuries,[6] migraines, asthma, eczema, reflux, and chronic left-sided neck pain. *See* Pet'r's Ex. 3 at 1, 13; Pet'r's Ex. 4 at 1; Pet'r's Ex. 7 at 2, 31; Pet'r's Ex. 16 at 4, 9; Pet'r's Ex. 47 at 66.

Twenty-six days after the flu vaccine, on November 4, 2014, Petitioner presented to Jeffrey Varner, D.C., at Crossroads Chiropractic Clinic with complaints of left-sided neck and arm pain that was constant and worsening. Pet'r's Ex. 4 at 1. Petitioner described the symptoms as "shooting, stabbing pain and tightness." *Id.* Petitioner reported a whiplash incident four years prior that resulted in chronic left-sided neck pain and "jaw trouble ever since." *Id.* Dr. Varner diagnosed Petitioner with cervical and thoracic sprains. *Id.*

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[4] Petitioner had a substantial amount of medical treatment from 2014 to 2022. While I have reviewed all of the medical records, this section only includes those most relevant to the issues in this Ruling. This section is largely taken from Respondent's brief, with edits, as I find it to be a comprehensive summary. For a more in-depth review of Petitioner's medical records, see Pet'r's Pre-Hearing Br. at 3–26.

[5] The vaccination record reflects that Petitioner received the flu vaccine in his right deltoid. However, for the reasons explained below, I find there is preponderant evidence that Petitioner received the vaccination in his left deltoid, and the vaccination record is incorrect.

[6] These included: (1) whiplash; (2) bilateral acromioclavicular ("AC") joint separations; (3) a right knee partial meniscal tear with hairline tibia fracture; (4) a left ulna cartilage tear; (5) a dislocated right shoulder; (6) a left wrist reconstruction; and (7) multiple right thumb subluxations. *See* Pet'r's Ex. 3 at 1, 13; Pet'r's Ex. 4 at 1; Pet'r's Ex. 7 at 31; Pet'r's Ex. 16 at 4, 9; Pet'r's Ex. 47 at 66.

On November 6, 2014, Petitioner presented to physiatrist Thomas Balfanz complaining of chronic left-sided neck pain that had flared "over the past three weeks or so." Pet'r's Ex. 3 at 1. He dated his symptom onset as October 15, 2014. *Id.* Petitioner again reported his previous whiplash injury and stated that "his neck ha[d] never quite been the same ever since." *Id.* Petitioner reported that "over the last two weeks [he] ha[d] developed a feeling of numbness and tingling in the left arm as well as pain down to the tips of all of his digits of the left hand in no one particular dermatomal distribution." *Id.* He reported his pain was worse at night. *Id.* at 2. Petitioner also reported headaches and reduced strength in his left upper extremity. *Id.* at 1. On examination, Petitioner had reduced cervical range of motion, left-sided cervical radicular pain, reduced left arm strength, and normal left arm sensation. *Id.* at 3. Range of motion testing did not cause radicular symptoms into the arms. *Id.* Cervical magnetic resonance imaging ("MRI") was unremarkable. *Id.* at 3, 6–7. Dr. Balfanz diagnosed Petitioner with cervical spine pain and deconditioning syndrome, and he ordered a left brachial plexus MRI. *Id.* at 3–4. Dr. Balfanz also noted that he discussed Petitioner's case with his colleague, Dr. Mark Thibault, who "also suggested the possibility of Parsonage Turner syndrome [("PTS")], which could be detected by [electromyography ("EMG")]." *Id.* at 4.

On November 11, 2014, Dr. Balfanz noted in an addendum that Petitioner's left brachial plexus MRI was normal, but he "still could have a brachial plexopathy (neuritis) or [PTS]." Pet'r's Ex. 3 at 5. Dr. Balfanz prescribed an oral steroid and referred Petitioner to neurology. *Id.*

On November 17, 2014, Petitioner presented to the St. Cloud Hospital ("St. Cloud") Emergency Department ("ED") complaining of left-sided neck and arm pain that began seven days after a "flu shot on October 14th [sic]." Pet'r's Ex. 7 at 1. Petitioner described his left arm pain as "a shooting pain from his shoulder down [] to his fingers." *Id.* He also complained of headaches, dizziness, and a "shooting pain down his left leg intermittently" that day. *Id.* On examination, the provider noted normal strength in all extremities. *Id.* at 2. The provider noted "[t]here was a question of some weakness in [Petitioner's] left arm, but [the provider] could not see any atrophy to his muscles." *Id.* A brain MRI was normal, and Petitioner was diagnosed with "questionable brachial plexus neuritis" and referred to neurology. *Id.* at 2–3.

On November 18, 2014, Petitioner presented to neurologist Moeen Masood with complaints of "left shoulder and arm pain and numbness" that "started shortly [after] receiving a flu shot in his left arm on October 14th [sic]." Pet'r's Ex. 5 at 2. Petitioner reported that his symptoms, including pain in his left shoulder under his clavicle, began "[a]bout a week later." *Id.* About a week after that, Petitioner "started experiencing shooting pains down his left arm. This was followed shortly by numbness in his arm and hand and continual pain." *Id.* He reported he improved briefly while he was on steroids. *Id.* Petitioner also reported "periodic loss of function of his [left] hand," left arm and hand weakness, left leg pain, dizziness, and falling three times. *Id.* He also reported his pain was worse in the morning and at night. *Id.* On examination, Dr. Masood noted normal strength, sensation, and reflexes in all extremities. *Id.* at 4. Dr. Masood diagnosed Petitioner with "a brachial plexopathy which is very patchy, most likely autoimmune such as seen with [PTS]," and he ordered an EMG and prescribed an additional round of oral steroids. *Id.*

Petitioner returned to his chiropractor on November 26, 2014, where he reported that the "[n]eurologist told him he ha[d] brachial plexus neuritis from a recent flu shot." Pet'r's Ex. 4 at 7. On December 1, 2014, Petitioner called the St. John's University Health Center and reported "a reaction to the flu injection that was done in October [and w]as told to have it documented." Pet'r's Ex. 6 at 4.

> [Petitioner] report[ed] that one week after flu shot he experienced pain shooting to the clavicle area to left side of neck and down to left arm patient stated he has lost 80% of strength in his left arm and lost function of left had. The doctors believe[d] that the flu shot triggered this rection but [cannot] prove it.

Id.

Later that evening, also on December 1, 2014, Petitioner presented to the St. Cloud ED complaining of "uncontrollable" left-sided neck, shoulder, and arm pain. Pet'r's Ex. 7 at 35. He reported that he received flu shot in October and seven days later, He noticed "pain in his left scapular and shoulder areas and pain that radiate[d] down his arm." *Id.* On examination, Petitioner's left scapular area and shoulder were tender, and he had reduced strength and sensation in his left arm. *Id.* at 37. Petitioner was diagnosed with "brachial plexus neuropathy according to his neurologist," and he was admitted into St. Cloud "for further treatment of what appear[ed] to be neuropathic pain." *Id.* at 37–38. The admitting physician noted Petitioner's presentation seemed "most consistent with [PTS] or neurologic amyotrophy" but that an EMG was needed. *Id.* at 34. Other differential diagnosis was "an atypical variant [of Guillain-Barré syndrome ("GBS")] which thus far ha[d] only affected one arm but with the atypical painful variant of [GBS] . . . this is probably much less likely." *Id.*

Petitioner was hospitalized for eleven days for "excruciating left shoulder and arm pain" that was "very difficult to control" but was successfully treated with a combination of intravenous Dilaudid, steroid infusions, trigger point injections, and oral medications. Pet'r's Ex. 7 at 25. During this hospital admission, on December 2, 2014, neurologist Kathleen Rieke had a consult with Petitioner and her impression was that Petitioner's presentation and history was "classic for brachial amyotrophy." *Id.* at 46. Repeat MRIs and an EMG were unremarkable. *Id.* at 175–76. On December 8, 2014, neurologist Kevin Xie noted that Petitioner's pain was "of unclear etiology," and that "[h]e had a flu shot one week before these symptoms started." *Id.* at 51. On examination, Petitioner was "very sensitive to touch on the left upper extremity." *Id.* Dr. Xie wrote that he "decided not to pursue [intravenous immunoglobulin ("IVIG")] because there [was] no demyelination on the [EMG]." *Id.* Also during his hospitalization, Petitioner had consults with pain management and orthopedics. *Id.* at 26. At petitioner's discharge from St. Cloud on December 12, 2014, Dr. Xie was "very optimistic about [a] full recovery." *Id.*

On December 19, 2014, Petitioner established care with primary care provider ("PCP") Angelina Ausban, M.D. Pet'r's Ex. 8 at 10. Dr. Ausban noted that Petitioner had developed "a very rare complication of a flu vaccine, brachial plexus neuritis/neuropathy." *Id.* Petitioner reported "that he got a flu shot in the left arm on October 14 [sic]" and "about a week later had a little bit of left-sided neck and shoulder pain." *Id.* "Over time, his left arm became weak and he developed severe pain in the shoulder radiating down the arm." *Id.* It was noted he was diagnosed

with brachial neuritis buy the neurologist. *Id.* Petitioner reported his pain was improving since his hospitalization. *Id.* at 10–11. Petitioner was participating in formal occupational therapy ("OT") and physical therapy ("PT").[7] *Id.* at 11. On examination, Dr. Ausban noted that "[s]trength testing and range of motion was not assessed in the left arm due to issues with pain." *Id.* at 12. Dr. Ausban adjusted Petitioner's prescription pain medications and recommended a recheck in two months. *Id.*

On January 4, 2015, Petitioner traveled to the Netherlands to be seen by neurologist and neuralgic amyotrophy specialist Dr. J. Raaphorst. Pet'r's Ex. 9 at 1. On presentation, Petitioner complained of "[m]ainly pain and diminished energy, fatigue." *Id*. at 3. Patient history noted:

> [Petitioner] had a vaccination for [flu] in [O]ctober 2014, a week later he suffered of a severe attack of pain in the left shoulder and neck region, pain score (numeric rating scale NRS) [four]. There were no other [precipitating] factors beside the vaccination. Pain gradually increased over the weeks until[] a pain score (NRS) 10 was reached in [D]ecember 2014, for which admission into a hospital was necessary for pain management. [A]pproximately [two] weeks after onset there was severe muscle weakness in hand an arm, there was a flail arm with scapular winging. The other arm showed no[] complaints.

Id. at 1. Dr. Raaphorst noted on examination that "[d]ue to [Petitioner's] severe pain[,] no definite conclusions [were made] on muscle weakness." *Id.* at 2. Dr. Raaphorst diagnosed Petitioner with neuralgic amyotrophy in the left shoulder "possibly related to [the] flu-shot" and "neural pain due to subpectoral impingement." *Id.* at 3. Dr. Raaphorst advised Petitioner that recovery can take over two years, and he recommended PT. *Id.*

On May 11, 2015, seven months post vaccination, Petitioner was hospitalized at St. Cloud for left upper back pain and shortness of breath that began the day prior. Pet'r's Ex. 7 at 728; Pet'r's Ex. 8 at 62–65. PCP Dr. Ausban wrote that it was "[u]nclear if this [was] a flare of the original symptoms or if [Petitioner] might have nerve entrapment in the thoracic vertebrae." Pet'r's Ex. 7 at 730. Petitioner's pain did not respond to a steroid infusion, and he experienced episodes of bradycardia, tachycardia, syncope, and panic attacks during his hospitalization. *Id.* at 791–92.

On May 18, 2015, neurologist Dr. Xie consulted with radiologist Nathan Danielson who reviewed Petitioner's diagnostic imaging and "reaffirmed that there [was] no significant finding on the brachial plexus at all." Pet'r's Ex. 7 at 861. Dr. Xie also consulted with neurologist Christopher Klein at Mayo Clinic who agreed that "the MRI study [was] pretty sensitive and specific as well for the brachial neuritis pathology." *Id.* Dr. Xie wrote that he "[did] not recommend the IVIG unless [there were] more objective findings either on the MRI or on the EMG." *Id.* However, on May 20, 2015, Dr. Xie started IVIG therapy, and Petitioner's pain gradually improved. *Id.* at 791, 835. Twelve days after admission, Petitioner was discharged from St. Cloud after his fifth IVIG treatment on May 23, 2015, with a diagnosis of acute neuritis. *Id.* at 724, 836.

[7] From December 16, 2014, to April 22, 2015, Petitioner attended 20 OT sessions and 27 PT sessions. Pet'r's Ex. 8 at 16–45. Petitioner demonstrated a good response to treatment. *See id.* A December 18, 2014 PT evaluation noted the "[m]echanism of injury" was "flu shot to the left shoulder is suspected." *Id.* at 20.

Discharge notes indicated Petitioner also saw psychiatry, psychology, cardiology, and orthopedics while hospitalized. *Id.* at 792.

On June 18, 2015, Petitioner was hospitalized at St. Cloud a third time for pain management. Pet'r's Ex. 7 at 1467. Admission notes stated that Petitioner had "very complex neurological issues." *Id.* Petitioner reported that his left-sided neck and arm pain returned after he was tapped on the back the day prior. *Id.*; Pet'r's Ex. 4 at 21. During his hospitalization, Petitioner's pain did not respond to IVIG treatments or steroid infusions, but it did improve with a left basilic ganglion (nerve) block. Pet'r's Ex. 7 at 1462, 1470. Petitioner was discharged from St. Cloud eight days after admission on June 26, 2015. *Id.* at 1462.

On July 12, 2015, Petitioner presented to pain management specialist Pradeep Chopra, M.D. Pet'r's Ex. 16 at 1. Notes indicated that five days after a flu vaccine, Petitioner woke up with pain in his left anterior infraclavicular area. *Id.* Petitioner described the pain as "knife stabbing" pain. *Id.* Dr. Chopra detailed Petitioner's clinical course from October 2014 to the date of appointment. *Id.* at 1–4. On examination, Dr. Chopra conducted a thorough examination of Petitioner and diagnosed Petitioner with complex regional pain syndrome ("CRPS")[8] in all extremities, chest, and upper abdomen, Ehlers-Danlos syndrome ("EDS"),[9] postural orthostatic tachycardia syndrome ("POTS"),[10] and thoracic outlet syndrome ("TOS").[11] *Id.* at 4–10. Dr. Chopra wrote, "[Petitioner] may have possible compression of the left brachial plexus secondary to an unstable clavicle. He has a history of separation of the left [AC] joint which along with his diagnosis of [EDS] may possibly be causing a dynamic compression of the left brachial plexus." *Id.* Dr. Chopra recommended additional diagnostics and several treatments, including a repeat MRI of the left brachial plexus,[12] low-dose ketamine infusions for pain, and specialized PT. *Id.* at 10–11. Petitioner received several ketamine infusions and nerve blocks to control his pain throughout the rest of July. *Id.* at 13–27; Pet'r's Ex. 8 at 85–86.

On August 18, 2015, vascular surgeon, Dr. Robert Thompson performed a "left supraclavicular thoracic outlet decompression including anterior and middle scalenectomy,

[8] CRPS is "a chronic pain syndrome of uncertain pathogenesis, usually affecting an extremity, and characterized by intense burning pain, changes in skin color and texture, increased skin temperature and sensitivity, sweating, and edema." *Complex Regional Pain Syndrome*, DORLAND'S MED. DICTIONARY ONLINE.

[9] EDS is "a group of inherited disorders of connective tissue; formerly subdivided into ten numbered types, they have been reclassified into six descriptive types. Prominent manifestations include hyperextensible skin and joints, easy bruisability, and friability of tissues with bleeding and poor wound healing, with additional symptoms specific for individual types." *Ehler-Danlos Syndrome*, DORLAND'S MED. DICTIONARY ONLINE.

[10] POTS is "a group of symptoms . . . that sometimes occur when a person assumes an upright position, including tachycardia, tremulousness, lightheadedness, sweating, and hyperventilation; . . . the etiology is uncertain." *Postural Orthostatic Tachycardia Syndrome*, DORLAND'S MED. DICTIONARY ONLINE.

[11] TOS is "any of a variety of neurovascular syndromes resulting from compression of the subclavian artery, the brachial plexus nerve trunks, or less often the axillary vein or subclavian vein, by thoracic outlet abnormalities such as a drooping shoulder girdle, a cervical rib or fibrous band, an abnormal first rib, or occasionally compression of the edge of the scalenus anterior muscle." *Thoracic Outlet Syndrome redirects to Inferior Thoracic Aperture Syndrome*, DORLAND'S MED. DICTIONARY ONLINE.

[12] It is not clear if this repeat MRI of the brachial plexus was performed.

brachial plexus neurolysis, and resection of the first rib" and "left pectoralis minor tenotomy." Pet'r's Ex. 15 at 107–09. Among the operative findings were "postinflammatory scar tissue surrounding brachial plexus nerve roots" and "[b]rachial plexus compression in the left subcoracoid space." *Id.* at 107. Petitioner's pre- and post-operative diagnoses were left neurogenic TOS and left pectoralis minor syndrome. *Id.*

On September 11, 2015, Petitioner followed up with PCP Dr. Ausban for his CRPS, TOS, and POTS. Pet'r's Ex. 8 at 93. Dr. Ausban wrote, "It is felt that his pain was being fueled by nerve compression from the [TOS]." *Id.* Dr. Ausban outlined a care plan for Petitioner's POTS, and, regarding his post-operative TOS, she noted that he was referred back to PT. *Id.* at 94–95. From the remainder of 2015 and into 2016, Petitioner attended PT and periodically received ketamine infusions for breakthrough pain. *See generally id.* at 152–63; Pet'r's Ex. 12, 14; Pet'r's Ex. 15 at 400–05.

On March 4, 2016, Petitioner presented to Lakewood Health Systems for a flare in his CRPS after falling on ice a week prior and hitting his knee on the car door the day before. Pet'r's Ex. 12 at 4–7. Petitioner received a ketamine infusion for his pain. *Id.*

By April 2016, Petitioner was discharged from PT and it was noted that he was doing well with his home exercise program and started golfing without flare-ups. Pet'r's Ex. 8 at 163. Petitioner followed up with Dr. Ausban again on August 12, 2016. *Id.* at 105. Dr. Ausban noted that overall, Petitioner had "markedly improved from a year ago." *Id.*

In June and July 2016, Petitioner attended rehab for deconditioning syndrome during which he reported neck tightness and pain. *See* Pet'r's Ex. 3 at 17–33.

On December 12, 2016, Petitioner presented to allergist Mohamed Yassin and was diagnosed with idiopathic mast cell activation syndrome ("MCAS"). *See generally* Pet'r's Ex. 10.

On March 23, 2017, Petitioner followed up with vascular surgeon Dr. Thompson and reported complete recovery of his left arm. Pet'r's Ex. 18 at 16. However, he reported he started to develop symptoms, to those he initially had on his left side, on his right side. *Id.* Dr. Thompson diagnosed him with right TOS and recommended surgery. *Id.*

On April 27, 2017, prior to Petitioner's pending right-sided TOS surgery, his father wrote a letter to Dr. Thompson stating that the left-sided TOS surgery "almost [two] years ago [] had a fantastic result." Pet'r's Ex. 15 at 769. Petitioner's father also described each of Petitioner's "unusual medical conditions:" CRPS, EDS, POTS, and MCAS. *Id.* at 769–71. Petitioner's right sided TOS surgery was performed on May 9, 2017, operative findings included "postinflammatory scar tissue surrounding brachial plexus nerve roots." Pet'r's Ex. 18 at 18–20.

In 2018 through 2020, Petitioner was treated for multiple flares of his MCAS. *See generally* Pet'r's Ex. 44. In 2021 through 2022, Petitioner was treated by physiatrist Kelly Collins (who specializes in EDS), psychologist Lisa Jensen, chiropractor Amanthi Demuth, and PCP Dr. Ausban. *Id.*; *see generally* Pet'r's Ex. 47, 48.

B. Petitioner's Affidavit and Testimony

Petitioner executed an affidavit on October 9, 2017. Pet'r's Ex. 17. Prior to vaccination, Petitioner asserted that while he had a few minor sports-related injuries, he was "very healthy." *Id.* at ¶ 7; *see also* Tr. 16–18 (describing his previous sports-related injuries). He occasionally had minor neck tightness. Tr. 19. At the time of his vaccination, Petitioner had just finished his first season of golf at the collegiate level. *Id.* In addition to golf practice, he worked out multiple times per week. *Id.* He also excelled academically and rarely missed class. *Id.*

On October 9, 2014, Petitioner received the flu vaccine at the St. John's University flu shot clinic for student athletes. Pet'r's Ex. 17 at ¶ 2. Petitioner maintained that he received the vaccine in his left arm. *Id.*; Tr. 27, 83. In his hearing testimony he explained why the vaccination record indicated he received it in his right shoulder. He explained that he went to the flu shot clinic shortly before it was ending for the day and that it was very chaotic with the amount of people left in line. Tr. 21. There was only one nurse administering the vaccines and Petitioner recalled her "barking out instructions" on how to fill out the vaccination form. Tr. 21–23 (citing Pet'r's Ex. 2 at 2). The nurse instructed the students in line to fill out the form before it was their turn. Tr. 23. Under the "[s]ite of administration" question on the form, Petitioner testified that the nurse instructed everyone to circle their dominant arm. Tr. 25. Petitioner is right-handed so he circled "[r]ight deltoid." *Id.* The nurse told them to circle their dominant arms "because the soreness would be reduced faster if you're using the arm more." *Id.* By the time he reached the nurse in line to receive the vaccine, he decided he wanted to receive the vaccine in his left arm since he had a test the next day and would be writing a lot with his right hand. Tr. 26. He did not want "any adversity for the test with [his] writing arm." *Id.* Petitioner asked the nurse if he could receive it in his left arm and explained his reasoning. *Id.* He recalled the nurse "agreed to it, but she didn't seem super happy that she was going to have to reposition herself." *Id.* During the hearing when asked why Petitioner did not go back and have the form corrected to reflect that his left shoulder received the vaccine, he stated the nurse "was in a hurry, and as far as [he] thought, it was just a routine flu shot, and [he] didn't really see a reason to go back and change it." Tr. 28, 85.

Immediately after vaccination, Petitioner testified there was "nothing overtly wrong." Tr. 27; *see also* Tr. 85. "[I]t just kind of felt sore and had this dull ache for a couple days after the fact, where it was just kind of right around the injection site." Tr. 27. "[I]t was very sore and tender, but it was like a dull ache that eventually went away on about . . . the third day after the vaccination." *Id.* There was no burning or stabbing pain in the first few days after vaccination. Tr. 30.

In his affidavit, Petitioner asserted that his intense pain began the night he received the vacation. Pet'r's Ex. 17 at ¶ 2.

> [T]hat night, [he] tried to study and noticed that [he] was having trouble concentrating due to the pain in [his] left shoulder. During this time, [his] entire arm began to hurt and [his] fingertips would periodically go numb. At about 11:00 p.m., [he] tried to go to bed. The pain was so intense [he] had trouble getting to sleep, which was very abnormal for [him]. [He] later woke up from a sharp pain in [his] shoulder around 4:00 a.m. and was unable to get back to sleep. [He] remained in pain the rest of the day.

Id. At the hearing, he clarified that these events described in his affidavit were from six days after vaccination, not the night of vaccination. Tr. 42–43. He testified that he did not agree with the timeline set forth in his 2017 affidavit. Tr. 40–41. He explained that paragraph two in his affidavit "does not really detail how the pain occurred or the timeline it occurred. It [] does not seem to distinguish between the pain that [he] had from . . . just the soreness in [his] arm that day and then what occurred six days later." Tr. 40. Petitioner testified the general injection pain immediately after vaccination was "very different" than what he experienced six days later, as described in paragraph two of the affidavit. Tr. 41.

This affidavit was constructed by Petitioner's former attorney. Tr. 39–40. In preparing his affidavit, Petitioner recalled only focusing on the pain, symptoms, and how he felt, and not getting into details of the timeline or when certain symptoms occurred. Tr. 40, 86. He believed the symptoms described in paragraph two were accurate but accurate approximately one week after vaccination, not the night of vaccination. Tr. 41, 86. He testified that he thought the timeline of the affidavit was incorrect, but everything else in the affidavit was correct. Tr. 86. Petitioner explained that he felt he had to review the affidavit quickly to get his case filed and when he was quickly reviewing it, he was looking for the accuracy of his symptoms and regrets letting the timeline go inaccurate. Tr. 41, 44.

Petitioner testified that on the sixth day after vaccination,

> [he] woke up with [] sharp pain, deep in [his] shoulder. It was like a stabbing, shooting, burning, searing pain that was underneath [his] my collarbone. It was like this deep, internal pain that I had never experienced before, and it was starting to travel down my arm and then up my neck, and it was a pain like I hadn't experienced before, and it was very, very uncomfortable and got my attention right away.

Tr. 30–31. He described the pain as a "searing, hot, stabbing pain" that he had never experienced before even with his sports-related injuries. Tr. 32. The pain travelled to his neck, but Petitioner felt the pain originated deep within the shoulder. Tr. 31. Over time, he gradually experienced numbness and weakness. Tr. 33. He struggled to lift a textbook and hold his lunch tray with his left arm. *Id.*

He explained the "excruciating" pain was worse at night. Pet'r's Ex. 17 at ¶ 2–3. Because of the pain, he was only sleeping two hours at night. *Id.* at ¶ 3. The function and strength in his left hand diminished making it difficult to type for school. *Id.* He also had altered sensation throughout his arm causing pain. *Id.* at ¶ 11. Petitioner fell behind in his schoolwork and it took a toll on him mentally. *Id.* at ¶ 3. He ended up having to drop three quarters of his classes because he could not keep up. *Id.*

For the first week after the onset of his intense symptoms, Petitioner tried self-treating. Tr. 46. Then "[t]here was a time where [he] decided that this was something beyond what [he] could contain on [his] own." Tr. 47. Petitioner first sought treatment for his pain in November 2014. Pet'r's Ex. 17 at ¶ 4. He testified he presented to the chiropractor first because he was the first one with an opening. Tr. 47. Petitioner reported his "left shoulder and radiating left arm pain, numbness

and weakness following [his] vaccination and problems to multiple providers." Pet'r's Ex. 17 at ¶ 4. He distinguished the pain he was experiencing from a prior whiplash injury and that it was not a flare-up of a prior condition or injury. Tr. 50, 53, 82, 96–99. Petitioner recalled that after seeing several providers, a neurologist eventually diagnosed him with brachial neuritis and noted his history of recent vaccination. Pet'r's Ex. 17 at ¶ 4; Tr. 60–62. He also went to see a specialist in the Netherlands, Dr. Raaphorst, who believed Petitioner had neuralgic amyotrophy or PTS from the flu shot and that nothing else in his medical history would explain it. Tr. 67–68. Dr. Raaphorst told Petitioner that while there was a small tear visible on the MRI, it would not be causing the symptoms he had. *Id.* The pain became so "severe and uncontrollable" that was hospitalized for 10 days where he received a "confirmed diagnosis of a vaccine adverse reaction with left brachial neuritis." Pet'r's Ex. 17 at ¶ 4. He was hospitalized four more times over the next several months for pain control where he received high-dose IV steroids and IVIG. *Id.* at ¶ 5. Petitioner testified that although he was also diagnosed with CRPS, EDS, POTS, and TOS, he understood those to be additional diagnoses on top of his brachial neuritis injury, not instead of. Tr. 69–70, 75. Petitioner recalled continued treatment for his shoulder pain and eventually had left shoulder surgery in August 2015. Pet'r's Ex. 17 at ¶ 6; Tr. 71. He testified that he did not believe the TOS surgery helped all of his brachial neuritis symptoms. Tr. 74, 90.

III. Experts

A. Expert Qualifications

1. Petitioner's Expert, Dr. Justin Aaron Willer, M.D.[13]

Dr. Willer is a board-certified neurologist with added qualifications in clinical neurophysiology. Tr. 104, 106; Pet'r's Ex. 20 at 1. He received his M.D. from Chicago Medical School. Tr. 105. Thereafter, he completed an internship in internal medicine, a neurology residency, and fellowships in epilepsy and neuromuscular EMGs. *Id.* He is an active physician that specializes in neurology, specifically neuromuscular disorders and epilepsy. Tr. 104-05. In his clinical practice he sees about one patient per year with a brachial plexus injury. Tr. 107. Dr. Willer submitted three expert reports and testified at the hearing. Pet'r's Exs. 20, 32, 37; Tr. 3.

2. Petitioner's Expert, Dr. Marc Serota, M.D.

Dr. Serota is board certified in pediatrics, allergy and immunology, and dermatology. Tr. 170-71; Pet'r's Ex. 39 at 1. He received his M.D. from the University of Missouri-Kansas City. Tr. 171; Pet'r's Ex. 40 at 1. Thereafter, he completed a pediatrics residency, and allergy and immunology fellowship, and a dermatology residency. Pet'r's Ex. 40 at 1. In his current medical practice, he focuses on patients with "complicated allergic immunologic diseases." Tr. 171. He will consult with patients with neuropathies when it comes to determining an immunologic mechanism or potential trigger." Tr. 175. Dr. Serota submitted two expert reports and testified at the hearing. Pet'r's Exs. 39, 42; Tr. 3, 279.

[13] Petitioner did not file a CV for Dr. Willer.

3. Respondent's Expert, Dr. Mark Boyd Bromberg, M.D., Ph.D.

Dr. Bromberg is board certified in psychiatry and neurology. Tr. 282; Resp't's Ex. A at 1. He received his M.D. from the University of Michigan and his Ph.D. in neurophysiology from the University of Vermont. Resp't's Ex. F at 1. Dr. Bromberg completed a neurology residency and a fellowship in EMG and electrodiagnosis. Tr. 281. He is clinically active "primarily seeing patients with nerve and muscle disorders and performing electrodiagnostic studies," including patients with brachial neuritis (less than one patient per year) Tr. 282-83. Dr. Bromberg has over 100 peer-reviewed publications mainly in the field of neuromuscular diseases. Tr. 283. Dr. Bromberg submitted two expert reports and testified at the hearing. Resp't's Exs. A, C; Tr. 279.

4. Respondent's Expert Dr. Robert Shin Fujinami, Ph.D.

Dr. Fujinami received his Ph.D. in immunology and microbiology from Northwestern University. Tr. 358; Resp't's Ex. G at 1. He completed postdoctoral training at the Scripps Research Institute. Resp't's Ex D at 1. He has been a professor where he taught autoimmunology and immunologic tolerance and performed experiments on molecular mimicry and viral pathogenesis. Tr. 359-60. Dr. Fujinami has over 200 peer-reviewed publications mainly on molecular mimicry and viral pathogenies. Tr. 361. Dr. Fujinami submitted two expert reports and testified at the hearing. Resp't's Exs. D, E; Tr. 279.

B. Expert Opinions

1. Petitioner's Expert, Dr. Willer

a. Diagnosis

Dr. Willer believed Petitioner's correct diagnosis is brachial neuritis, also referred to as PTS or neuralgic amyotrophy. Pet'r's Ex. 20 at 8–9; Tr. 11; *see also* Tr. 139, 149. He explained that brachial neuritis is "characterized by inflammation that is painful and involves the brachial plexus or [one] or more branch nerve[s] in the shoulder girdle or upper extremity." Pet'r's Ex. 20 at 3 (citing Pet'r's Ex. 21 at 1);[14] Tr. 113–14. He added it is also "characterized by the acute onset of severe and usually unilateral upper extremity pain." Pet'r's Ex. 20 at 3. Feinberg et al. wrote that the onset of "[a]cute pain is followed by development of denervation, weakness, and atrophy of involved muscles." Pet'r's Ex. 21 at 1. It "often has a varied clinical expression and may affect a single or multiple peripheral nerves . . . and result in mild to severe neurologic deficits." *Id.*; *see also* Pet'r's Ex. 22 at 4 (stating that neuralgic amyotrophy primarily involves the peripheral nerves more commonly than the roots of the plexus).[15] Medical literature provides that imaging "will reveal widespread denervation of the involved muscle group(s)," but an EMG "has to be performed three weeks after the onset of symptoms to show any significant findings." Pet'r's Ex. 21 at 1;

[14] Joseph H. Feinberg et al., *The Electrodiagnostic Natural History of Parsonage-Turner Syndrome*, 56 MUSCLE NERVE 737 (2017).
[15] Mark A. Ferrante & Asa J. Wilbourn, *Lesion Distribution Among 281 Patients with Sporadic Neuralgic Amyotrophy*, 55 MUSCLE NERVE 858 (2017).

Pet'r's Ex. 25 at 2.[16] Feinberg et al. wrote that the etiology of brachial neuritis or PTS is unclear, but inflammatory, immune, and ischemic mechanisms have been proposed. Pet'r's Ex. 21 at 1. The medical literature reported that the condition "frequently follows a precipitating event, such as a viral upper respiratory infection, immunization, surgery, trauma, or strenuous exercise." *Id.*; *see also* Pet'r's Ex. 24 at 1 ("The cause of paralytic brachial neuritis usually is considered to be a postinfectious reaction or a reaction secondary to an allergic or hypersensitivity response.");[17] Pet'r's Ex. 59 at 2 (noting that while the exact pathogenesis is unclear, one of the theories regarding the development of brachial neuritis is "an autoimmune response to the viral infection or to the viral antigen in the immunization").[18] Dr. Willer testified that brachial neuritis is thought to be an autoimmune process. Tr. 136.

It was Dr. Willer's opinion that Petitioner's presentation was "consistent with the typical clinical picture for brachial neuritis." Pet'r's Ex. 20 at 8. He had an acute onset of pain followed later by the development of weakness in the left upper extremity and some degree of atrophy, as well as "evidence of an inflammatory process in the nerve roots supplying the brachial plexus." Tr. 162; *see also* Tr. 112, 151; Pet'r's Ex. 20 at 8. While the MRI of the plexus was normal, it did not make Dr. Willer question this diagnosis. Tr. 132. He opined the finding on the tissue biopsy was consistent with an autoimmune process such as brachial neuritis. Pet'r's Ex. 20 at 9. And likewise, while Dr. Willer acknowledged that the EMG was unrevealing, he opined that "the operative finding of 'post-inflammatory scar tissue surrounding the nerve root' is a direct objective finding consistent with an inflammatory process such as brachial neuritis." Pet'r's Ex. 20 at 9 (citing Pet'r's Ex. 18 at 19).

As an electromyographer, Dr. Willer described how EMGs work generally and that the correct muscles must be tested. Tr. 115–17, 119, 142–43, 145–46, 259–60. Dr. Willer opined that the "normal" EMG performed by Dr. Xie on December 8, 2014, was "somewhat misleading." Pet'r's Ex. 32 at 3. "The study was inadequate for evaluation of the brachial plexus as the most sensitive sensory nerve for assessing the upper portion of the plexus (the lateral antebrachial cutaneous) was not performed." *Id.*; *see also* Tr. 145–46. He wrote that "there should have been a significant number of muscles on the left side with sub-maximal recruitment as compared to the right side," but the report indicated there was no significant difference between the two sides. Pet'r's Ex. 32 at 4. Dr. Willer also criticized Dr. Xie's ability to properly perform a brachial plexus study as there is no evidence he has specialty training in EMG/electrodiagnostics. *Id.*; *see also* Pet'r's Ex. 37 at 2–5 (discussing his contentions with Dr. Xie's EMG). Ultimately, Dr. Willer opined this was not an appropriate brachial plexus study and it is "impossible to tell if the reason the EMG portion of the study was normal was because it really was normal or if the examiner failed to examine the appropriate shoulder girdle muscles or if due to inexperience could not correctly identify the appropriate abnormalities." Pet'r's Ex. 32 at 5; *see also* Tr. 146.

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[16] Michael Ortiz Torres & Fassil B. Mesfin, *Brachial Plexitis (Parsonage Turner Syndrome, Brachial Neuropathy, Brachial Radiculitis)*, STATPEARLS (last updated Oct. 27, 2018).
[17] M.I. Weintraub & D.T.S. Chia, *Paralytic Brachial Neuritis After Swine Flu Vaccination*, 34 ARCHIVES NEUROLOGY 518 (1977).
[18] Joseph H. Feinberg & Jeffrey Radecki, *Parsonage-Turner Syndrome*, 6 HOSPITAL SPECIAL SURGERY J. 199 (2010).

Assuming Dr. Xie performed the EMG correctly, it would still not change Dr. Willer's opinion for two reasons. Tr. 146–47. First, "even if everything is done right, sometimes the EMG is negative in brachial neuritis." Tr. 147–48; *see also* Pet'r's Ex. 32 at 5. For example, Weintraub & Chia found only "excess polyphasic activity with poor recruitment patterns" and Tsairis et al.[19] reported normal nerve conduction studies and electromyography in three patients. Pet'rs Ex. 32 at 5 (citing Pet'r's Ex. 23; Pet'r's Ex. 24). Second, Dr. Willer testified that Petitioner received two trials of steroids, and it is "very possible that the steroids eliminated whatever active denervation he might have had." Tr. 147. He testified that there is no good reason to treat with steroids before giving an EMG "because you're going to reduce enough of the inflammation that when you go put an EMG needle in, you may find a lot less active denervation than you would if you hadn't given the steroids." Tr. 132. He also added that "as time progresses, active denervation can disappear, so you have two factors working against you if you give steroids first in terms of confirming the diagnosis." Tr. 133. Thus, there is "no way to know if the testing would have been normal if he hadn't given the steroids." Tr. 132; *see also* Tr. 163.

Dr. Willer did not agree with Petitioner's treating physicians that Petitioner also had TOS. Pet'r's Ex. 32 at 7; Pet'r's Ex. 20 at 8; Tr. 157. He also did not believe Petitioner had EDS or CRPS. Pet'r's Ex. 32 at 8; Tr. 164.

b. Causation

Dr. Willer cited medical literature to opine that the connection between flu vaccination and brachial neuritis is "reasonably well established." Pet'r's Ex. 20 at 7. Torres & Mesfin reported that vaccination has been associated with 15% of patients with brachial neuritis. Pet'r's Ex. 25 at 1. They explained that while the exact pathophysiologic mechanism is unknown, there are some possible explanations including (1) that "patients with the disease have increased the immunologic activity of lymphocytes when exposed to brachial plexus nerve extracts versus sacral plexus nerve extracts," and (2) that "in patients with early disease, there is an increase in antibodies to peripheral nerve myelin." *Id.* "These findings, along with the association of disease occurrence with recent infection or vaccination, serve as a basis for the immunologic mechanism of the diseases." *Id.*

Tsairis et al. surveyed 99 patients who had brachial neuritis to analyze if they had viral or vaccination antecedents. Pet'r's Ex. 23 at 1. Fourteen patients received a vaccination prior to onset. *Id.* at 3. Of those 14, four received the flu vaccine and one simultaneously received the flu and tetanus toxoid vaccines. *Id.* The patients developed symptoms 10 to 21 days after vaccination and symptoms developed in either the injected or non-injected limb.[20] *Id.* Of the 99 patients surveyed, 85 had an EMG or nerve conduction study. *Id.* at 6. The authors did not reach a conclusion regarding the causal association, if any, between vaccination and brachial neuritis. Weintraub & Chia described a case report of a patient developing brachial neuritis following the swine flu

[19] Peter Tsairis et al., *Natural History of Brachial Plexus Neuropathy*, 27 ARCHIVES NEUROLOGY 109 (1972).

[20] On this note, Dr. Willer wrote that "[w]hile the record is conflicting as to which arm was injected with the vaccination, this is truly a non-issue. It does not make a difference in terms of developing brachial neuritis related to vaccination." Pet'r's Ex. 20 at 8; *see also* Pet'r's Ex. 32 at 6; Tr. 112–13.

vaccination. Pet'r's Ex. 24 at 1. Shaikh et al.[21] described a patient who developed brachial neuritis within one week of receiving the flu vaccine. Pet'r's Ex. 26 at 1. Wells[22] described a patient who developed brachial neuritis three days after flu vaccination, and Hansen[23] discussed a patient who developed brachial neuritis six days after flu vaccination. Pet'r's Exs. 62–63. Lastly, in Sinha & Gupta,[24] a patient developed acute shoulder pain and weakness one week after the flu vaccine and was diagnosed with brachial neuritis. Pet'r's Ex. 60.

Dr. Willer opined Petitioner's onset of brachial neuritis symptoms began one week after he received the vaccination. Tr. 112, 127. This is consistent with the medical literature he cited. *See* Pet'r's Ex. 20 at 8–9. He also testified that he interpreted Petitioner's characterization of the acute onset of symptoms as new and different from any pain that was there before. Tr. 126–27.

2. Petitioner's Expert, Dr. Serota

a. Causation[25]

Dr. Serota opined Petitioner's brachial neuritis was more likely than not triggered by the flu vaccination. Pet'r's Ex. 42 at 5; Tr. 177. He explained that while the etiology of brachial neuritis remains to be fully elucidated, "literature suggests that antibodies directed against peripheral nerve myelin appear to play a central role." Pet'r's Ex. 42 at 1 (citing Pet'r's Ex. 43(f);[26] Pet'r's Ex. 41(f) (explaining the involvement of T cells and B cells in an autoimmune inflammatory process such as brachial neuritis);[27] Pet'r's Ex. 42 at 5 ("Immune-mediated inflammatory reaction against brachial plexus nerve fibers involving complement, antiperipheral nerve myelin antibodies and T cell responses play a role" in the mechanism of autoimmune brachial neuritis); Pet'r's Ex. 39 at 6; Pet'r's Ex. 26; Pet'r's Ex. 43(h) (finding antibodies to peripheral nerve myelin were increased in patients with brachial neuritis)).[28] He testified that autoimmune diseases are "multifactorial, meaning there's not just one thing that makes autoimmune diseases happen." Tr. 179; *see also* Tr. 189–90 (testifying on the two components of a perfect storm—genetic predisposition and loss of regulatory control); Tr. 202–03; Pet'r's Ex. 42 at 4 (discussing a combined trigger and genetic predisposition).

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[21] Maliha Farhana Shaikh et al., *Acute Brachial Neuritis Following Influenza Vaccination*, BMJ CASE REPORTS (2012).
[22] C.E.C. Wells, *A Neurological Note on Vaccination Against Influenza*, 3 BRITISH MED. J. 755 (1971).
[23] Otto Hansen, *Acute Brachial Neuropathy Following Influenza Vaccination*, 167 WEEKLY J. PHYSICIANS 1297 (2005).
[24] Anupam Sinha & Shivani Gupta, *Parsonage-Turner Syndrome Following Influenza Vaccination: A Case Report*, 9 PM&R S216 (2017).
[25] Dr. Serota reviewed this case from the perspective of immunology and pathophysiology. Pet'r's Ex. 39 at 3. Therefore, for the purpose of his opinions, he assumed that the correct diagnosis is brachial neuritis. *Id.*; *see also* Tr. 178.
[26] Jeroen J.J. van Eijk et al., *Neuralgic Amyotrophy: An Update on Diagnosis, Pathophysiology, and Treatment*, 53 MUSCLE NERVE 337 (2016).
[27] G.A. Suarez et al., *Immune Brachial Plexus Neuropathy: Suggestive Evidence for an Inflammatory-Immune Pathogenesis*, 46 NEUROLOGY 559 (1996).
[28] Francine J. Vriesendorp et al., *Anti-Peripheral Nerve Myelin Antibodies and Terminal Activation Products of Complement in Serum of Patients with Acute Brachial Plexus Neuropathy*, 50 ARCHIVES NEUROLOGY 1301 (1993).

Dr. Serota proposed the theory of molecular mimicry.[29] Pet'r's Ex. 39 at 3–4; Tr. 181. Cusick et al.[30] explained that molecular mimicry occurs when "the immune system recogniz[es] self-antigens as foreign, which can lead to inflammation and destruction of specific tissues and organs (immunopathology)." Pet'r's Ex. 41(a) at 1. "Although a number of immune cells are responsible for secreting proinflammatory cytokines, the primary cell types implicated in a vast majority of autoimmune disorders are autoreactive B and T cells, or antibody recognition of self." *Id.* The authors noted that "molecular mimicry is the prevailing hypothesis as to how viral antigens initiate and maintain autoimmune responses which lead to specific tissue damage." *Id.* at 2. "The overall concept of molecular mimicry and an association with antigenic stimuli from both de novo infection and from vaccination are well established in the scientific literature." Pet'r's Ex. 39 at 4.

Dr. Serota supported his opinion by relating brachial neuritis, a peripheral nerve disorder, to GBS, another peripheral nerve disorder, that has been linked to various types of vaccines via molecular mimicry. *See, e.g.*, Tr. 438 (comparing brachial neuritis to GBS because both involve the peripheral nerves and sheathing around them); Pet'r's Ex. 39 at 4; Pet'r's Ex. 42 at 3. One way brachial neuritis and GBS differ however, is by the "specific proteins and antigens and glycoproteins that are associated with the brachial plexus in particular, as opposed to just peripheral nerves in general." Tr. 438. Thus, he explained that "[d]epending on what target the immune system mistakenly begins to attack, the phenotype of the disease would manifest differently but the concept would be the same." *Id.*

Cusimano et al.[31] evaluated pathology results from two patients with brachial neuritis. Pet'r's Ex. 41(e) at 1. The authors found "onion bulb formation, mild to moderate loss of nerve fibers and randomly scattered dense focal angiocentric infiltrates of lymphocytes, histiocytes, plasma cells[,] and macrophages, radiating into the endoneurium between nerve fibers." *Id.* at 4. One of the cases suggested to the authors that "a local exposure to [interferon] that in turn could have been induced by a compartmentalized local event such as a persisting viral infection or deposition of antigen-antibody complexes." *Id.* at 7. Dr. Serota noted that "these finding[s] are consistent with the proposed immunologic mechanism involving an immune response following exposure to antigen." Pet'r's Ex. 39 at 5.

Morishima et al.[32] discussed immunotherapy in patients with brachial neuritis based on the hypothesis that autoimmunity plays a role in the pathogenesis of the disease. Pet'r's Ex. 41(g) at 1. The authors wrote that "[s]ome reports have discussed the possible role of the autoimmune process and antiganglioside antibodies." *Id.* at 4.

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[29] In addition to molecular mimicry, Dr. Serota noted there are other parallel pathophysiologic mechanisms such as T cell sampling. Tr. 228–30, 442–43.

[30] Matthew F. Cusick et al., *Molecular Mimicry as a Mechanism of Autoimmune Disease*, 42 CLINICAL REVS. ALLERGY IMMUNOLOGY 102 (2012).

[31] Michael D. Cusimano et al., *Hypertrophic Brachial Plexus Neuritis: A Pathological Study of Two Cases*, 24 ANNALS NEUROLOGY 615 (1988).

[32] Ryo Morishima et al., *Chronic Brachial Plexus Neuritis That Developed into Typical Neuralgic Amyotrophy and Positively Responded to Immunotherapy*, 57 INTERNAL MED. 1021 (2018).

Dr. Serota also cited case series on brachial neuritis in support of his opinions. *See, e.g.*, Pet'r's Ex. 43(d) (finding two patients had a preceding tetanus toxoid immunization prior to onset);[33] Pet'r's Ex. 34 (finding 4.3% of patients had antecedent vaccinations);[34] Pet'r's Ex. 43(c) (using data from VAERS to conclude that the association between vaccination and some cases of brachial neuritis is not entirely coincidental)).[35]

He pointed out that the tetanus vaccine specifically is accepted as a cause of brachial neuritis. Tr. 202, 206. The 1994 Institute of Medicine ("IOM")[36] report found the tetanus toxoid vaccine to be causally related to brachial neuritis. Pet'r's Ex. 51.[37] Dr. Serota explained that in reaching the conclusion that the tetanus vaccine can cause brachial neuritis, the IOM looked at the same studies cited here, such as Tsairis et al. Tr. 209. He testified that the same studies that supported the tetanus vaccine as a cause also reported on the flu vaccine and that there is nothing different about the two vaccines in terms of the knowledge of the pathophysiology of them. Tr. 210. He hypothesized one reason for why the IOM found tetanus causal and not flu is because clinically, the tetanus vaccine "is much more likely to cause significant inflammatory response than a flu vaccine might." *Id.* But he maintained that there is nothing in the literature that "separates a mechanism for tetanus vaccine and not flu vaccine on [] a homology level or on a pathophysiology level." Tr. 211.

The IOM specifically wrote,

> Although the mechanisms of brachial neuritis are not well understood, there is biologic plausibility that vaccines could cause an allergic or hypersensitivity reaction that manifests as brachial neuritis. This provides reasonably good, although sparse, evidence that brachial neuritis can occur in relation to tetanus toxoid, although controlled epidemiologic studies designed to look at this relation do not exist.

Pet'r's Ex. at 9. Dr. Serota opined that "in some respects, there's better data for the [flu] vaccine, because we know that there are certain homologous targets for [flu] and nerve proteins compared to tetanus." Tr. 211; *see* Pet'r's Ex. 42 at 5 ("In the case of [flu] vaccines[,] it is known there it shares homology with GM1 [] and this mechanism is the likely cause of brachial neuritis as well."

[33] Ettore Beghi et al., *Brachial Plexus Neuropathy in the Population of Rochester Minnesota, 1970-1981*, 18 ANNALS NEUROLOGY 320 (1985).
[34] Nens van Alfen & Baziel G.M. van Engelen, *The Clinical Spectrum of Neuralgic Amyotrophy in 246 Cases*, 129 BRAIN 438 (2006).
[35] Shreya Shah et al., *Brachial Plexopathy After Influenza Vaccination in Adults in the USA. A Report from the CDC/FDA Vaccine Adverse Event Reporting System (1990-2017) (P2.431)*, 90 NEUROLOGY (2018).
[36] The IOM is now the National Academy of Medicine ("NAM").
[37] Inst. of Med., *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality* (Kathleen Stratton et al. eds., 1994).

(citing Pet'r's Ex. 43(i);[38] Pet'r's Ex. 43(b));[39] *see also* Tr. 183, 202–04. He testified that while the IOM makes this statement for tetanus, "it's equally applicable to [flu], based on similar data from the same studies they're quoting here, in addition to the fact that we know [flu] proteins can also stimulate immune responses for peripheral nerves." *Id.*; *see also* Tr. 236.

In summary, Dr. Serota asserted that "[a]ntigen presenting cells would present the [flu] antigens that share homology to GM1 proteins to T-cells which would then trigger a B cell response via T-cell help to induce the production of anti-GM1 antibodies." Pet'r's Ex. 42 at 5.

As it relates to Petitioner, Dr. Serota opined that Petitioner "was exposed to antigens in the [flu] vaccine that have been known to stimulate an antibody directed autoimmune response against peripheral nerve myelin." Pet'r's Ex. 42 at 1. "This would then induce an inflammatory cascade and complement fixation that results in the tissue damage and clinical symptomology that presented in [Petitioner's] case." Pet'r's Ex. 42 at 5.

He opined the onset of Petitioner's symptoms is consistent with the literature for a vaccine-induced autoimmune brachial neuritis, specifically as reported in Tsairis et al. and Shah et al. Pet'r's Ex. 39 at 5–6 (citing Pet'r's Ex. 23); Pet'r's Ex. 42 at 3 (citing Pet'r's Ex. 43(c)); Tr. 214 218. Additionally, Dr. Serota opined the "obvious antecedent post-vaccination symptoms fit with [Petitioner's] vaccination as the likely trigger" and he could not identify any other likely trigger. Pet'r's Ex. 39 at 3.

In response to Respondent's experts concerns regarding why Petitioner did not develop brachial neuritis from prior flu vaccines, Dr. Serota asserted it can be for several reasons. Tr. 436; *see also* Tr. 234–35. First, people can develop sensitivities, like allergies, overtime. Tr. 436. Second, there could be medical trauma such as a vaccine causing excessive inflammation "and the breakdown of the barrier that normally exists between the blood and perineurium of the nerve." *Id.* And third, the flu vaccine is different every year with different components to account for that year's seasonal flu. Tr. 437.

Like Dr. Willer, Dr. Serota testified that brachial neuritis can develop on the same or opposite arm in which there is mechanical trauma, in this case, vaccination. Tr. 185–89, 438. He explained the only way to have an injury in the contralateral arm is by using something that travels and surveils the body: the immune system. Tr. 438. He stated mechanical trauma is "more than saying it's damaging the nerve . . . it's elaborating the -- the nerve proteins are breaking down the barrier that normally exists between the nerves and the blood vessels, so that the immune system can actually sample those nerves." Tr. 185. "[T]hat explains why sometimes it can be in the opposite arm." *Id.* He explained the brachial nerves are immunologically different than other nerves in the body. *Id.* "So if you elaborate the nerve proteins in the arm, for example, in the brachial plexus sheathing of nerves, those look different to your immune system." *Id.* In sum, Dr. Serota testified that if you have a vaccination in one arm, and develop symptoms in the other arm, "that can't be from just direct trauma." Tr. 438. "That has to be because there's an immune

[38] Yahel Segal & Yehuda Shoenfeld, *Vaccine-Induced Autoimmunity: The Role of Molecular Mimicry and Immune Crossreaction*, 15 CELLULAR & MOLECULAR IMMUNOLOGY 586 (2018).
[39] Irving Nachamkin et al., *Anti-Ganglioside Antibody Induction by Swine (A/NJ/1976/H1N1) and Other Influenza Vaccines: Insights into Vaccine-Associated Guillain-Barré Syndrome*, 198 J. INFECTIOUS DISEASES 226 (2008).

mechanism that is traveling and sampling those proteins and then finding where else in the body those proteins exist." *Id.*

3. Respondent's Expert Dr. Bromberg

a. Diagnosis

Dr. Bromberg did not believe Petitioner had brachial neuritis.[40] Resp't's Ex. C at 5–6; Tr. 290, 319-20. He wrote that "there was no clinical evidence to support [brachial neuritis], and the diagnosis should have been questioned in the setting of no muscle atrophy, no contraction fasciculations, no objective weakness, and no denervation on EMG studies." Resp't's Ex. A at 7*; see also* Resp't's Ex. C at 4 (writing that there is "no evidence of muscle atrophy, varying degrees of ability to move the left arm, intact reflexes, and normal distal sensory nerves studies that innervate clinically insensate skin").

Dr. Bromberg testified that brachial neuritis is assumed to be autoimmune in nature although the triggers are not yet clear. Tr. 288. He stated it is generally monophasic and if there is a recurrence, the recurrence also tends to be monophasic. Tr. 288–89, 331–32. However, he admitted on cross-examination that someone with brachial neuritis can continue to have pain for a lengthy period of time even though it is a monophasic disease. Tr. 347.

Dr. Bromberg's opinion was inconsistent on whether pain (subjective) and weakness are two separate stages of the clinical course, and if both need to be present on physical examination when diagnosing the condition. For example, he explained that brachial neuritis starts with acute pain, usually in the proximal arm area, and as pain subsides over the following days or weeks, weakness becomes apparent. Tr. 287; *see also* Tr. 323 (testifying after the acute onset of pain, it subsides, and patients manifest weakness); Resp't's Ex. A at 6 (writing that pain is a presenting feature but usually abates within two to three weeks and any lingering discomfort is associated with weakness). He also stated, if making a diagnosis by physical examination alone,[41] there would need to be pain, and "the degree of weakness and the distribution of weakness and the underlying atrophy of muscles" would need to be present. Tr. 293; Resp't's A at 6–7; *see also* Tr. 323 (stating that he thinks the weakness is there from the beginning, but the pain makes it hard for patients to realize). Further, in his first expert report, he noted that "weakness is usually extreme," but then in his testimony stated that "profound weakness" such as the arm falling off a table or unable to cut food is "a surprising degree of weakness" for brachial neuritis. Tr. 293. Finally, in his first expert report he opined that all individuals develop weakness but, in his testimony, indicated there may be no weakness. Resp't's A at 6; Tr. 294 (explaining that if there is complete recovery and no

[40] Dr. Bromberg refers to the subject diagnosis as PTS; however, I will refer to it as brachial neuritis for consistency. At the hearing, Dr. Bromberg indicated one of his issues with the diagnosis was that no one questioned it. He stated it "is not a classic case, so there are clearly arguments against the diagnosis." Tr. 320. But no one questioned it, and the label just got carried throughout his clinical course. *Id.* He said the doctors in the Netherlands never confirmed the diagnosis that just said Petitioner's presentation was consistent or supportive of it. *Id.* Dr. Bromberg understood this to mean that there was "a degree of uncertainty." *Id.*

[41] Dr. Bromberg stated this is not the preferred method and would also want to perform electrodiagnostic studies. Tr. 293.

weakness present, he would not expect there to be any atrophy; if there was mild weakness he would expect mild atrophy; and if there is marked weakness, he would expect more marked atrophy).

He testified about the weakness component:

> The weakness is verified as being due to damage to motor nerve fibers going to groups of muscles. It can be somewhat patchy within the realm of muscles that are innervated by the brachial plexus, and then depending upon the degree of damage, there can be axonal outgrowth to reinnervate the muscles, and there can be collateral reinnervation of the remaining intact nerves, sprouting branches to take over some of the innervation of the denervated muscle fibers.

Tr. 287.

Clinically, Dr. Bromberg found no evidence of brachial neuritis here, because he did not see distinct periods comprised of an initial bout of pain, followed by weakness and partial recovery, before a new period of pain began. Tr. 290. He testified Petitioner's degree of weakness was irregular in that he reported his arm flopped off the table, and he was unable to hold a fork or knife properly. Tr. 333. Dr. Bromberg noted that none of the physicians tested Petitioner's strength "according to standardized scales" so he did not know how much weakness Petitioner actually had. Tr. 333–34. When confronted on cross-examination with the strength tests conducted by Petitioner's physicians, he testified that when in pain, a person's ability to give full effort may be compromised and affect test accuracy. Tr. 335–36.

Most of Dr. Bromberg's objections to the diagnoses revolved around the normal EMG. He wrote, "[n]eedle EMG is the most sensitive test available for evidence for denervation, even when the degree of denervation is mild and insufficient to cause weakness. A normal EMG study does not support the diagnosis [brachial neuritis]." Resp't's Ex. A at 7. He testified that electrodiagnostic studies should be performed two to three weeks after the onset of symptoms. Tr. 296–97; *but see* Tr. 326 (suggesting conducting an EMG at three to four weeks post onset). He explained any time before or after this, would limit what can be seen, due to the disease still developing and reinnervation.[42] Tr. 296–97.

In contrast to Dr. Willer, Dr. Bromberg opined "a full accounting of sensory and motor nerve conduction values" was performed here. Resp't's Ex. C at 2. He found that Dr. Xie's detailed impression of Petitioner's EMG showed that Dr. Xie "knew the spectrum of pathologic electrodiagnostic features to look for to exclude a diagnosis of [brachial neuritis]." *Id.* (citing Pet'r's Ex. 7 at 174–75). He explained there are two components to an EMG: "one is searching for abnormal spontaneous activity . . . when the muscle is at rest; and the other is assessing recruited motor units." *Id.* According to Dr. Bromberg, because no positive sharp waves or fibrillation potentials were detected, "their absence is the strongest indication that there was no loss of motor nerves to account for [Petitioner's] left arm reduced function." *Id.*

[42] On cross-examination, when asked why Dr. Bromberg would perform an EMG at three to four weeks, he answered: "I like to look at the pathology, and that's the best way I can look at the pathology." Tr. 326.

Additionally, Dr. Bromberg found there was no evidence of "hypersensitivity in the nerve elements" or denervation changes in muscle on the MRI. Tr. 291; *see also* Resp't's Ex. A at 7 (noting Petitioner's MRI studies were normal and not indicative of brachial neuritis); *see* Resp't's Ex. C, Tab 4;[43] Resp't's Ex. C, Tab 5.[44] He opined that because there was no denervation and thus no true weakness, this would be a "sensory-only form" of brachial neuritis which he said does not exist. Resp't's Ex. C at 6. He also criticized Dr. Willer's reliance on the medical literature regarding electrodiagnosis. *Id.* at 4.

He was unable to confidently answer the question about whether a patient can have all of the clinical presentations of brachial neuritis but have a normal EMG and still be considered to have brachial neuritis. Tr. 329–30. As to Dr. Willer's contention that the steroids influenced the EMG, Dr. Bromberg testified that he did not find data on that for a neurogenic disease process. Tr. 300. He did not see any issue with giving a patient steroids at time of onset prior to obtaining an EMG. Tr. 325–26.

Next, he found Petitioner's severe and prolonged pain to be "out of proportion" for brachial neuritis. Resp't's Ex. A at 6. For example, he notes the need for IV narcotics is "distinctly unusual" in his experience for brachial neuritis and is not described in the literature. *Id.* at 7; *see also* Resp't's Ex. C at 5 (noting the "unusual magnitude and endurance of [Petitioner's] pain"). He concluded that the "extreme degree of pain" experienced by Petitioner "was not associated with demonstrable nerve damage as evidence by no muscle atrophy, no clinical weakness, and no abnormalities on EMG examination." Resp't's Ex. A at 6.

On cross-examination, Dr. Bromberg, testified that Petitioner's weakness and atrophy were "not clear" and he "just [did not] have a good feeling to label it as a classic [brachial neuritis]." Tr. 333. Dr. Bromberg did not provide an alternative diagnosis in lieu of brachial neuritis.

Dr. Bromberg agreed with Dr. Willer that Petitioner does not have TOS or CRPS. Resp't's Ex. A at 8–10. Dr. Bromberg did not reach a conclusion on whether Petitioner had EDS, but noted that if he did, it would explain more of Petitioner's symptoms than the other diagnoses offered. *Id.* at 10; Resp't's Ex. C at 6.

Dr. Bromberg opined that "[t]he diagnosis of vaccination related [brachial neuritis] by [Petitioner's] treating doctors appears to be solely based on the temporal association between a vaccination and pain with no supporting clinical, electrodiagnostic or MRI imaging features." Resp't's Ex. A at 6.

As to location of vaccination, Dr. Bromberg wrote in his first expert report that if accepting the vaccine record as accurate, "there would appear to be no basis for injuries in the left arm due to the vaccine." Resp't's Ex. A at 5. But in his second expert report, he conceded that brachial neuritis symptoms, though rare, have been observed on the contralateral side. Resp't's Ex. C at 5.

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[43] Darryl B. Sneag et al., *MRI Bullseye Sign: An Indicator of Peripheral Nerve Constriction in Parsonage-Turner Syndrome*, 56 MUSCLE & NERVE 99 (2017).

[44] Darryl B. Sneag et al., *Hourglass-Like Constrictions on MRI are Common in Electromyography-Confirmed Cases of Neuralgic Amyotrophy (Parsonage-Turner Syndrome): A Tertiary Referral*, MUSCLE & NERVE 2023.

Dr. Bromberg could not differentiate between the tetanus vaccine and flu vaccine as a potential mechanism for brachial neuritis. Tr. 352–53. All he could say was that there are different pathophysiologic features of the two. Tr. 353. Dr. Bromberg did not dispute an onset of mid-October or six to nine days after vaccination. Resp't's Ex. C at 1; Tr. 348.

4. Respondent's Expert Dr. Fujinami

a. Causation[45]

Dr. Fujinami opined "[t]here is no data indicating that the [flu] vaccine is associated with the development of brachial neuritis." Resp't's Ex. E at 1. His opinions focused on the proposed mechanism of injury and "why the timing of the vaccination in relation to the onset of brachial neuritis purported by the Petitioner's experts is not correct." Resp't's Ex. D at 1.

He asserted there is a lack of evidence for molecular mimicry and autoimmunity as a mechanism for brachial neuritis. Resp't's Ex. D at 6; *see also* Tr. 411 (stating molecular mimicry is not a reasonable explanation for the flu vaccine causing brachial neuritis). Dr. Fujinami testified that for molecular mimicry to induce disease, there has to be more than homology and when there is homology, it has to be at a disease-inducing site. Tr. 370, 406–07. He criticized Dr. Serota for not discussing potential mimicking regions contained in the flu vaccine that would be relevant for molecular mimicry. Resp't's Ex. D at 7. He also noted that Dr. Serota did not show "what the cross-reacting (mimicking) portion from the vaccine and some component in the brachial plexus/nerve" are. *Id.*; *see also* Tr. 368. In fact, he testified that antigens associated with the flu vaccine have not been demonstrated to lead to disease through molecular mimicry. Tr. 371. He also testified that there is no evidence in the literature supporting Dr. Serota's T cell sampling activation theory. Tr. 378.

Dr. Fujinami testified that infections, but not vaccinations, "can generate cross-reacting immune responses that then lead to an immune response against the microbe that cross-reacts against something in the human body." Tr. 369. Dr. Fujinami opined that Dr. Serota incorrectly tried to equate an active infection with a vaccination. Resp't's Ex. D at 6. He stated the flu vaccine is not an acute infection and comparing the two is like "comparing apples and oranges." Resp'ts Ex. E at 3; *see also* Resp't's Ex. D at 7. The flu vaccine "contains only viral proteins, not the whole infectious virus." Resp't's Ex. E at 2. The flu vaccine contains neither "a powerful adjuvant . . . nor does the vaccine have the ability to replicate" like an infection does. *Id.* He wrote that since the flu vaccine "lacks the ability to replicate[,] it cannot 'grow,' infect cells in the body, and disseminate systemically throughout the body." *Id.* He testified that "you need very powerful immune responses, such as an infection or using very powerful adjuvants that mirror an actual infection, to actually break immune tolerance." Tr. 377.

Dr. Fujinami critiqued the relevancy of medical literature filed by Petitioner's experts. Resp't's Ex. D at 5; Tr. 420–24 (reluctant to accept that Feinberg and Radecki found immunizations to be an antecedent event). For example, in Torres and Mesfin, Dr. Fujinami noted

[45] Dr. Fujinami's opinions on this case focused on immunology and pathology. Resp't's Ex. D at 2. He is not a neurologist or a physician and therefore defers to Dr. Bromberg regarding diagnosis. *Id.*

that while they reported vaccinations were associated with 15% of the cases, they did not state "how many or what percentage of these 15% of cases were preceded by [flu] vaccination, nor did they indicate the time interval between vaccination and onset of [brachial neuritis]." Resp't's Ex. D at 5. He testified that the Nachamkin et al. article, discussing how the flu vaccine can induce anti-GM1 antibodies, is not relevant because even if it were correct (which Dr. Fujinami did not believe), then Petitioner would have developed GBS, not brachial neuritis. Tr. 372.[46] Thus, he opined it does not contribute to the discussion regarding the flu vaccine causing brachial neuritis. Resp't's Ex. D at 5; Tr. 420–24. Alternatively, Dr. Fujinami cited Hwang et al.,[47] which studied the safety of two flu vaccinations administered five weeks apart. *Id.* (citing Resp't's Ex. D, Tab 9). The authors found that "[n]o deaths or adverse events such as optic neuritis, cranial neuropathy, and brachial neuropathy or [GBS] were reported." Resp't's Ex. D at 1. Dr. Fujinami found this article speaks against Petitioner's expert's opinions that the flu vaccine is causal for brachial neuritis. Resp't's Ex. D at 5.

In addition to disagreeing with a causal relationship between flu vaccine and brachial neuritis, Dr. Fujinami also disagreed that the tetanus vaccine can cause brachial neuritis. Tr. 398–99. On cross-examination when confronted with the 1994 IOM report concluding that the tetanus vaccine can cause brachial neuritis, Dr. Fujinami testified that he was "not sure how they came to the conclusion" based on the data they reviewed. Tr. 403; *see also* Tr. 425–28 (admitted the IOM found biological plausibility between tetanus vaccination and brachial neuritis but reluctant to accept it as proven). He stated the composition for the tetanus and flu vaccines are different but did not specify how. Tr. 403.

Dr. Fujinami opined the timing proposed by Petitioner's experts, six days, has not been established as medically acceptable in the literature. Resp't's Ex. D at 5; Tr. 429–32. Tsairis et al. found that patients who received the tetanus vaccine developed symptoms six to 31 days after inoculations, and the patients who received the flu vaccine developed symptoms 10 to 21 days after inoculation. Pet'r's Ex. 23 at 3; Tr. 429. Dr. Fujinami testified this is inconsistent with the onset alleged here. Tr. 430–31. He did not believe any autoimmune disease can develop in six days. Tr. 431–32.

Dr. Fujinami questioned what was special about or different with the October 9, 2014 vaccine, when Petitioner had 12 previous vaccinations and did not develop brachial neuritis. Resp't's Ex. D at 6.

[46] Dr. Fujinami countered the Nachamkin et al. article with the Lei et al. article. Tr. 373–74 (citing Resp't's Ex. E, tab 3). Ting Lei et al., *Anti-Ganglioside Antibodies Were Not Detected in Human Subjects Infected With or Vaccinated Against 2009 Pandemic Influenza A (H1N1) Virus*, 30 VACCINE 2605 (2012). He opined Lei et al. speaks against cross-reacting GM1 antibodies being generated in humans by the flu vaccine because the antibodies were not found in individuals who developed GBS post flu vaccination which is what was reported by Nachamkin et al. Tr. 374, *see also* Tr. 424.

[47] Kao-Pin Hwang et al., *Immunogenicity and Safety of a Trivalent Inactivated 2010-2011 Influenza Vaccine in Taiwan Infants Aged 6-12 Months*, 32 VACCINE 2469 (2014).

IV. Applicable Legal Standards

To receive compensation under the Vaccine Act, a petitioner must demonstrate either that: (1) the petitioner suffered a "Table injury" by receiving a covered vaccine and subsequently developing a listed injury within the time frame prescribed by the Vaccine Injury Table set forth at § 14, as modified by 42 C.F.R. § 100.3; or (2) that petitioner suffered an "off-Table injury," one not listed on the Table, as a result of his receiving a covered vaccine. *See* § 11(c)(1)(C); *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1319–20 (Fed. Cir. 2006). Petitioner does not allege a Table injury in this case; thus, she must prove that her injury was caused-in-fact by a Table vaccine.

To establish causation-in-fact, a petitioner must demonstrate by a preponderance of the evidence that the vaccine was the cause of the injury. § 13(a)(1)(A). A petitioner is required to prove that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321–22 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)).

In the seminal case of *Althen v. Sec'y of the Dept. of Health & Hum. Servs*, the Federal Circuit set forth a three-pronged test used to determine whether a petitioner has established a causal link between a vaccine and the claimed injury. *See* 418 F.3d 1274, 1278–79 (Fed. Cir. 2005). The *Althen* test requires petitioners to set forth: "(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. To establish entitlement to compensation under the Program, a petitioner is required to establish each of the three prongs of *Althen* by a preponderance of the evidence. *Id.* "[C]lose calls regarding causation are resolved in favor of injured claimants." *Id.* at 1280. Further, evidence used to satisfy one prong of the test may overlap to satisfy another prong. *Capizzano*, 440 F.3d at 1326.

Under the first prong of *Althen*, a petitioner must offer a scientific or medical theory that answers in the affirmative the question: "can the vaccine[] at issue cause the type of injury alleged?" *Pafford v. Sec'y of Health & Hum. Servs.*, No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *mot. for rev. den'd*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006). 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 theory must only be "legally probable, not medically or scientifically certain." *Id.* at 548–49. Petitioners are not required to identify "specific biological mechanisms" to establish causation, nor are they required to present "epidemiologic studies, rechallenge[] the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities." *Capizzano*, 440 F.3d at 1325 (quoting *Althen*, 418 F.3d at 1280). Scientific and "objective confirmation" of the medical theory with additional medical documentation is unnecessary. *Althen*, 418 F.3d at 1278–81; *see also Moberly*, 592 F.3d at 1322. However, as the Federal Circuit has made clear, "simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) (citing *Moberly*, 592 F.3d at 1322). Indeed, the Federal Circuit has "consistently rejected theories that the vaccine only 'likely caused' the injury and reiterated that a

'plausible' or 'possible' causal theory does not satisfy the standard." *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1360 (Fed. Cir. 2019) (citing *Moberly*, 592 F.3d at 1322 and *LaLonde*, 746 F.3d at 1339). Rather, "[a] petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case." *Moberly*, 592 F.3d at 1322. In general, "the statutory standard of preponderance of the evidence requires a petitioner to demonstrate that the vaccine more likely than not caused the condition alleged." *LaLonde,* 746 F.3d at 1339.

Furthermore, 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 claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357,1361 (Fed. Cir. 2000). The Supreme Court's opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.* requires that courts determine the reliability of an expert opinion before it may be considered as evidence. 509 U.S. 579 (1993). However, in the Vaccine Program, the *Daubert* factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (2010) ("[U]niquely 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."); *see also 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)). Under *Daubert*, the

> 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 are "meant to be helpful, not definitive." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 151 (1999). The factors do not "constitute 'a definitive checklist or test'" and may be applied differently depending on the facts of a particular case. *Id.* at 150 (quoting *Daubert*, 509 U.S. at 593).

"In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Daubert*, 509 U.S. at 590 (citation omitted). Thus, for Vaccine Act claims, 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. 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 v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 743 (2009) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)); *see also D'Tiole v. Sec'y of Health & Hum. Servs.*, No. 15-085V, 2016 WL 7664475, at *24 (Fed. Cl. Spec. Mstr. Nov. 28, 2016) (stating that the Vaccine Act "require[s] a chain of reliable propositions supporting [a] petitioner's theory").

Under the second prong of *Althen*, a petitioner must prove that the vaccine actually did cause the alleged injury in a particular case. *See Pafford*, 2004 WL 1717359, at *4; *Althen*, 418 F.3d at 1279. 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; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). A petitioner does not meet this obligation by showing only a temporal association between the vaccination and the injury; instead, the petitioner "must explain *how* and *why* the injury occurred." *Pafford*, 2004 WL 1717359, at *4 (emphasis in original). The special master in *Pafford* noted petitioners "must prove [] both that her vaccinations were a substantial factor in causing the illness . . . and that the harm would not have occurred in the absence of the vaccination." *Id.* (citing *Shyface*, 165 F.3d at 1352). A reputable medical or scientific explanation must support this logical sequence of cause and effect. *Hodges v. Sec'y of Health & Hum. Servs.*, 9 F.3d 958, 961 (Fed Cir. 1993) (citation omitted). Nevertheless, "[r]equiring epidemiologic studies . . . or general acceptance in the scientific or medical communities . . . impermissibly raises a claimant's burden under the Vaccine Act and hinders the system created by Congress." *Capizzano*, 440 F.3d at 1325–26. "[C]lose calls regarding causation are resolved in favor of injured claimants." *Althen*, 418 F.3d at 1280.

In Program cases, contemporaneous medical records and the opinions of treating physicians are favored. *Capizzano*, 440 F.3d at 1326 (citing *Althen*, 418 F.3d at 1280). Indeed, when reviewing the record, a special master must consider the opinions of treating physicians. *Capizzano*, 440 F.3d at 1326. This is because "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.'" *Id.* In addition, "[m]edical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). However, there is no "presumption that medical records are accurate and complete as to all of the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021) (finding that a special master must consider the context of a medical encounter before concluding that it constitutes evidence regarding the absence of a condition). While a special master must consider these opinions and records, they are not "binding on the special master or court." § 13(b)(1). Rather, when "evaluating the weight to be afforded to any such . . . [evidence], the special master . . . shall consider the entire record." *Id.*

In determining the accuracy and completeness of medical records, special masters will consider various explanations for inconsistencies between contemporaneously created medical records and later given testimony. The Court of Federal Claims has identified four such explanations for explaining inconsistencies: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014).

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

Although a temporal association alone is insufficient to establish causation, under the third prong of *Althen*, a petitioner must also show that the timing of the injury fits with the causal theory. *See Althen*, 418 F.3d at 1278. The special master cannot infer causation from temporal proximity alone. *See Thibaudeau v. Sec'y of Health & Hum. Servs.*, 24 Cl. Ct. 400, 403–04 (1991); *see also Grant*, 956 F.2d at 1148 ("[T]he inoculation is not the cause of every event that occurs within the ten[-]day period . . . [w]ithout more, this proximate temporal relationship will not support a finding of causation." (quoting *Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1983))).

A petitioner who satisfies all three prongs of the *Althen* test has established a prima facie showing of causation. *Hammitt v. Sec'y of Health & Hum. Servs*., 98 Fed. Cl. 719, 726 (2011). A petitioner who demonstrates by a preponderance of the evidence that he suffered an injury caused by vaccination is entitled to compensation unless the respondent can demonstrate by a preponderance of the evidence that the injury was caused by factors unrelated to the vaccination. *See Althen*, 418 F.3d at 1278; *Knudsen*, 35 F.3d at 547. In such a case, the government must not merely prove the existence of an alternative cause, but that such an alternative actually caused the injury. *Knudsen*, 35 F.3d at 549. Consequently, when and if the petitioner establishes a prima facie case, the burden then shifts to the government to prove that an alternative cause, unrelated to the administration of the vaccine, was the "sole substantial factor" in causing the alleged injury. *See de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1354 (Fed. Cir. 2008); *see also Hammitt*, 98 Fed. Cl. at 726 (explaining that the Respondent's burden is to show that the "factor unrelated" was the "sole substantial factor" in causing the injury). Additionally, a factor unrelated "may not include 'any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness or condition.'" § 13(a)(2); *see also Doe v. Sec'y of Health & Hum. Servs.*, 601 F.3d 1349 (Fed. Cir. 2010) (stating that an idiopathic diagnosis cannot be a "factor unrelated," as it is idiopathic).

V. Discussion

A. Diagnosis

As Federal Circuit precedent establishes, in certain cases it is appropriate to determine the nature of an injury before engaging in the *Althen* analysis. *See Hibbard v. Sec'y of Health & Hum. Servs.*, 698 F.3d 1358, 1364-65 (Fed. Cir. 2012); *Lombardi v. Sec'y of Health & Hum. Servs.*, 656

F.3d 1343, 1353 (Fed. Cir. 2011); *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1346 (Fed. Cir. 2010) (finding that in a case where the injury itself is in dispute, it is appropriate for the special master to "first determine which injury was best supported by the evidence presented in the record before applying the *Althen* test so that the special master could subsequently determine causation relative to the injury."). Here, diagnosis is at issue, and so it is appropriate to address first.

I find that Petitioner has presented preponderant evidence that he suffered from brachial neuritis for the purpose of his causation-in-fact claim. Petitioner's treating physicians continuously entertained a diagnosis of brachial neuritis. On November 6, 2014, Dr. Balfanz consulted with Dr. Thibault who suggested the possibility of brachial neuritis (PTS). Dr. Balfanz maintained the Petitioner could still have brachial neuritis even after the MRI of his brachial plexus was normal. On November 17, 2014, Petitioner presented to the ED complaining of left-sided neck and arm pain that began seven days after the flu shot. The visit summary noted "[t]here was a question of some weakness in [Petitioner's] left arm, but [the provider] could not see any atrophy to his muscles." Pet'r's Ex. 7 at 2. Petitioner was diagnosed with "questionable brachial plexus neuritis." *Id.* at 3. The next day, neurologist Dr. Masood diagnosed Petitioner with brachial neuritis that was "most likely autoimmune." Pet'r's Ex. 5 at 4. He reported to the ED again in December 2014 and the admitting physician wrote that Petitioner's presentation was "most consistent" with brachial neuritis. Pet'r's Ex. 7 at 34; *see also* Pet'r's Ex. 7 at 46 (neurologist Dr. Rieke opining Petitioner's presentation and history was "classic for brachial amyotrophy"). In January 2015, Petitioner traveled to the Netherlands where Dr. Raaphorst documented that Petitioner had a severe onset of shoulder pain and approximately two weeks later, had onset of muscle weakness. *See* Pet'r's Ex. 9 at 1–2.

Furthermore, Petitioner's presentation is consistent with that described in the literature filed in this case. All the literature described the acute onset of intense shoulder pain. It "may begin rather insidiously but quickly amplifies in severity and intensity." Pet'r's Ex. 59 at 1. In his affidavit and testimony, Petitioner averred that immediately after the flu vaccination, there was "nothing overly wrong" besides soreness at the injection site. Tr. 27. That went away about the third day after vaccination. Six days after the vaccination, "he woke up with [] sharp pain, deep in [his] shoulder." Tr. 30. The pain is followed by weakness and/or sensory loss. Tsairis et al. and Torres & Mesfin reported the onset of weakness may appear simultaneously with the pain or after a variable period. Over time, Petitioner gradually experienced numbness and weakness. *See* Tr. 33. The pain is described in the literature as constant with "variable quality" and can be exacerbated with movement and is worse at night. Pet'r's Ex. 25 at 2. Petitioner described how the pain was worse at night and the function and strength in his left hand eventually diminished. The Torres & Mesfin article noted that pain may be extended into the neck with radiation down the arm. Petitioner described his left arm pain as "a shooting pain from his shoulder down [] to his fingers." Pet'r's Ex. 7 at 1.

"Weakness may also not be recognized if it involves muscles that are difficult to manually isolate." Pet'r's Ex. 59 at 2. There may also be marked atrophy. MRI, EMG, and nerve conduction studies "may provide important clues toward the diagnosis," with EMG being the best study for evaluating demyelination of the brachial plexus. Pet'r's Ex. 25 at 2. Torres &Mesfin wrote that brachial neuritis is a diagnosis of exclusion, meaning these tests "are good at ruling in or out other

diagnoses but not at confirming a diagnosis of brachial [neuritis]." *Id.* at 3. *But see* Pet'r's Ex. 59 at 4 (writing that "diagnosis is very dependent on the EMG" but also writing that brachial neuritis is a clinical diagnosis although EMG "can better identify, isolate, and grade severity of denervation"). Petitioner's EMG was unremarkable. However, pursuant to the literature, this is not detrimental for diagnosis of brachial neuritis. Additionally, Dr. Willer noted "the operative finding of 'post-inflammatory scar tissue surrounding the nerve root' is a direct objective finding consistent with an inflammatory process such as brachial neuritis." Pet'r's Ex. 20 at 9 (citing Pet'r's Ex. 18 at 19).

While Dr. Bromberg initially opined Petitioner did not have brachial neuritis, he later wavered on this opinion. He testified that he "just [did not] have a good feeling to label it as a classic [brachial neuritis]." Tr. 333. And, he could not confidently answer the question about whether a patient can have all of the clinical presentations of brachial neuritis but have a normal EMG and still be considered to have brachial neuritis. He referred to Petitioner's clinical presentation and imaging as "irregular," "out of proportion," "distinctly unusual," and simply "not a classic case" of brachial neuritis. Tr. 320, 333; Resp't's Ex. A at 6–7. However, he never provided an alternative diagnosis.

Dr. Bromberg also objected to the diagnosis based on the normal EMG and MRI findings, but there are cases of normal imaging in brachial neuritis patients. Furthermore, the condition has been described as a clinical diagnosis that does not require objective findings on EMG. *See, e.g.*, Pet'r's Ex. 23. Similarly, I'm not persuaded by Dr. Bromberg's argument regarding the apparent lack of distinct periods of weakness and pain, as it has been reported that the two can occur simultaneously. Lastly, none of the filed literature excluded brachial neuritis as a diagnosis when there were frequent hospitalizations for severe pain. Dr. Bromberg simply declared that it was unusual without support for his conclusion. I find his opinion unpersuasive to overcome the medical evidence in this case. After consideration of the medical record and the expert's analysis, I find that Petitioner presented preponderant evidence that he suffered from brachial neuritis.

B. *Althen* Prongs

1. *Althen* Prong One – Medical Theory

I find Petitioner has provided preponderant evidence of a sound and reliable medical theory explaining how the flu vaccine can cause brachial neuritis. While Dr. Serota conceded that the exact etiology of brachial neuritis remains unknown, it is thought to be an immune-mediated condition, and Respondent's experts do not dispute this point.

The focus of Dr. Serota's proposed mechanism was molecular mimicry. *See* Pet'r's Ex. 39 at 4; Pet'r's Ex. 42 at 3. He admitted that it is unknown whether there is specific peptide homology between the flu vaccine and brachial neuritis. Program petitioners sometimes present homologies between vaccine components and human tissues, but such is not required to meet the preponderant standard for a theory of molecular mimicry. However, there must be some form of preponderant evidence that a cross reaction between the vaccine and body part at issue can occur. Indeed, "Petitioners cannot simply invoke the concept of molecular mimicry and call it a day. . . . Rather, they need to offer *reliable* and persuasive medical or scientific evidence of some kind . . . that

suggests the vaccine components could interact with self structures as maintained." *Johnson v. Sec'y of Health & Hum. Servs.*, No. 14-254V, 2018 WL 2051760, at *26 (Fed. Cl. Spec. Mstr. Mar. 23, 2018). Dr. Serota analogized brachial neuritis to GBS to illustrate how molecular mimicry is accepted by the medical community as a biological mechanism for vaccine-caused peripheral neuropathy. An expert may "extrapolate from existing data" where the reasons for extrapolation are transparent and persuasive. *K.O. v. Sec'y of Health & Hum. Servs.*, No. 13-472V, 2016 WL 7634491 (Fed. Cl. July 7, 2016) (quoting *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 743 (2009)). Dr. Serota explained that both brachial neuritis and GBS are immune-mediated conditions that involve the peripheral nerves and their corresponding myelin sheaths. Accordingly, he explained that the concept of molecular mimicry in the context of GBS would be the same for brachial neuritis, with the major difference being what specific target the immune system mistakenly begins to attack. Respondent's experts did not dispute the comparison made between brachial neuritis and GBS as to their peripheral nerve origins.[48]

Dr. Serota referred to the filed medical "literature [focused on brachial neuritis to] suggest[] that antibodies directed against peripheral nerve myelin appear to play a central role" in the pathogenesis. Pet'r's Ex. 42 at 1, 5 ("Immune-mediated inflammatory reaction against brachial plexus nerve fibers involving complement, antiperipheral nerve myelin antibodies and T cell responses play a role" in the mechanism of autoimmune brachial neuritis). Shaikh et al. described an immune-mediated inflammatory reaction against brachial plexus nerve fibers involving complement, anti-peripheral nerve myelin antibodies, and T cells. Vriesendorp et al. discussed the same theory—"[d]etection of anti-PNM antibodies and complement activation products in the serum of three patients with acute brachial plexus neuropathy supports the hypothesis that complement-dependent, antibody-mediated demyelination may participate in initial peripheral nerve damage." Pet. Ex. 43(h) at 3. Based on the medical literature, Dr. Serota provided that the proposed targets attacked in brachial neuritis are anti-peripheral nerve myelin antibodies. He explained that there are B cell responses, antibody responses, and complement fixation associated with brachial neuritis and "if you were developing antibodies against a homologous antigen," then those B cell responses and created antibodies would target proteins by stimulation with the flu vaccine. Tr. 183.

Other cases in the Program where petitioners' experts unsuccessfully identified the relevant proteins and affected body systems have failed because the disease pathogenesis was not consistent with the identified immune response. *See Jewell v. Sec'y of Health and Hum. Servs.*, No. 11-138V, 2016 WL 5404165 (Fed. Cl. Spec. Mstr. Aug. 29, 2015) (petitioners failed to prove that cytokine activity is capable of impacting the brain's 5-HT system in the ways proposed by petitioners' experts); *see also Dougherty v. Sec'y of Health and Hum. Servs.*, No. 15-1333V, 2018 WL 3989519 (Fed. Cl. Spec. Mstr. July 5, 2018) (finding petitioner failed to provide evidence that antibodies reacting to hypocretin-2 receptors would only damage these receptors if located in a limited region in the brain, despite their widespread presence in other regions of the body). Here, Petitioner has argued persuasively that the flu vaccine has been shown to cause (in GBS) an autoimmune disease that attacks peripheral nerve myelin, via molecular mimicry; that brachial neuritis and GBS are similar in that they are both autoimmune, peripheral-neurological diseases;

[48] When I asked Dr. Fujinami at the entitlement hearing if he agreed with Dr. Serota that GBS and brachial neuritis involve the same peripheral nerve sheathing, he answered "I don't know." Tr. 432.

and that brachial neuritis is an immune-mediated inflammatory reaction against peripheral nerve myelin that results in nerve damage.

Dr. Fujinami took issue with the fact that Dr. Serota could not identify potential mimic regions and that there was not epidemiological evidence to support Petitioner's position. But as stated above, neither specific homology, nor large-scale studies are required for a claim to be successful. Dr. Fujinami further opined that infections have been shown to cause disease via molecular mimicry, but vaccines have not, and "infections are very different than vaccines." Tr. 413. While infections are different than vaccines, special masters have found preponderant evidence that some vaccines can cause some diseases via molecular mimicry; therefore, I find his general assertion that vaccines cannot ever cause disease via molecular mimicry overbroad and unpersuasive. *See, e.g.*, *Conte v. Sec'y of Health & Hum. Servs.*, No. 17-403V, 2020 WL 5743696, at *57 (Fed. Cl. Spec. Mstr. July 27, 2020) (noting the theory of molecular mimicry in a GBS case is "well-established and well-settled in the Vaccine Program"); *Barone v. Sec'y of Health & Hum. Servs.*, No. 11-707V, 2014 WL 6834557, at *8-9 (Fed. Cl. Spec. Mstr. Nov. 12, 2014) (noting molecular mimicry "has been accepted in other Program cases as a reliable medical explanation for how various autoimmune conditions could develop after the receipt of different kinds of vaccinations").

The studies filed are also supportive of Petitioner's position as they show an association between vaccination and brachial neuritis. Tsairis et al., a clinical analysis of 99 patients, reported that 14 patients received a vaccination prior to the onset of brachial neuritis. Petitioner also filed four case reports where each patient developed brachial neuritis after the administration of a flu vaccine. Case reports generally do not represent strong evidence of causation but can be helpful in analyzing a petitioner's case. *See K.O.*, 2016 WL 7634491; *see also Whitecotton v. Sec'y of Health & Hum. Servs.*, 81 F.3d 1099, 1108 (Fed. Cir. 1996) (indicating that special masters have discretion in how they weigh evidence). For example, Shaikh et al., which described a patient who developed brachial neuritis within one week of receiving the flu vaccine, wrote that while "a causal association of acute brachial neuritis postinfluenza vaccination is only suggested," their case report lends weight to the theory. Petr'r's Ex. 26 at 1; *see also* Pet'r's Ex. 60 at 1 (presenting a case of brachial neuritis following flu vaccination and writing, the "cause is considered to be a postinfectious reaction or a reaction secondary to a hypersensitivity response"); Pet'r's Ex. 63 at 4 (presenting a case of brachial neuritis following flu vaccination and writing that the flu vaccine "may be the cause of humoral or cell-mediated immune reactions in brachial [neuritis] and [GBS]").

Petitioner also raised the similarity in evidence between the tetanus vaccine causing brachial neuritis (a Table claim)[49] and the flu vaccine causing brachial neuritis.[50] Petitioner

[49] Brachial neuritis is on Vaccine Injury Table for tetanus toxoid vaccines creating a rebuttal presumption of causation if symptoms manifested between two and 28 days. 42 C.F.R. §§ 100.3(a)(I).

[50] Petitioner does not argue the vaccines are similar, rather, Petitioner attempts "to create an evidentiary barometer for the Court to evaluate [Petitioner's] evidence on causation." Pet'r's Post-Hearing Reply at 14; *see also* Pet'r's Post-Hearing Reply at 2 ("The science used to support an absolute legal causal relationship between [tetanus], and brachial neuritis is the same science used to support the legal causal relationship between [flu] vaccine and brachial neuritis, thereby proving that there is preponderant evidence that the flu vaccine can cause brachial neuritis."). Petitioner questioned: "If the [tetanus] vaccine

primarily pointed out that when the IOM reached the conclusion that the tetanus vaccine can cause brachial neuritis,[51] they looked at the same studies cited in this case. The IOM relied on Tsairis et al. and five case reports. Tsairis et al., reported the onset of brachial neuritis in six cases after the tetanus vaccine and in five cases after the flu vaccine. Here, Petitioner presented Tsairis et al. and case reports on brachial neuritis after flu vaccination including Weintraub & Chia, Shaikh et al., Hansen, and Wells. Despite the IOM findings and the Vaccine Injury Table, Dr. Fujinami disagreed that there is a causal relationship between the tetanus vaccine and brachial neuritis.[52]

Although the Vaccine Injury Table only provides for a claim of brachial neuritis after receipt of the tetanus vaccine, special masters have, on many occasions, found preponderant evidence was presented that other vaccines—including the flu vaccine—might also be causal of the condition. *Morgan v. Sec'y of Health & Hum. Servs.*, No. 16-269V, 2023 WL 3984415 (Fed. Cl. Spec. Mstr. June 12. 2023) (finding two to three days post-intradermal flu vaccination and the progression of pain and weakness over several days to be an acceptable temporal association); *Abels v. Sec'y of Health & Hum. Servs.*, No. 18-558V, 2022 WL 2036101 (Fed. Cl. Spec. Mstr. May 6, 2022) (flu vaccine deemed causal of brachial neuritis); *Patton v. Sec'y of Health & Hum. Servs.*, 157 Fed. Cl. 159 (2021) (The Court of Federal Claims finding Petitioner offered preponderant evidence that the flu vaccine can cause brachial neuritis via molecular mimicry). The presumption of causation for brachial neuritis following the tetanus toxoid vaccine has not been extended to other vaccines, and that is not at issue here. Petitioner has not argued that the IOM analysis alone is sufficient to meet his burden, nor did he seek to meet the heightened standard for a presumption of causation. Here, Petitioner argued that the same evidence used to put brachial neuritis on the Table for tetanus should be considered as probative evidence in his case, and when combined with the other evidence presented, is sufficient to meet the preponderant standard for a sound and reliable theory. Petitioner used some of the evidence considered by IOM to draw an analogy between the tetanus and flu vaccines, but his submission of additional evidence is an acknowledgement that this alone would not satisfy his burden.

In total, Petitioner has presented preponderant evidence, including but not limited to the presumed pathogenesis of brachial neuritis, the comparison to GBS for molecular mimicry, and Tsairis et al., of a sound and reliable vaccine causation theory linking the flu vaccine to brachial neuritis. Therefore, I find Petitioner has satisfied *Althen* prong one.

2. *Althen* Prong Two – Actual Causation

Before turning to an analysis of logical sequence of cause and effect, I first find that there is preponderant evidence that Petitioner received the flu vaccine at issue in his left shoulder. While his vaccine record indicates it was administered in his right shoulder, there is ample evidence to

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can absolutely cause (since it is a Table Injury) brachial neuritis based on Tsairis [et al.] and five case reports, then why can the flu vaccine not preponderantly cause brachial neuritis based on Tsairis [et al.] and five case reports." *Id.* at 19.

[51] It is important to point out that the IOM used a different standard than applied here to conclude that vaccines can cause a reaction that manifests as brachial neuritis. *See* Pet'r's Ex. 51. Here, we are evaluating whether there is preponderant evidence of a scientific or medical theory that causally connects the vaccination to the injury. *Althen*, 418 F.3d at 1278; *Pafford*, 2004 WL 1717359, at *4.

[52] Dr. Fujinami also does not believe the flu vaccine can cause GBS despite being a Table injury.

the contrary. In his affidavit and hearing testimony, Petitioner explained the chaotic environment in which he received the vaccination, the instructions from the nurse, and why he ended up choosing his left arm over his right arm. He also explained why he did not find any reasons to correct the record for a routine flu shot at that time, and later, did not see a reason to go back and change it. I found Petitioner's explanation reasonable, and his recollection of events credible. Additionally, the subsequent medical records indicated Petitioner's left shoulder pain began after receiving a vaccine in that arm. I find this evidence preponderantly establishes that the flu vaccination was administered in Petitioner's left shoulder.[53]

Next, I find that Petitioner has provided preponderant evidence of a logical sequence of cause and effect consistent with the proposed mechanism. In evaluating whether this prong is satisfied, the opinions and views of the vaccinee's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("[M]edical 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 trustworthy evidence, since they are created contemporaneously with the treatment of the vaccinee. *Cucuras*, 993 F.2d at 1528.

Petitioner's treating physicians referred Petitioner's injury back to his vaccination or noted an association. For example, on November 18, 2014, Dr. Masood noted that Petitioner's pain and numbness that started shortly after his flu shot and that his presentation was likely autoimmune. Pet'r's Ex. 5 at 2, 4; *see also* Pet'r's Ex. 8 at 10 (Dr. Ausban writing that Petitioner developed "a very rare complication of a flu vaccine, brachial plexus neuritis/neuropathy"); Pet'r's Ex. 7 at 51 (Dr. Xie noting the etiology was unclear but that Petitioner did have a flu shot one week prior to symptom onset); Pet'r's Ex. 9 at 2 (Dr. Raaphorst writing that Petitioner's brachial neuritis was "possibly related to [the] flu-shot"); Pet'r's Ex. 16 at 1 (Dr. Chopra noting Petitioner's pain onset approximately five days after flu vaccine). Beyond disagreeing with the diagnosis, Respondent did not dispute the opinions of Petitioner's treating physicians.

Dr. Serota opined that Petitioner "was exposed to antigens in the [flu] vaccine that have been known to stimulate an antibody directed autoimmune response against peripheral nerve myelin." Pet'r's Ex. 42 at 1. "This would then induce an inflammatory cascade and complement fixation that results in the tissue damage and clinical symptomology that presented in [Petitioner's] case." Pet'r's Ex. 42 at 5. Petitioner received the flu vaccine on October 9, 2014. He experienced a sore and "dull ache" around the injection site, but it eventually went away after the third day. Tr. 27, 30. Six days after vaccination, Petitioner "woke up with that sharp pain, deep in [his] shoulder." Tr. 30. He gradually experienced numbness and weakness and had initial improvement with steroids. As discussed above in the diagnosis section, Petitioner's presentation was consistent with brachial neuritis, an inflammatory autoimmune disease—which in and of itself is evidence of an autoimmune reaction.

[53] I note that this is immaterial to causation as brachial neuritis can develop on either side regardless of the side in which someone was vaccinated.

Finally, I do not find any evidence in the record of an alternative cause.[54] Although Respondent does not have an obligation to present evidence of alternative cause prior to Petitioner's prima facia establishment of entitlement, such evidence can be considered in rebuttal to Petitioner's prong two evidence during Petitioner's case in chief analysis. However, Respondent did not present such evidence for consideration at any stage in this case. For all of these reasons, I find that Petitioner has provided preponderant evidence of a logical sequence of cause and effect, satisfying *Althen* prong two.

3. *Althen* Prong Three – Temporal Association

Prior to the flu vaccine on October 9, 2014, Petitioner did not have severe or prolonged shoulder pain. While he had previous musculoskeletal injuries and occasional ongoing neck pain, it was not to the degree of severity or in the same location as Petitioner's brachial neuritis symptoms. Approximately six days post vaccination, or around October 15, 2014, he woke up with "searing, hot, stabbing pain" that he had never experienced before. Tr. 32. The medical records continuously report the date of onset approximately one week after the flu vaccine. None of the experts dispute the date of onset.

Dr. Serota opined that the timeline from Petitioner's vaccination to progression of pain and weakness was consistent with an immune-mediated process. The Shaikh et al., Hansen, and Sinha & Gupta case reports reported patients developing symptoms of brachial neuritis approximately one week after vaccination. Tsairis et al. found patients developed symptoms 10 to 21 days after vaccination. Petitioner again analogized the flu vaccine to the tetanus vaccine in which causation is presumed if brachial neuritis symptoms occur within two to 28 days after vaccinations. Dr. Fujinami did not think an autoimmune disease can develop in six days but did not provide further explanation or an otherwise appropriate timeframe in rebuttal to Dr. Serota's.

I find that Petitioner has presented preponderant evidence of an appropriate temporal association between his flu vaccination and onset of brachial neuritis, given the asserted mechanism of molecular mimicry; therefore, Petitioner has satisfied the third *Althen* prong.

VI. Conclusion

After a careful review of the record, and for the reasons discussed above, I find that Petitioner has established by preponderant evidence that his flu vaccine administered on October 9, 2014, caused him to develop brachial neuritis. Therefore, Petitioner is entitled to compensation. A separate damages order will issue.

IT IS SO ORDERED.

s/Herbrina D. S. Young
Herbrina D. S. Young
Special Master

[54] Both parties' experts agreed that Petitioner did not have TOS, CRPS or EDS, accordingly, I will not address those conditions and the relevance, if any, to Petitioner's clinical course or alternative cause.