

OFFICE OF SPECIAL MASTERS

No. 99-031V

(Filed: September 28, 2006)

GAIL DEVONSHIRE,

Petitioner,

v.

SECRETARY OF THE DEPARTMENT OF
HEALTH AND HUMAN SERVICES,

Respondent.

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To be PUBLISHED
Tetanus, Causation-in-fact,
Brachial Neuritis, Cervical
Radiculopathy

Clifford J. Shoemaker, Esq., Vienna, Virginia, for Petitioner,
Michael Milmo, Esq., United States Department of Justice, Washington, D.C., for Respondent.

ENTITLEMENT DECISION¹

ABELL, Special Master

I. BACKGROUND

On 20 January 1999, the Petitioner brought an action under the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act" or "Act")² alleging that she suffered a vaccine-related injury from a tetanus immunization received 20 January 1997. In particular, the Petitioner alleges that the vaccination resulted in a brachial neuritis which aggravated a degenerative cervical disc condition. Complicating this case is a lack of objective evidence concerning the alleged brachial neuritis coupled with evidence of a cervical radiculopathy.

¹ Petitioner is reminded that, pursuant to 42 U.S.C. § 300aa-12(d)(4) and Vaccine Rule 18(b), a petitioner has 14 days from the date of this decision within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, "the entire decision" may be made available to the public per the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002).

² The statutory provisions governing the Vaccine Act are found in 42 U.S.C. §§300aa-10 *et seq.* (West 1991 & Supp. 1997). Hereinafter, reference will be to the relevant subsection of 42 U.S.C.A. §300aa.

Though this petition was filed in 1999, no medical records were received from Petitioner till May 2001. Thereafter, the case remained in record collection mode for several years much to the dismay of the Court. Finally, on 3 July 2003 the Petitioner filed an expert report from Dr. Carlo Tornatore, a neurologist at Georgetown University Hospital. His report was expected to complete the evidentiary record. However, Dr. Tornatore instead indicated that additional testing should take place "to address whether there is a brachial plexopathy that can be distinguished from the C6 radiculopathy."³ Additional time was given for that testing and numerous extensions were granted. Roughly nineteen months later, those tests finally took place but, according to the Petitioner, were "of no assistance since they do not demonstrate any residual injury in the brachial plexus." Even so, the Petitioner opted to pursue the petition to its ultimate conclusion. Thus, a hearing was held on 14 October 2005. To the consternation of the Court, at trial, both parties referenced medical literature that had not previously been filed. After the hearing, those articles were filed, and a briefing schedule was set for closing argumentation. The petition is now ripe for a decision.

The Vaccine Act authorizes the Office of Special Masters to make decisions on petitions which shall include findings of fact and conclusions of law. §12(d)(3)(A)(I).

II. Factual Record

In general, this Court may not rule in favor of a petitioner based on his asseverations alone; rather, a petitioner's claims must be substantiated either by medical records or by medical opinion. §13(a)(1). Before addressing the medical records or opinions, the Court first turns to the medical literature referenced by the parties that describes a brachial neuritis versus a cervical radiculopathy.

A. Medical Literature

In summation, brachial neuritis is an inflammatory condition affecting the bundle of nerves known as the brachial plexus that are located around the shoulder area. A brachial neuritis is known by several different names including Parsonage-Turner syndrome, neural amyotrophy, brachial plexitis, or brachial plexopathy. Meanwhile, a radiculopathy is a "disease of the nerve root" with a cervical radiculopathy affecting "cervical nerve roots, often manifesting as neck or shoulder pain."⁴ A helpful diagram of the brachial plexus including the nerve roots that feed into it from the cervical spine was filed with Respondent's post-hearing exhibits at page eleven.⁵

³ Petitioner's original expert report was filed 3 July 2003 without an exhibit number. Petitioner later sought to correct this oversight by filing it on 14 October 2005 as Exhibit 13 but subsequently filed a medical article abstract with that same exhibit number.

⁴ DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 1562.

⁵ No exhibit number accompanied the filing, so the Court will reference it as Respondent's Exhibit ("R. Ex.") B.

Neither of the parties disputes whether a tetanus shot can cause a brachial neuritis. See Tr. at 161. In fact, it is one of the conditions listed on the Vaccine Injury Table whereby a Petitioner is granted a presumption of causation if a brachial neuritis occurs within two to twenty-eight days of a vaccine containing tetanus toxoid. The Qualification and Aids to Interpretation that accompany the Vaccine Injury Table describe brachial neuritis as follows:

Brachial neuritis is defined as dysfunction limited to the upper extremity nerve plexus (i.e., its trunks, divisions, or cords) without involvement of other peripheral (e.g., nerve roots or a single peripheral nerve) or central (e.g., spinal cord) nervous system structures. A deep, steady, often severe aching pain in the shoulder and upper arm usually heralds onset of the condition. The pain is followed in days or weeks by weakness and atrophy in upper extremity muscle groups. Sensory loss may accompany the motor deficits, but is generally a less notable clinical feature. The neuritis, or plexopathy, may be present on the same side as or the opposite side of the injection; it is sometimes bilateral, affecting both upper extremities. Weakness is required before the diagnosis can be made. Motor, sensory, and reflex findings on physical examination and the results of nerve conduction and electromyographic studies must be consistent in confirming that dysfunction is attributable to the brachial plexus. The condition should thereby be distinguishable from conditions that may give rise to dysfunction of nerve roots (i.e., radiculopathies) and peripheral nerves (i.e., including multiple mononeuropathies), as well as other peripheral and central nervous system structures (e.g., cranial neuropathies and myelopathies).

42 C.F.R. § 100.3(6).

At trial, Petitioner's expert, Dr. Carlo Tornatore, referenced an article from the Journal of Bone and Joint Surgery regarding Parsonage-Turner syndrome (or acute brachial neuritis) which described the characteristic symptoms as "sudden onset of severe pain in or about the shoulder girdle, followed shortly thereafter by weakness of at least one of the muscles about the shoulder." Petitioner's Exhibit ("Pet. Ex.") 14 at 2. It does not appear that the remainder of the article is particularly helpful since Petitioner's case would not have fit the study criteria. However, the article does note that, while the exact etiology of brachial neuritis is uncertain, it is known to follow viral infection and immunization. Id. at 4. It also acknowledges that Parsonage-Turner can be difficult to differentiate from a central radiculopathy but can be distinguished by the "sudden onset of intense pain, with no inciting trauma and with normal findings on examination of the neck and shoulder. The diagnosis becomes more obvious when the pain decreases spontaneously and weakness develops. Electromyography at that time should confirm the neuropathy." Id. The most difficult differentiation to make is between a brachial neuritis versus a peripheral nerve compression. Further, a brachial neuritis typically evinces with a sudden, intense pain that resolves spontaneously; whereas, the pain associated with a peripheral nerve compression has "a more insidious onset of pain." Id.

The Petitioner likewise filed a section from Preston and Shapiro's Electromyography and Neuromuscular Disorders: Clinical-Electrophysiologic Correlations that describes brachial neuritis as follows:

The onset of shoulder pain follows within several days to a few weeks. The pain is

severe, often awakening the patient from sleep. Early on, muscle weakness may be difficult to detect on examination because of the prominent pain. However, as the pain subsides, typically after 1-2 weeks, significant underlying weakness becomes apparent. Muscle atrophy follows. Although paresthesias and sensory loss may also be present, it is not unusual to find only mild or minimal sensory abnormalities on examination.

Pet. Ex. 15 at 2.

An article filed by Respondent concerning brachial neuritis indicates that with "the majority of patients a sudden onset of severe pain occurs first, followed by muscle weakness, atrophy, or both with limited sensory involvement." R. Ex. B at 13. The pain is described as "lancinating, burning, sharp, boring, throbbing, or as a severe ache" and "often will radiate from the shoulder down into the lateral arm or up along the neck." *Id.* at 14. Further, "85% of patients report some weakness within the first month after symptoms begin." *Id.* at 15. The article acknowledges that diagnosis can be tricky, particularly "when patients present soon after the onset of symptoms." *Id.* The authors urge that "acute upper cervical disease should be eliminated (C4, C5, or C6) as a cause of the symptoms. A patient with an acute cervical disc causing nerve root compression may have pain similar to the pain experienced by someone with brachial neuritis; however, pain usually is exacerbated with extension of the neck." Moreover, "[P]atients with these conditions usually present with a more insidious onset of pain instead of the acute severe pain seen in patients with brachial neuritis. Patients with peripheral nerve compression or injury do not get the rapid resolution of pain symptoms that may occur spontaneously in patients with brachial neuritis." *Id.*

The "most helpful" tool for diagnosing a brachial neuritis is an electromyographic test ("EMG") which "typically reveal the presence of acute denervation." *Id.* at 6. Likewise, MRIs may be helpful in showing diffuse muscle atrophy when taken several months out. *Id.*

Respondent also filed an article on Intervertebral Disc Disorders and Other Spondyloarthropathies which describes the pain associated with cervical radiculopathies as "constant, gnawing, deep, dull, poorly localized, disturbing neck and arm ache, which in the acute stages is punctuated by a sharp pain. Radiation to the medial part of the scapula, the shoulder, and eventually to the arm, forearm, and occasionally to the hand and fingers may be present from the start or develop after a period of neck pain." *Id.* at 7-8. Less than 12% of patients suffering from cervical radiculopathies opt to have surgery. *Id.* Additionally, the symptoms associated with such typically subside within a few weeks. *Id.*

In addition, several items were filed by Respondent in support of its expert's proposition that, as regards the diagnosis of a cervical radiculopathy, abnormalities in the paraspinal muscles should be present in an EMG but the absence of such is not unusual. R. Ex. B at 8, 9. In fact, the aforementioned article indicates that radiculopathies may present without the involvement of the paraspinal muscles. R. Ex. B at 7.

Certain articles also indicate that a brachial neuritis can be distinguished from a cervical

radiculopathy by whether certain movements exacerbate pain in the neck but not in the shoulder, in which case a cervical radiculopathy is more likely, or in the shoulder and not the neck, in which case a brachial neuritis is more likely. Id. at 27.

The medical literature proffered by both parties indicate that brachial neuritis is a diagnosis of exclusion and that it is necessary, though difficult, to rule out other conditions that present with similar symptoms including cervical radiculopathies.

B. Medical Records

The records, including fact witness testimony and affidavits, indicate that Petitioner, then in her late forties and employed as an orthodontist's assistant, suffered during the course of her employment a cut to her right hand. Prompted by her employer, Petitioner received a tetanus vaccination that day, 20 January 1997. Pet. Ex. 1 at 1.

The Court has no medical records from Petitioner for the years prior to the immunization. The Petitioner testifies that she was a healthy individual, despite a rather lengthy smoking history, and had never experienced any sort of neuromuscular pain prior to receiving the 20 January 1997 vaccination. The histories recorded in the various medical records filed with this Court likewise indicate that onset of Petitioner's symptomatology started shortly after the vaccination.

The day after, the Petitioner experienced a "tingy feeling" in her left arm where the shot was administered, which felt "like if you put your tongue on a nine volt battery." Hearing Transcript ("Tr.") at 9. Petitioner avers that the pain got progressively worse until it felt like an abscessed toothache – an apt description given her occupation. Weeks later, her employer, noting her obvious discomfort, recommended that she seek medical attention. Tr. at 11-12.

On Saturday, 8 February 1997, some nineteen days after vaccination, the Petitioner visited a walk-in clinic at the Marquette Regional Medical Center where she initially received the shot. She complained of "[l]eft arm pain. She had a Tetanus shot 3 weeks ago and ever since then has had a dull ache in the left arm. She occasionally gets a more intense pain that travels up to her neck." At that time they noted she had full range of motion with normal sensation and strength. Dr. Scott Doughty believed it to be "likely inflammation around the nerve secondary to deep injection of Tetanus." Pet. Ex. 1 at 2.

On 10 February 1997, Petitioner was seen by a physician's assistant, Michael Kreis, with FamilyCare Doctors at Marquette. He noted "no previous history of neck, shoulder, or arm pains" and an "onset of symptoms approximately 2 days after she received a Tetanus shot in this clinic." Her range of motion was "full without pain or crepitus."⁶ An X-ray of the left shoulder and upper arm

⁶ Joint crepitus is defined as "the grating sensation caused by the rubbing together of the dry synovial surfaces of joints; called also *articular crepitus*." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 433.

was normal. The assessment reads, "Left shoulder pain of questionable etiology, (?) subsequent to the Tetanus shot versus that of muscular pain." Pet. Ex. 1 at 7.

On 11 February 1997, the Petitioner was seen at Marquette General Hospital by a Dr. Daniel Beaver who notes a complaint of "left deltoid muscle pain." According to the history taken in that record, following the tetanus vaccination the Petitioner was pain free for two days with "only very vague, practically nonexistent twinges of mild discomfort in the deltoid region. Thereafter, however, she began having intermittent spasms of pain in the deltoid which seem to radiate up into the latent aspect of the neck and in the saddle of her shoulder." Dr. Beaver notes that her condition had been treated as musculoskeletal pain, but no relief had been had from that treatment. She described the pain "like a toothache in her shoulder. She is a poor historian when asking about the connection between shoulder and deltoid. She does know however, that she gets some degree of relief, very ill-defined, however, when she holds her left arm over her head. No numbness, tingling or weakness of the upper extremity." Pet. Ex. 1 at 11. On Examination, Dr. Beaver noted a "large trapezius muscle spasm at the nape of the neck. Range of motion testing of the wrist, elbow, pronation, supination, shoulder, all are entirely pain free actively and passively. No pain can be elicited by palpating the origin of the pain in her deltoid." Id. at 12. His provisional diagnosis was "Acute trapezius muscle spasm." Id.

That same day, Petitioner was seen on consultation by Dr. Jeff Gephart who records that "she gradually noted, by the second week, the onset of pain in the shoulder." On examination, Dr. Gephart noted that the Petitioner had no weakness and full range of motion with intact reflexes and sensation. "It is even difficult to find out exactly where she hurts as it is more spasmodic than continuous." According to Dr. Gephart, "We apparently have some type of vaccine reaction, which is unusual in that it is 22 days out and presents with no cutaneous manifestations whatever." Pet. Ex. 1 at 15. However, following an essentially normal MRI of the left shoulder on 13 February 1997, Dr. Gephart reconsidered his initial assessment, noting instead, "I actually think the tetanus shot is probably not related to what we are doing, and I think this is an overuse syndrome probably related to work." Pet. Ex. 7 at 2.

On 18 April 1997, nearly three months post-vaccination, Petitioner returned to FamilyCare Doctors for follow up on the left arm issues and physical therapy at which time she reported that "her symptoms have greatly improved." It was likewise noted, "The significant/severe pain that she was receiving in her left shoulder had pretty much resolved." But Petitioner complained that she "does still have some paresthesias in her left distal fingertips." Yet, the examination showed "no decrease of sensation on sharp/dull touch on the distal fingertips of the left hand." The diagnosis by PA Kreis was "left shoulder pain of questionable etiology, improved, however not resolved." Pet. Ex. 6 at 1.

On 9 May 1997, the Petitioner saw Dr. Carl Eiben with U.P. Rehabilitation Medicine Associates. Dr. Eiben notes that Petitioner "feels that she is 75% improved at this time." However, she described a "pulsation" in the left deltoid and local pain but no longer traveling up into her neck. She also reported numbness and tingling in her fingertips on the left hand. Dr. Eiben's impression

is "[l]eft shoulder pain, status post tetanus toxoid injection" and "[l]eft hand paresthesias. Rule out carpal tunnel syndrome." Pet. Ex. 5 at 1.

On follow-up 13 May 1997, roughly four months post vaccination, Dr. Eiben notes that an Electromyography test ("EMG") showed no evidence of "axillary neuropathy, cervical radiculopathy, or left median neuropathy, including carpal tunnel syndrome." Pet. Ex. 5 at 3.

Later, on 20 August 1997, Dr. Eiben expresses some concern that the Petitioner, on exam "is moderately anxious and a little angry" and "is becoming somewhat preoccupied somatically." He notes normal strength and sensation with full range of motion and no tenderness about the shoulder. His assessment is "myofascial pain syndrome" with an element of anxiety and is also concerned about the "long shot" possibility of an injury to the central nervous system or cervical spine disease. Hence, Dr. Eiben recommended that she see a neurologist. Pet. Ex. 5 at 5.

The next record available is a 22 January 1998 self-referral to Dr. Vijay Singh with Pain Diagnostics Associates. At that time, the Petitioner explained that her "pain in the injection site started out gradually and then intensified over a couple of weeks and then gradually improved over several months but still persists." *Id.* at 6. She described her pain as a 10 at the worst but on average a 5 or 6, presumably out of 10. On exam, nothing abnormal was indicated, except Dr. Singh did note "slight atrophy at the left posterior deltoid." Pet. Ex. 5 at 7. His diagnosis reads "Neuropathic pain in the left deltoid region, probable cause related to axillary nerve injury." *Id.*⁷

The Petitioner returned to Dr. Singh on 13 March 1998 for an axillary nerve block. However, her symptoms were not markedly reduced by that block. Dr. Singh's diagnosis then changed to "Neuropathic pain left deltoid region" and "Probable left cervical radiculopathy." Pet. Ex. 5 at 10. This marks the first diagnosis of a cervical radiculopathy, though Dr. Eiben suspected a possible cervical spine injury. As a result of this visit, Petitioner was scheduled for a cervical MRI examination.

That MRI, conducted 27 March 1998, was problematical due to a significant motion artifact but appeared nevertheless to reveal "spinal stenosis"⁸ at C5-6 and, to a lesser degree, at C4-5 and C6-7 . . . likely caused by degenerative changes and possible posterior osteophytosis,⁹ although there is

⁷ The axillary nerve's root exits from the cervical spine from whence it eventually travels through the brachial plexus. R. Ex. B at 11.

⁸ Spinal stenosis, is a "narrowing of the . . . intervertebral foramina of the . . . spine caused by encroachment of bone upon the space; symptoms are caused by compression of the cauda equina and include pain, paresthesias, and neurogenic claudication. The condition may either be congenital or due to spinal degeneration. See also *spinal compression* under *compression*." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 1758.

⁹ An osteophyte is "a bony excrescence or osseous outgrowth." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 1336.

the appearance of a central disc bulge, perhaps slightly to the left of the midline causing spinal stenosis." Pet. Ex. 5 at 12.

On 13 April 1998, Petitioner saw Dr. David Breznick with Pain Diagnostic Associates. In response to Petitioner's concerns regarding a possible vaccine-related injury, Dr. Breznick responded, "I felt that this was likely not due to her tetanus injection. Rather, degenerative changes including posterior osteophytes and disc bulges are more commonly age related." Pet. Ex. 5 at 13. He felt the age related changes in Petitioner's cervical spine were more likely the cause of her complaints rather than the "tetanus shot or other unlikely explanation." Id.

An EMG conducted 18 May 1998 was normal and showed no evidence of a brachial neuritis nor of a cervical radiculopathy. Pet. Ex. 5 at 16.¹⁰

On 18 June 1998, Dr. Singh referred the Petitioner to the Mayo clinic. Pet. Ex. 5 at 20. However, Petitioner first sought medical attention at the Marshfield Clinic in Wisconsin.

Hence, on 17 August 1998, Petitioner was seen at Marshfield by a neurologist, Dr. Evan K. Sandok. Pet. Ex. 3 at 1. The Petitioner described "some atrophy, primarily with what appears to be her left deltoid and left triceps but this now appears to have resolved." After reviewing her history, including the diagnostic tests, and examining the patient, Dr. Sandok stated "the two most likely diagnoses are that of a variant of Parsonage-Turner syndrome (an inflammatory mono- or poly neuritis) and/or a cervical radiculopathy or myelopathy." Id. at 2. He recommended that another MRI of the cervical spine be conducted given the problems with the first. "Should the MRI not disclose any significant spinal stenosis or evidence of myelopathy or radiculopathy, it would be my suggestion to continue to treat this conservatively as a partial Parsonage-Turner syndrome at least temporally related to the administration of the tetanus shot a year and a half ago." Id.

However, that second MRI did indeed show evidence of "cervical spondylosis as described, including a rather large central left disc herniation at C5-6 and a severe left neural foraminal stenosis at C6-7." Pet. Ex. 3 at 9.

Based on that finding, Dr. Sandok dropped the diagnosis of Parsonage-Turner syndrome and instead "explained to [Petitioner] that the cervical myelopathy and cervical disc that she has could produce all of the symptoms that she has. The patient is quite certain that she sustained an axillary nerve injury with the injection as noted in my previous note. I explained to the patient that while this may in fact be true, all of her symptoms could be explained by the findings on the MRI referable to the neck itself." Pet. Ex. 3 at 11.

Returning for a time to FamilyCare Doctors, Petitioner expressed some frustration at the care she was receiving and with her case management and complained "no one will believe" that her

¹⁰ The EMG record indicates that the right side was tested; however, at trial it was explained that it was, in fact, the left side that was examined by that EMG.

injuries were vaccine-related. Pet. Ex. 6 at 3, 5. During that time, a Vaccine Adverse Event Reporting System (VAERS) report was submitted to the Centers for Disease Control by FamilyCare Doctors regarding Petitioner's post-vaccinal medical course. Id. at 5.

Notwithstanding his colleague's assessment, Dr. Sanjay Rao, a neurosurgeon with the Marshfield clinic indicated that, despite the evidence of a cervical radiculopathy "it is difficult to attribute this patient's left arm pain symptoms . . . [I]t is unlikely that her left upper arm symptoms are secondary to this and that other causes of this needed to be explored." Pet. Ex. 3 at 16.

Meanwhile, on 30 October 1998, Dr. Owen Keenan, an orthopaedist at Marshfield signed off on a report indicating, "We can find absolutely no correlation of her symptom complex to her suggested relationship with the tetanus injection she received in the past." Pet. Ex. 3 at 18.

Several miscellaneous items of note occurred during this time frame. A central C6 root block was conducted at Marshfield to little or no effect. Pet. Ex. 3 at 21. During an exam 11 November 1998, Dr. Rao noted "mild left biceps weakness as well as numbness in the left C6 distribution." Id. at 22. And also during this time, at Petitioner's request, a test was done to check her immune protection against tetanus infection. There is some indication from the medical records that Petitioner was concerned about her symptoms resembling a tetanus infection. However, no indication of such an infection was ever found, and her protective levels against such infection were within normal limits, which by inference indicates the 20 January 1997 vaccination was effective. See Pet. Ex. 6 at 9 (wherein Dr. David Luoma concludes there is no evidence of a tetanus infection but speculates, "It is possible that pain guarding spasm and so forth that she experienced caused this to become uncovered and both problems are contributing at this time.").

At Marshfield, Dr. Rao, the neurosurgeon, suggested surgical intervention to arrest the degenerative cervical spine issues but could not guarantee that the surgery would address the complaint of left arm pain. Pet. Ex. 3 at 21-22. Petitioner declined Dr. Rao's suggestion and instead sought answers at the Mayo Clinic.

At the Mayo Clinic, Petitioner was seen by Dr. Andrew Stalker who identified some weakness in the left triceps and wrist. Pet. Ex. 2 at 2. His impression is "Possible causes for her shoulder pain include: (1) brachial plexitis or neuritis related to the DT injection similar to a Parsonage-Turner syndrome, (2) less likely, musculoskeletal shoulder pain. I think it is very unlikely that the disk herniation in her neck is responsible for her current symptoms." Id. He suggested another EMG to check for residual evidence of a plexopathy or neuropathy. Id.

At the Mayo Clinic, the Petitioner was also seen by Dr. Burton A. Sandok, purportedly the father of Dr. Evan Sandok of Marshfield. He originally thought "her additional symptoms are most compatible with a brachial plexus neuritis (the Parsonage-Turner syndrome) which may occur following immunization. Her persistent symptoms sound more musculoskeletal than neurogenic to me." Pet. Ex. 2 at 4. Dr. Sandok, the elder, noted that, though some cervical disc disease was evident, "I do not think this is very symptomatic and does not account for her chief complaint." Id.

The petitioner also saw Dr. Bruce Pollock, a neurosurgeon at the Mayo Clinic. He felt that "though possible, it is less likely that this herniated disk is the root of her problems." Pet. Ex. 2 at 5. Hence, he did not suggest surgery at that time but did suggest additional testing including a CT/myelogram.

In the meantime, an EMG ordered by Dr. Stalker showed no evidence of a plexopathy or neuropathy but did show "fibrillation potentials and large motor unit potentials in left C6 innervated and cervical paraspinal muscles." In other words, the EMG revealed "an active left C6 radiculopathy." Pet. Ex. 2 at 9. The previous MRIs, meanwhile, were reviewed by the technicians at the Mayo Clinic who found no changes between the two and described them as "essentially negative." Id. at 7.

Based on the EMG findings, Dr. Sandok expressed uncertainty "as to the cause of her pain but brachial plexus now seems less likely and a cervical disk seems more likely." His diagnosis reads "Left arm pain, etiology? (brachial plexus neuritis vs. a C6 neuropathy)." Pet. Ex. 2 at 8. In the end, he remained unsure as to whether the changes seen on MRI and EMG were responsible for the Petitioner's arm pain. Id. at 11. It does not appear that either Dr. Stalker or Dr. Pollock reviewed or opined on the EMG or MRI results.

Petitioner opted to return home for further treatment. Pet. Ex. 2 at 11.

As had been recommended by Dr. Pollock at the Mayo Clinic and as similarly suggested by Dr. Rao, a cervical myelogram was performed to "rule out any definitive ongoing compression of the C6 nerve root." Pet. Ex. 3 at 24. Due to issues with that test, however, it was felt a postmyelogram CT might provide more definitive answers. The postmyelogram CT showed "evidence of a disc bulge combined with unconvertible hypertrophy and compression of the C6 nerve root" as well as compression of the C7 nerve root but to a lesser degree. These results were considered consistent with the numbness and tingling in Petitioner's left hand but "[i]t was difficult to explain her localized left shoulder pain as a result of all of these tests." Pet. Ex. 3 at 27. Based on this conflicting explanation, the Petitioner opted not to undergo surgery. Instead, she continued to seek a definitive explanation for her condition.

On 17 January 2001, Dr. Christopher Bixler with Neurology Associates of Marquette sent a letter to PA Kreis explaining:

Since I did not have the opportunity to examine her four years ago when this began, and because she had another neurologic condition (a radiculomyelopathy), which can cause identical symptoms and EMG changes, I cannot and will never be able to tell whether she actually had a brachial neuritis from her injection or not. Because we do not have any cervical spine films from 1997, and we do not really know when she definitively developed her cervicular radiculomyelopathy, I do not think it is going to be possible to answer that question. Pragmatically, we do know and it is very well documented, that she has a left C6-7 radiculomyelopathy with weakness and

numbness. Often this sort of syndrome is quite painful, and can have referred pain to the shoulder.

Pet. Ex. 9 at 4. He later notes that the neurologists, orthopaedists, and neurosurgeons seen by the Petitioner "felt that she had some combination of a Parsonage-Turner syndrome from her tetanus shot, a left cervical radiculopathy, and an impingement of her left shoulder." Pet. Ex. 9 at 8. And he considered that a brachial neuritis might be the diagnosis of exclusion if, after being cleared orthopedically and having her cervical spine repaired surgically, she was still experiencing pain.

It appears that the Petitioner was cleared orthopedically but did not undergo surgery.

An MRI conducted May 2001 showed "Advanced spondylosis of the cervical spine with discongenic spurring at the C4-5, 5-6, and 6-7 levels, stenosis at 5-6, some stenosis centrally at 4-5, and narrowing of the canal at 6-7." Pet. Ex. 9 at 9.

On 21 February 2002, Dr. Frederick Maynard with U. P. Rehabilitation Associates noted an impression of "a persistent pain problem in her neck and left shoulder following a vaccination injection that fit the Parsonage-Turner syndrome but certainly appears to have run its course and is now at a stable level." Pet. Ex. 8 at 2. However, he did not have access to the EMG done by the Mayo Clinic and other testing, and when those came available his perspective appears to have changed a bit. He decided to conduct his own EMG to see whether such would "still shows active denervation after three years in the C6-C7 innervated muscles" or whether "the findings now look as if there was an old chronic radiculopathy, but it is no longer active." Pet. Ex. 8 at 4.

That EMG was essentially negative, but he did see "old motor unit findings compatible with a chronic radiculopathy. It looks as if there has been extensive muscle remodeling, but certainly nothing that suggested active denervation in the neck or the arm." Pet. Ex. 8 at 5. He later indicated that the findings were compatible with either "her old cervical radiculopathy or brachial plexus problems from Parsonage-Turner syndrome." Pet. Ex. 8 at 7.

Records from June 2002 indicate that Dr. Maynard suggested that Petitioner return to the Mayo Clinic; Dr. Rovin, a neurosurgeon, did not suggest surgery; and Dr. Eppinga, an orthopedist, did not recommend orthopedic intervention. Commenting on these developments, Dr. Bixler indicates, "I do not have anything else to offer her other than pain medicine" and notes that "Paxil worked for her pain 50%." Pet. Ex. 10 at 1-2.

Petitioner continued to question whether surgical intervention might not be a proper solution to her ongoing issues. Hence, Dr. Bixler ordered a cervical myelogram, conducted 28 March 2003, which showed, "Cervical spondylosis 4-5, 5-6, and 6-7 levels appears to be mainly central disc material narrowing the subarachnoid space. The 5-6 and 6-7 level stenosis is caused by spur disc complex, which is broad based. There is also left foraminal stenosis at 5-6 and 6-7 and asymmetric filling of the root sleeves, at these two levels on the left, particularly 5-6 from spur." Pet. Ex. 10 at 18. Dr. Bixler also ordered an MRI, conducted 1 April 2003, which showed "Cervical spondylosis at the C4-5, 5-6, and 6-7 levels with acquired stenosis. The C4-5 level stenosis appears to be central

disc material and the 5-6 and 6-7 stenosis appears to be from spondylitic spur, disc complex similar to the myelogram." And furthermore, "Left foraminal stenosis at 5-6 and 6-7 from degenerative changes"; however, "The underlying cord signal is maintained." Pet. Ex. 10 at 15. Moreover, an EMG conducted 3 May 2003 by Dr. Bixler showed "evidence [of] reinnervation of the right (sic) pronator teres and right (sic) triceps muscles consistent with a chronic right (sic) C7 radiculopathy. This correlates with her complaints of cervical pain and tingling in digits 2 and 3 in the right (sic) hand." In addition, "No evidence of a median neuropathy or polyneuropathy in the right (sic) upper extremity exists on this study." *Id.* at 14. At trial it was explained that reference to the right side was a scrivener's error. On 30 May 2003, Dr. Bixler offered the following analysis:

I believe the picky feeling in digits one through three is due to symptomatic left C7 nerve root involvement indicated on her EMG and MRI, and the referred pain into her shoulder region is probably from that as well. She does have degenerative changes diffusely in her cervical spine which is contributing to her cervicogenic headaches. [The Petitioner] has not done well with medical therapy, epidural steroid injections have not been beneficial and physical therapy has not been helpful. For that reason, I think she is at a point now where she either is going to have to accept these symptoms as something that she can live with or she should see the surgeon she saw at Mayo Clinic with the question whether to decompress the left C7 nerve root. [The Petitioner] is not sure that she really wants to do that at this point.

Pet. Ex. 10 at 9.¹¹

C. Medical Opinions

In addition to those opinions contained in the medical records from the treating medical care providers, Petitioner offered live testimony as well as two written reports from Dr. Carlo Tornatore, a board certified neurologist on staff at Georgetown University Hospital. Tr. 60-62.

In his first written filing, Dr. Tornatore notes that, while the timing and quality of the pain experienced by Petitioner following vaccination could be indicative of a brachial neuritis, "The confounding issue in this case is the finding of a left C6 radiculopathy which can cause left arm pain." Dr. Tornatore notes that certain tests originally showed no evidence of a radiculopathy, and the C6 nerve block had little to no effect on Petitioner's pain. Yet, in the end, he recommended that "a more Comprehensive EMG/NCS specifically done to address whether there is a brachial plexopathy that can be distinguished from the C6 radiculopathy would be of great benefit" and "may help to unambiguously establish the diagnosis of brachial neuritis."

That testing, finally conducted 4 February 2005 at Georgetown, showed "chronic motor unit changes for muscles with C7 innervation. Chronic C7 radiculopathy is possible. No evidence of brachial plexopathy." Pet. Ex. 14.

¹¹ That is the most recent medical record filed by Petitioner in this case. However, presumably any further records would be of little assistance in answering the core question concerning causation.

Dr. Tornatore authored a supplemental report incorporating his previous discussion of the records and noting that, despite there being "no electrographic evidence of a residual plexus injury" there remains the possibility that Petitioner suffered a brachial neuritis. He explains that a brachial neuritis can occur following a tetanus vaccination and can occur without there being evidence on EMG, particularly where a patient's symptoms are primarily sensory, as they were here, rather than motoric in nature. Dr. Tornatore bolsters his theory by pointing to numerous treating physicians who "felt that her symptoms were consistent with brachial neuritis" despite later EMG evidence of a cervical radiculopathy.

Dr. Tornatore offered much the same by way of testimony at trial. In particular, he emphasized the "striking temporal relationship between the time of the vaccination and the onset of the symptoms." Tr. at 63. He also noted the lack of any abnormality regarding the paraspinal muscles in the early EMGs. Such involvement, indicative of a cervical radiculopathy, was not evident on EMG until some 24 months after the onset of Petitioner's symptoms. Eggo, explains Dr. Tornatore, the alterations in the cervical spine may have been causally related to the brachial neuritis. In fine, Dr. Tornatore alleges that the pain associated with the brachial neuritis caused the Petitioner to hold her body in such a way that an underlying degenerative condition was aggravated, and that would not have been but for a vaccine-related injury. Tr. at 83-84.

Dr. Tornatore explains that, reading between the lines of the medical records, it becomes apparent that the doctors considered her injury to have been a brachial neuritis and, regardless of the doubts expressed, continued to treat it as such. For instance, Dr. Singh conducted a nerve block on the axillary nerve, which comes off the brachial plexus.¹² Tr. a 95-97. Moreover, the medicine prescribed was for neuropathic pain and not for cervical pain. Tr. at 97-99. Further, while some neurosurgeons urged surgical intervention, many did not, including the neurosurgeon at the Mayo Clinic – and this despite MRI and EMG evidence of cervical spine issues.

Dr. Tornatore explains that weakness and atrophy, which are hallmarks of a brachial neuritis, were not present in this instance because unlike most instances of brachial neuritis, in Petitioner's case the "motor component was not a big part of her picture. It was more pain and sensory with a little bit of motor involvement." Tr. at 131.

According to Dr. Tornatore, "As all the physicians here did, they said well you know it could be brachial neuritis. It sounds right. The story is right." Tr. at 134.

In counterpoint, the Respondent proffered a written report and live testimony from Dr. Gerald Winkler, a board certified neurologist on staff at Massachusetts General Hospital and on faculty at Harvard Medical School. Tr. at 138.

¹² As seen on the diagram filed by Respondent, the axillary nerve originates in the cervical spine, a fact not acknowledged by Dr. Tornatore. Hence there is some question as to whether an axillary nerve block points to a concern regarding the brachial plexus or the nerve root. Tr. at 147.

Following a detailed review of the medical records, Dr. Winkler opines in his written report that Petitioner's symptomatology is not consistent with a brachial neuritis. However, it is consistent "both in nature and localization, with progressive impingement on cervical nerve roots supplying the left arm as a result of slowly progressive narrowing of the foramina of exit of the nerve roots because of slowly progressive cervical spondylosis." R. Ex. A at 13. Dr. Winkler acknowledges that the onset of Petitioner's pain began shortly after a tetanus vaccination, but reminds the reader that "sequence does not prove consequence." Id.

At trial, Dr. Winkler explained that the onset of Petitioner's pain the day after the vaccination and manner in which the pain slowly progressed is not in line with the "sudden" onset of pain typically associated with a brachial neuritis but is more indicative of the insidious onset of pain that accompanies a cervical radiculopathy. Moreover, Dr. Winkler notes there is no contemporaneous documentation of weakness nor muscle atrophy as would be expected with a brachial neuritis. Contrary to Dr. Tornatore's asseverations, Dr. Winkler explained that paraspinal muscle involvement will not always show up on initial EMGs where a cervical radiculopathy is concerned but may later become apparent as the compression increases. Tr. at 187. Furthermore, the Petitioner's sensory issues with the hand and fingertips is much more commonly associated with a compression of the cervical spine at C5 or C6. Tr. at 155. Dr. Winkler also explained that, depending on whether the motor nerve root is compromised or the sensory nerve root is compromised, because these nerve roots are separate at the level of the foramen, an EMG would not reflect a purely sensory radiculopathy. In this case, explains Dr. Winkler, Petitioner's symptoms are primarily sensory or pain and only later turned into motor problems as the compression progressed to encompass the motor root as evidenced in the latter EMGs. Tr. at 157.

Dr. Winkler agrees that, in outlying cases of brachial neuritis, pain can get progressively worse over time. But as regards his opinion, "I don't claim certainty. That is a rare luxury in medical practice. I'm trying to explain my opinion based upon the fact that the symptoms and signs and ancillary findings correspond to the probable pattern that you can expect from cervical radiculopathy, especially for herniation of a C-5, 6 disc. They do not correspond to the probable pattern that is associated with brachial neuritis." Tr. at 153.

According to Dr. Winkler, "[T]he patient's pain and electromyographic changes are due to a slowly progressive cervical spondylosis, This is a degenerative process causally unrelated to the tetanus vaccine." R. Ex. A as 13.

II. LEGAL STANDARDS

In legal terms, "Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole -

- (A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa-11(c)(1) of this title, and
- (B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the

administration of the vaccine described in the petition.

The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." §13(a)(1).

Under section 300aa-11(c)(1), the Petitioner may demonstrate entitlement to compensation by showing either that she received an injury recognized by the Vaccine Injury Table, 42 C.F.R. § 100.3, ("Vaccine Table" or "Table") within the statutorily prescribed time period or, in the alternative, that she "sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine referred to in subparagraph (A)." §11(c)(1)(C)(I) & (ii)(I).

In this particular case, the Petitioner is not claiming a "Table Injury." Although the Petitioner is claiming that she suffered a brachial neuritis, a condition listed on the Table following a vaccine containing tetanus toxoid, there is some question as to whether the Petitioner's injury occurred within the two to twenty-eight day time period set forth in the Table since the medical records and fact witness testimony indicate that her issues began within 24 hours of immunization. Regardless, Petitioner's symptoms do not fit the definition of a brachial neuritis as set forth in the Qualification and Aids to Interpretation that accompany the Vaccine Act. 42 C.F.R. § 100.3(6). Specifically, her condition was not limited to the nerve plexus but showed signs of a cervical radiculopathy. No weakness was noted, which "is required before the diagnosis can be made." Id. No medical tests ever attributed dysfunction to the brachial plexus. Moreover, her condition was not "distinguishable from conditions that may give rise to dysfunction of nerve roots (i.e., radiculopathies)." Id.

Therefore, the Petitioner must affirmatively demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused the injury alleged. See 11(c)(1)(C)(ii)(I) & (II); Grant v. Secretary of HHS, 956 F.2d 1144 (Fed. Cir. 1992); Strother v. Secretary of HHS, 21 Cl. Ct. 365, 369-70 (1990), aff'd, 950 F.2d 731 (Fed. Cir. 1991). The Federal Circuit has indicated that every petitioner must:

show a medical theory causally connecting the vaccination and the injury. Causation in fact requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect.

Grant, 956 F.2d at 1148 (citations omitted); see also Strother, 21 Cl. Ct. at 370. Additionally, merely showing an absence of an alternative cause of injury does not meet petitioner's burden of proof. Grant, 956 F.2d at 1149. Neither can the Court infer causation from temporal proximity alone. In fact, it has been held that where a petitioner's expert views the temporal relationship as the "key" indicator of causation, the claim must fail. Thibaudeau v. Secretary of HHS, 24 Cl. Ct. 400, 403 (1991). Rather, a petitioner must explain how and why the injury occurred. Strother, 21 Cl. Ct. at 370. After all, inoculation is not the cause of every event that follows. Hasler v. United States, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984). That being said, where several potential causes present themselves, a petitioner need not show that the vaccination was the sole cause of the injury but may demonstrate that it was a "substantial factor" in causing the alleged injury

which would not have occurred "but for" the vaccine. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir.1999).

The Federal Circuit recently articulated an alternative three-part causation-in-fact analysis as follows:

[Petitioners'] burden is to show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen v. Secretary of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). And furthermore, "[R]equiring that the claimant provide proof of medical plausibility, a medically-acceptable temporal relationship between the vaccination and the onset of the alleged injury, and the elimination of other causes-is merely a recitation of this court's well-established precedent." Id. at 1281.

According to the court in Althen, the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." 418 F.3d at 1280. Therefore, "close calls regarding causation are resolved in favor of injured claimants." Id.; but cf., Knudsen v. Secretary of HHS, 35 F.3d 543, 550 (Fed. Cir. 1994) (when evidence is in equipoise, the party with the burden of proof failed to meet that burden) and Hines v. Secretary of HHS, 21 Cl. Ct. 634, 646 (1990), aff'd, 940 F.2d 1518 (Fed. Cir. 1991).

Concerning the framework set forth in Althen, the Federal Circuit has held that 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.'" Capizzano v. HHS, No. 00-759V, 2004 WL 1399178 (Fed. Cl. Spec. Mstr. June 8, 2004), aff'd, 63 Fed. Cl. 227 (2004) (Merow, J.), rev'd, No. 05-5049, slip op. at 14 (Fed. Cir. Mar. 9, 2006) (quoting Althen, 418 F.3d at 1280); see also Zatuschni v. Secretary of HHS, 69 Fed. Cl. 612, 624 (2006).

If a petitioner demonstrates entitlement to compensation, the burden of proof then shifts to Respondent to show that the claimant's injuries are "due to factors unrelated to the administration of the vaccine described in the petition." § 13(a)(1)(B); Whitecotton v. Secretary of HHS, 17 F.3d 374, 376 (Fed. Cir. 1994).

Ultimately, however, there is "no hard and fast rule for what specific, individual elements of proof a petitioner must present in order to establish a prima facie case of causation-in-fact; the rule is really one of reason, in which the Special Master gives greater weight to certain factors in certain cases depending on the facts of that particular case and the medical developments existing at that time." Pafford v. Secretary of HHS, 64 Fed. Cl. 19, *31 (2005), aff'd, Pafford v. Secretary of HHS, 2006 WL 1679714, slip op. (Fed. Cir. June 20, 2006) (emphasis in original) (citing Knudsen, 35 F.3d at 548 ("Causation in fact under the Vaccine Act is thus based on the circumstances of the particular case, having no hard and fast per se scientific or medical rules.")).

IV. DISCUSSION

Stated succinctly, Petitioner claims that, without prior complaint, she suffered a brachial neuritis shortly after receiving a vaccination containing tetanus toxoid and that injury caused (or exacerbated an underlying) cervical spine disease thereby resulting in a cervical radiculopathy. Put in legal terms, the Petitioner is arguing, under Althen and its progeny, that she has posited a medical theory that causally connects via a logical sequence of cause and effect the vaccine with the injury alleged, particularly given the "striking" temporal relationship.

Petitioner's medical theory and logical sequence is not patently unreasonable. In fact, many knowledgeable doctors considered the possibility and certainly did not exclude it out of hand. It is well known that a brachial neuritis – an inflammatory condition affecting the brachial plexus – can occur from a tetanus vaccination. Moreover, the temporal relationship between the vaccination and the onset of Petitioner's condition is indeed quite striking.

But in order to prevail under the causation in fact standard provided in Althen, a petitioner must demonstrate by preponderant evidence a reliable medical theory that links, via "a logical sequence of cause and effect," the vaccination and the injury alleged, thereby "showing that the vaccination was the reason for the injury." While this Petitioner need not identify or prove that a specific biological mechanism occurred, Knudsen, 35 F.3d at 549, she cannot prevail simply by bootstrapping a plausible medical theory to a petition based solely on a proximate temporal relationship. Moreover, this Court has the obligation, in light of the "gatekeeping" function required by Daubert v. Merrow Dow Pharm. Inc., 509 U.S. 579, 597 (1993), to assess the reliability of medical or scientific opinion or testimony and the logical sequence of cause and effect attendant thereto. See, Terran v. Secretary of HHS, 195 F.3d 1302, 1316 (Fed. Cir. 1999); see also Ryman v. Secretary of HHS, 65 Fed. Cl. 35, 40 (a special master acts properly as a gatekeeper when he "determines whether expert testimony may be admitted, credited, or otherwise relied upon.").

A brachial neuritis, as demonstrated in the medical literature filed by both parties, presents in a particular sequence with certain identifiable indicia. First, it presents with the sudden onset of severe pain. That pain spontaneously resolves but is followed soon after by muscle weakness and then atrophy. The injury should be evident on EMGs and perhaps via MRIs.

There is some circumstantial evidence identified in the medical records that is corroborative of Petitioner's allegations. Fact witness testimony and the medical records indicate that Petitioner suffered severe pain within three weeks of the vaccination that led her to seek medical care. Several weeks thereafter, there are indications in the medical records that her pain largely resolved or had diminished by 75%. Moreover, while there is evidence of a cervical radiculopathy in the medical records, several doctors, including the neurosurgeons from Marshfield and the Mayo Clinic, did not believe that such wholly accounted for the Petitioner's primary complaint of left arm pain. Pet. Ex. 3 at 16; 2 at 2; and 2 at 5.

The Petitioner may rely on circumstantial evidence to meet her burden of proof particularly

in matters relating to causation. Althen v. Secretary of HHS, 418 F.3d 1274, 1280 (Fed. Cir. 2005). However, that circumstantial evidence must add up to a preponderance.

Much about Petitioner's symptomatology does not fit the medical theory and logical sequence of cause and effect proposed. For instance, brachial neuritis presents with the sudden onset of intense pain. Yet, Petitioner's pain started a day after the vaccination as an electric-like buzz and progressively intensified over a period of several weeks. In addition, brachial neuritis presents with muscle weakness and then atrophy or wasting. Yet, Petitioner showed no evidence of weakness or atrophy till long after the onset of her medical issues. Moreover, the literature indicates that a brachial neuritis should be evident on EMG testing and may be evident on MRI. However, despite numerous such tests conducted within months of onset and repeated multiple times over the ensuing years, there is no such evidence of a brachial neuritis.

In short, Petitioner has presented no objective medical or scientific proof that a brachial neuritis occurred. For instance, the EMG conducted in May 1997, four months after the onset of Petitioner's condition, shows no evidence of such. Had better or more specific testing been conducted closer to onset, perhaps some light would have been shed on the question of causation. Regardless, the tests that were done do not support Petitioner's contentions.

Here the Petitioner's case is predicated on the premise that she suffered a brachial neuritis following the tetanus vaccination administered 20 January 1997. In support of this proposition, the Petitioner proffers medical records, medical literature, and the medical opinion of Dr. Tornatore. Therefore, the Petitioner has presented evidence by which this Court may find in her favor. §13(a)(1). That is to say, more has been provided than Petitioner's naked asseverations.

In addition, Dr. Tornatore opines that Petitioner's presentation of brachial neuritis was one of the minority of cases that does not present with a sudden onset of pain, or with muscle weakness or atrophy, or with findings on EMG. Hence, the Petitioner argues for a rather unusual sequence of cause and effect.

However, as regards medical opinions and diagnosis offered in the evidentiary record, while the Vaccine Act adjures this Court to consider any such diagnosis, conclusion, medical report or impression contained therein, nevertheless it explicitly states that these "shall not be binding on the special master" but must be considered based on the entirety of the record and the course of the injury. §13(b)(1). Therefore, while this Court has always shown appropriate deference to the opinions, impressions, or diagnoses of medical experts, that is not to say that such are binding. Moreover, as regards the "logical sequence of cause and effect," the Federal Circuit in Capizzano indicates that the treating physicians are likely to be in the best position to answer that question.

In the present petition, a leitmotif runs throughout the medical records wherein doctors initially consider brachial neuritis as a possible diagnosis. However, it appears that none of the medical providers felt there was a sufficiency of proof to sustain that thought because, of all the tests performed, not only do they not support such a conclusion, but they actually support something

different. One doctor after another listed brachial neuritis as a possibility to be excluded. They noted some similarities between the Petitioner's condition and that prognosis and were concerned as to whether a brachial neuritis may have occurred. But then one by one they either downgrade it to a possibility, exclude it entirely, or believe her condition to have been more likely caused by something else. For example, Dr. Evan K. Sandok, a neurologist at the Marshfield Clinic originally thought Petitioner's condition might be "partial Parsonage-Turner syndrome at least temporally related to the administration of the tetanus shot." Pet. Ex. 3 at 2. But after certain diagnostic tests were conducted, he dropped that diagnosis in favor of the cervical radiculopathy. His father, Dr. Burton Sandok at the Mayo Clinic originally concluded that Petitioner's symptoms "are most compatible with a brachial plexus neuritis (the Parsonage-Turner syndrome) which may occur following immunization." Pet. Ex. 2 at 4. However, after reviewing test results, he concludes that a brachial neuritis "seems less likely and a cervical disk seems more likely." *Id.* at 8. Other doctors likewise concluded that the vaccination "is probably not related" and that her injury "was likely not due to her tetanus injection." Pet. Ex. 7 at 2; 5 at 13. Yet another doctor found "absolutely no correlation of her symptom complex to her suggested relationship with the tetanus injector she received in the past." Pet. Ex. 3 at 18. In specific response to that question, Dr. Bixler stated somewhat categorically that he "cannot and will never be able to tell whether she actually had a brachial neuritis from her injection or not. . . . I do not think it is going to be possible to answer that question." Pet. Ex. 9 at 4.

Based on the entirety of the records and evidence filed in this case, this Court is loathe to superimpose a diagnosis of brachial neuritis sua sponte. A myriad of tests have been performed and a number of doctors consulted to include several neurologists and neurosurgeons, and none of them, none of her treating physicians, ever reached this final conclusion. There is evidence that many doctors considered a brachial neuritis. But after ordering tests and on more careful observation, they could not confirm that diagnosis; and, in fact, most of them made statements per contra. Dr. Tornatore himself appeared reluctant to come to this conclusion until there had been additional medical tests. Those tests were not supportive of Dr. Tornatore's intent, but nevertheless he opined that it was still possible that an atypical case of brachial neuritis had occurred.

Is this theory plausible? Perhaps. But the alleged "logical sequence of cause and effect" is not supported by the treating physicians. Some doctors state that Petitioner's theory of vaccine causation is completely without basis while others thought it a possibility but considered an alternate cause more likely. As indicated in the medical literature, brachial neuritis is a diagnosis of exclusion, and one of the primary items that must be excluded is a possible cervical radiculopathy. Whereas brachial neuritis is an inflammatory condition that has been associated with tetanus toxoid, cervical radiculopathy, as a compression or structural issue, has not been associated with vaccination but with congenital or degenerative disease. As Dr. Winkler explained at trial, "[T]he symptoms and signs and ancillary findings correspond to the probable pattern that you can expect from cervical radiculopathy, especially for herniation of a C-5, 6 disc. They do not correspond to the probable pattern that is associated with brachial neuritis." Tr. at 153. Regardless, the Court is not herein deciding whether Petitioner suffered a brachial neuritis versus a more likely alternate cause identified in the records.

Instead, as regards the question of whether Petitioner has demonstrated a logical sequence of cause and effect showing that the vaccination was the reason for the injury, the Court considers Dr. Bixler's observations to be of some import and will quote him again in full:

Since I did not have the opportunity to examine her four years ago when this began, and because she had another neurologic condition (a radiculomyelopathy), which can cause identical symptoms and EMG changes, I cannot and will never be able to tell whether she actually had a brachial neuritis from her injection or not. Because we do not have any cervical spine films from 1997, and we do not really know when she definitively developed her cervicular radiculomyelopathy, I do not think it is going to be possible to answer that question.

Pet. Ex. 9 at 4.

Concerning factual findings, it is axiomatic to say that the Petitioner bears the burden of proving, by a preponderance of the evidence, that a particular fact occurred. Put another way, it is required that a special master, "believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the [special master] of the fact's existence." In re Winship, 397 U.S. 358, 371-72 (1970) (Harlan, J., concurring). Moreover, mere conjecture or speculation does not meet the preponderance standard. Snowbank Enterprises v. United States, 6 Cl. Ct. 476, 486 (1984).

In this case, there is a paucity of evidence from which this Court can conclude that Petitioner suffered a brachial neuritis following the administration of the tetanus vaccination. The Court can say that she had a cervical radiculopathy because every physician, including Dr. Tornatore, acknowledges that. But the Court cannot say when the cervical radiculopathy began or to what degree it affected Petitioner's condition. Some doctors describe it as relatively asymptomatic while others opine that it could have caused all of Petitioner's complaints. Perhaps Dr. Sandok the elder's diagnosis describes the quandary best, "Left arm pain, etiology? (brachial plexus neuritis vs. a C6 neuropathy)." Pet. Ex. 2 at 8. The etiology of Petitioner's symptoms remained a question mark for some of the best doctors in the country. It remains so for this Court as well.

The Petitioner has presented no objective evidence that she suffered a brachial neuritis and is relying almost exclusively on her medical expert, Dr. Tornatore, to connect the vaccine with her condition. Although there is a striking temporal relationship, the sort of post hoc ergo propter hoc¹³ reasoning offered by Dr. Tornatore has been consistently rejected by the Court and "is regarded as neither good logic nor good law." Fricano v. U.S., 22 Cl. Ct. 796, 800 (1991). His retroactive diagnosis is less than persuasive when confronted with the bulk of the medical records and the opinions of the treating physicians contained therein. While perhaps not impossible, Petitioner's alleged sequence of cause and effect, based largely on speculation and conjecture, does not satisfy the preponderance of the evidence standard. The treating doctors who saw the Petitioner over a period of some time refrained from associating her condition with the vaccination in question, and this Court must do the same.

¹³ Latin for "after this, therefore because of this."

Therefore, this Court must conclude that, while the Petitioner's medical theory and proposed logical sequence of cause and effect, as Dr. Tornatore described via circumstantial evidence, is not outside the realm of the possible, it does not rise to the level of preponderant evidence.

Because the Court finds, as a factual matter, that the Petitioner has not proved that she suffered a brachial neuritis, a claim upon which her petition must either rise or fall, and because the Petitioner, as a legal matter, has not connected by preponderant evidence a plausible medical theory with "a logical sequence of cause and effect showing that the vaccination was the reason for the injury"; therefore, the Petitioner has not proved by a preponderance of the evidence those matters required by §11(c)(1) of the Vaccine Act. Hence, the petition is **denied**. §13(a)(1)(A).¹⁴

V. CONCLUSION

Per the discussion supra, Petitioner has not proven that the vaccination in question caused the injuries alleged; therefore, her petition is **denied**. In the absence of a motion for review filed pursuant to RCFC, Appendix B, the clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

Richard B. Abell
Special Master

¹⁴ The Court does not reach the next question as to whether Petitioner's injuries were "due to factors unrelated to the administration of the vaccine." §13(a)(1)(B).