

OFFICE OF SPECIAL MASTERS

No. 04-1147V

(Filed: July 5, 2006)

BETHANY JONES,

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Petitioner,

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v.

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SECRETARY OF THE DEPARTMENT OF
HEALTH AND HUMAN SERVICES,

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Respondent.

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TO BE PUBLISHED
Tetanus, Brachial Neuritis,
Table Injury, Thoracic Outlet
Syndrome, Factor Unrelated

James R. Morrison, Esq., Peoria, Illinois, for Petitioner.

James A. Reistrup, Esq., United States Department of Justice, Washington, D.C., for Respondent.

ENTITLEMENT RULING¹

On 13 July 2004, a petition for compensation under the National Childhood Vaccine Injury Act of 1986 (Vaccine Act or Act)² was filed by Mrs. Bethany Jones alleging that she suffered a Table Injury, namely brachial neuritis, following the administration of a tetanus immunization on 3 February 2003.

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).

I. FINDINGS OF FACT

The Vaccine Act indicates that the Court may not rule in favor of a petitioner based on her

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.

asseverations alone. Rather, a petitioner's claims must be substantiated at the very least by medical records or by medical opinion. § 13(a)(1). Therefore, the Court turns first to the medical records filed in the above captioned case.

A. Medical Records

On 3 February 2003, Petitioner, then a forty-one year old preschool teacher and married mother of two, presented at the office of her children's physician, Dr. Barry Miller, for a new patient visit in order to undergo a two-year physical exam required by her employer and also for a general checkup. Petitioner's Exhibit ("Pet. Ex.") 39 at 4. Prior to that visit, Petitioner avers that she was in general good health and was not under the care of a physician. Transcript, 30 June 2005, ("Tr. I") at 15. During that visit, the Petitioner complained of some "puffiness in her left upper scapula in the supraclavical region" which Dr. Miller did observe and, as a result, ordered some additional testing including an x-ray. Also during that visit, Petitioner was given a tetanus booster in her right arm. Pet. Ex. 39 at 5. Dr. Miller stated that, on physical examine, he noted no "droopiness" or any other issue concerning the right arm. Id. at 1.

On 6 February 2003, Petitioner was seen for the x-ray ordered by Dr. Miller. Tr. I at 19. During that visit, the x-ray technician noted to Petitioner that her right arm was lower than the left. Id. Petitioner avers that she had noted no such difference previously. However, the records do indicate that, during the preceding Thanksgiving of 2002 some puffiness had been noted in her left shoulder, and she reported to numerous treating physicians in the ensuing months that she had been experiencing some issues with the right shoulder, including soreness of the shoulder and somewhat of the neck, that she attributed to carrying a heavy book bag to work and a heavy purse. See, e.g., Pet. Ex. 39 at 5; 40 at 4.

Petitioner returned to Dr. Miller on 12 February 2003 and expressed concern about the marked reduction in her right shoulder. He notes that, during the last visit there was a complaint of swelling in the left shoulder, but posits that might have simply been that the left was normal while the right was reduced. Pet. Ex. 39 at 5. He later confirmed that opinion, that the initial complaint regarding the left shoulder "was actually more that her right shoulder was drooping and that she had some scoliosis." Pet. Ex. 6 at 58. Continuing with the 12 February 2003 visit, Dr. Miller noted for the first time that Petitioner had a "mild scoliosis of the lower thoracic spine" which might be contributing to the droop in her right shoulder. Pet. Ex. 39 at 5. It is curious to the Court that the scoliosis was not discovered during the initial physical exam on 3 February. Regardless, at the 12 February 2003 visit, Petitioner denied any neurological issues or loss of strength. Pet. Ex. 39 at 5. And, on exam, Dr. Miller notes that the shoulder shrug and arm lift were equal on both sides. Id. His assessment is a decrease in the size of Petitioner's right trapezius muscle "secondary to entrapment syndrome from the patient using right shoulder all the time with her heavy purse as well as backpack." Pet. Ex. 39 at 6.

It should be noted that, at that visit, pain was noted as a 1-2 on a scale of 10. Id. at 5. And,

in fact, Petitioner testifies that she did experience some pain at the vaccination site shortly after receiving the shot but attributed it to the routine discomfort associated with such shots. Tr. I at 18.

However, on 20 February 2003, Petitioner returned to Dr. Miller's office with new complaints of right shoulder pain. She states that she had "no problems prior to being seen on 2/12/03" and at which time "there was no noted pain or weakness." Pet. Ex. 39 at 8. But since then, she had noted increasing discomfort "going down the right inner arm, forearm and the first three fingers with some paresthesias noted."³ Id. She also noted feelings of numbness and coldness in the right hand and that it would occasionally go to sleep. She noted sweatiness in her palm and an ache in her armpit. She was also experiencing what she described as tension headaches that started on the back of her head on the right side. Id. The Petitioner stated that the pain was a 4 on a scale of 10 but that it would increase during the day and might also include an occasional sharp stabbing pain down through the inner arm and into the fingers. Petitioner further indicated some difficulty in grasping objects with her right hand and described a feeling as though the right arm felt "heavy" and as though there was a "tight band" around her upper right arm. Id. On examination, Dr. Miller observed the following:

There is tenderness in the paraspinal muscles on the right side going into the trapezius muscle which definitely has more atrophy compared to the left trapezius muscle. Noted also some atrophy in the deltoid muscle on the right compared to the left. Decreased strength with shoulder shrug against force. Noted the patient is unable to actively move arm up overhead greater than horizontal unless she uses a lot of force and then is able to do so. Noted that she does strain quite a bit to do this and there is marked decrease in strength on the right arm to tension. Noted grip strength on the right is decreased from the left. Sensation of the right hand to light touch somewhat decreased in the third, fourth, and fifth finger as well as the palm of the hand and along the inner portion of the right arm around the ulnar nerve distribution.

Id. (emphasis added). Dr. Miller questioned whether there might be a lesion in the brachial plexus and therefore ordered an MRI. The Petitioner was referred to a neurologist and given Tylenol 3 for pain. Id. at 9.

In a notation from 24 February 2003, Dr. Miller's office was told that Petitioner's pain had increased over the preceding weekend and was now a 6 out of 10 and included "sharp stabbing type pains in the trapezius muscle and deltoid muscle." Pet. Ex. 39 at 9. Petitioner also reported that the weakness had increased since the 12 February visit and expressed concern that the symptomatology may be crossing over to her left side. Dr. Miller notes that an MRI conducted in the interim showed a normal brachial plexus with no lesion present. He ordered additional tests and also hastened Petitioner's neurology appointment. At that juncture, Dr. Miller first raises a question concerning a

³ Paresthesia is defined as "an abnormal touch sensation, such as burning, prickling, or formication, often in the absence of an external stimulus." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 1371.

possible reflex sympathy disorder ("RSD")⁴; however, he recognized that electromyographic ("EMG") and nerve conduction studies ("NCS") would be necessary for diagnostic purposes. Id.

On 28 February 2003, Petitioner saw neurologist Dr. Gregory Blume. According to Dr. Blume's objective observation, Petitioner "appears to have full strength" with the exception of the interosseous muscles in the right hand, which govern finger spreading. Pet. Ex. 40 at 6. However, due to Petitioner's level of discomfort, "It is somewhat difficulty [sic] to get full power on examination." Id. Likewise, Dr. Blume observed that Petitioner had good pinprick sensation though with some patchiness in her right hand. His impression was that "there is a potential that she could have an acute brachial plexitis"⁵ as that malady may exhibit with "varying degrees of weakness and sensory changes within the upper extremity and certainly these could fit a very non-dermatomal pattern." Id.

An EMG conducted 3 March 2004 by Dr. Blume demonstrated findings "compatible with a long standing spinal accessory nerve lesion and a superimposed, patchy neural irritation of the right brachial plexus such as neuralgic amyotrophy." Pet. Ex. 10 at 10.⁶ However, that EMG also showed "Normal nerve conduction studies of [right] upper extremity including ulnar nerve." Id. At trial, as will be discussed infra, Dr. Blume testified that his EMG findings, which implicated multiple nerve roots, is quite suggestive of a recent brachial plexitis as "the most-likely diagnosis." Tr. I at 96-97. However, as for the diminution of the right trapezius muscle, Dr. Blume thought, based on the EMG/NCS and clinical observation, that it represented a long standing injury that predated the vaccination and potential brachial plexitis. Pet. Ex. 40 at 2, 6. In the end, Dr. Blume observed, "this is difficult to put together with any one diagnosis." Id.

On 10 March 2003, Mrs. Jones was seen by an occupational therapist, Adam Drummer, on referral from Dr. Blume for "a diagnosis of brachial plexitis." Pet. Ex. 8 at 1. At that visit, she rated her discomfort at 4 of 10 and reported discomfort in her right upper extremity along with decreased sensation along the ulnar nerve distribution and in the fourth and fifth digits of her right hand. Mr. Drummer noted that her range of motion and strength in both upper extremities was five by five "except for elbow flexion and extension on the right which was 4/5." Pet. Ex. 8 at 1.

On 10 March 2003, Mrs. Jones also saw Dr. James Maxey at the Orthopaedic Institute of Illinois for an opinion on surgical intervention. Dr. Maxey notes that "[s]pecific and very careful testing was done today with regard to her muscle strength testing and is normal." Pet. Ex. 6 at 44.

⁴ Reflex Sympathy Dystrophy is defined as "a series of changes caused by the sympathetic nervous system, marked by pallor or rubor, pain, sweating, edema, or osteoporosis, following muscle sprain, bone fracture, or injury to nerves or blood vessels. When limited to the upper extremity it is called *shoulder-band syndrome*." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 581 (emphasis in original).

⁵ The medical providers use brachial neuritis, brachial plexitis or plexography and neuralgic amyotrophy interchangeably.

⁶ The spinal accessory nerve enervates the trapezius muscle. Transcript, 25 August 2005, ("Tr. II") at 120.

Through he did observe drooping in her right shoulder, he attributed such to "a long standing mild scoliosis." Id. Dr. Maxey recommended no surgical intervention. Pet. Ex. 8 at 3; 39 at 10.

On 20 March 2003, the Petitioner saw Dr. Jeffery Stedwill for a physical medicine and rehabilitate evaluation. At that visit, Petitioner reported intense pain that developed within a week of her initial symptoms which by this time had largely resolved and was now roughly a three or four out of ten. At this time she was taking no pain medication. Pet. Ex. 8 at 3. Dr. Stedwill notes that the Petitioner "has been considered [by Dr. Blume] to have neuralgic amyotrophy at the right upper limb." Id. As to that diagnosis, Dr. Stedwill indicates that the "right upper limb pain . . . appears consistent with neuralgic amyotrophy." Id. at 4; and 6 at 48. He likewise noted on exam a mild difference between her left and right shoulder but stated, "It is unclear to me whether the right shoulder 'drooping' is actually a new development, or whether this could have been present for a number of years or longer and is not necessarily related to any particular symptoms." Pet. Ex. 8 at 4.

On 27 March 2003, Petitioner saw Dr. Miller on follow up. At that time, Petitioner noted that the pain had decreased significantly though with some continue "nerve" pain and weakness in her arm. Concerning the scoliosis, Petitioner noted that her height had decreased by one and a half inches. Dr. Miller observed again the decreased muscle mass and shoulder droop; however, "flexion and extension of arm seem to be normal. No signs of any neurological deficit noted or decrease of grip strength." Pet. Ex. 39 at 10. Echoing Dr. Blume's diagnosis, Dr. Miller notes, "problems most likely consistent with neuralgic amyotrophy." Pet. Ex. 79 at 10.

On 3 April 2003, Mrs. Jones saw Dr. Blume again. On examination he noted "no frank change in strength throughout the right upper extremity compared to the left." He also noted changes in pinprick sensation particularly over the fifth digit. His impression remained "possible mild brachial plexitis" and "possible mild right ulnar neuropathy at the elbow."⁷ Pet. Ex. 40 at 13. Dr. Blume continued to be confounded by the shoulder asymmetry. However, it was noted during that visit that Petitioner's intense pain had subsided though pain did remain in her hand. Pet. Ex. 40 at 12.

On 30 April 2003, Petitioner returned to Dr. Miller's office. At that visit he apprised her that further testing had revealed severe osteoporosis that would require treatment. During that visit, Dr. Miller notes, "Forty-one-year-old with what seems to be spinal accessory nerve neuritis." Pet. Ex. 39 at 11.

On 15 May 2003, Mrs. Jones sought a second opinion from Dr. John Ratliff at the Chicago Institute of Neurosurgery and Neuroresearch. At that visit, Mrs. Jones again iterated that the pain began following the tetanus shot but "clearly denotes her right trapezius symptomatology is of much

⁷ Ulnar neuropathy is another name for cubital tunnel syndrome which is to say "a complex of symptoms resulting from injury or compression of the ulnar nerve at the elbow, with pain and numbness along the ulnar aspect of the hand and forearm, and weakness in the hand." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 1814.

greater duration than her right upper extremity pain and weakness." Pet. Ex. 6 at 52. Her history indicates that the symptomatology developed over 4 to 5 days with "coldness and numbness and tingling" in her right hand followed by extreme pain in her upper right extremity as well as significant diminution of strength. Id. Petitioner reported to Dr. Ratliff that her pain was significantly improved though some did remain along the latisimus dorsi and in her right shoulder. She also expressed concern about weakness in her right trapezius and the "clear asymmetry" of her shoulders. Id.

On examination, Dr. Ratliff noted some issues with the right trapezius muscle. He felt the asymmetry in her right shoulder "appears to be structural" in nature and not due to a trapezius palsy. His thorough physical examination revealed some reduced strength in the right upper extremity as well as the aforementioned diffuse sensory perception issues "over the ulnar distribution in her right hand." Pet. Ex. 6 at 52. Dr. Ratliff was critical of the EMG/NCS studies previously conducted and ordered additional, more specific testing. Id. at 53. In conclusion, Dr. Ratliff thought it "most likely this patient has a brachial plexitis which is resolving." Id. He also thought it unlikely that a heavy book bag could have resulted in what appeared in to be a "presumed right-sided spinal accessory nerve palsy." Id. Rather, he believed the profound asymmetry of the shoulders was structural in nature and perhaps related to her "thoracolumbar scoliotic deformity." Dr. Ratliff, though an expert surgeon in the field of brachial plexitis, advised her not to have surgery but to "allow the brachial plexus to resolve and then reassess this spinal accessory nerve function." Id.

On the recommendation of Dr. Ratliff, Mrs. Jones had an EMG/NCS study on 13 June 2003 conducted by Dr. Xuan Truong. Pet. Ex. 6 at 54. Dr. Truong related what is perhaps the most concise medical history seen in the records and reprinted here in full:

In the fall of 2002, after having carried many heavy school bags and grocery bags, the patient developed pain in the right trapezius area, and some pain and stiffness on the right side of the neck, which was aggravated by turning the head to the left. In 2/03, she had a routine tetanus booster in the right deltoid, and developed numbness and tingling in the medial right upper arm, elbow, forearm, and hand involving the last two digits, and coldness in these digits. She also developed pain in the right shoulder, axillary, and pectoral region, and severe weakness in the right shoulder with inability to raise her right arm, for a few days. She also had pain in the right shoulder on shoulder movements. Subsequently, the pain and weakness improved, but the paresthesia persisted, and she also has had persistent aching pain around the right shoulder, right trapezius area, and neck and in the right hand, with some generalized weakness in the right shoulder and right upper extremity, causing her to drop things from her right hand. She also has had tenderness over the volar aspect of the right hand, causing difficulty in turning door knobs. She has had frequent occipital headaches associated with her neck pain. Her symptoms sometimes woke her up at night, and she has had difficulty lying on her right side.

Prior to her present complaints, she has had chronic recurrent pain in the medial right elbow since an injury at the age of 9 . . . The present paresthesias in the right upper extremity are aggravated by elevation of the right hand, such as when using a hair dryer, by resting on her right elbow, and by holding a phone with her

right hand. She has known scoliosis of the upper back, but she has not noted a lowering of her right shoulder until her present complaints.

Pet. Ex. 6 at 54.

On physical exam, Dr. Truong found, "No definite focal muscular weakness or atrophy in the right upper extremity or shoulder girdle." Id. He found no scapular displacement but did note a "slight to moderate left upper thoracic scoliosis" which resulted in her holding her right scapula slightly lower than the left. Id. Dr. Truong also noted some tenderness in the right trapezius, in the lower right paracervical and in the right shoulder region with some pain on extreme movement of the right shoulder. Id.

As for the EMG and nerve conduction study conducted, Dr. Truong found, "No definite abnormal EMG findings in the upper right extremity, shoulder girdle, or paracervical muscles . . . with no definite EMG evidences of cervical radiculopathy, brachial plexopathy, accessory nerve, or trapezius injury." Pet. Ex. 6 at 55 (emphasis added). However his findings were compatible with an ulnar neuropathy in the right elbow. Id. At that time, Dr. Truong noted no particular evidence of Thoracic Outlet Syndrome.⁸ However, he did note a "slight left upper thoracic scoliosis with associated lowering of the right shoulder posture." Id. In a hand written note, Dr. Truong explains that the ulnar neuropathy (cubital tunnel syndrome) might explain the cold feelings in the hand and whatnot but not the initial pain in the shoulder and neck. Id.

On 23 June 2003, a frustrated Petitioner returned to Dr. Miller's office. Pet. Ex. 39 at 12. At that time she indicated that what had started as an issue with her ring finger and pinky "is now the whole hand." She reported a "perceived weakness" of the right hand, but according to a letter contemporaneously authored, Dr. Miller "could not really appreciate too much in a change of muscle strength." Pet. Ex. 39 at 12; 6 at 58. In that letter, he also states that her initial complaint of left shoulder puffiness or swelling "was actually more that her right shoulder was drooping and that she had some scoliosis." Pet. Ex. 6 at 58. At that time, Dr. Miller raised again and with more emphasis, "that she may be developing or may have had all along RSD." Pet. Ex. 6 at 58; 3 at 12. He had not the benefit of Dr. Truong's EMG/NCS and determined to await those results and, in the meantime, to communicate his concerns to Dr. Ratliff.

On 16 July 2003, Petitioner again saw Dr. Miller. At that time he noted the results from Dr. Truong's EMG/NCS were essentially normal save certain findings compatible with an ulnar neuropathy. On examination he noted tenderness, but "could not appreciate any muscle wasting."

⁸ Thoracic Outlet Syndrome is defined as

[A]ny of a variety of neurovascular syndromes resulting from compression of the subclavian artery, the brachial plexus nerve trunks, or less of the axillary vein or subclavian vein, by throacic 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. . . . Nerve compression causes atrophy and weakness of the muscles of the hand and, in advanced cases, of the forearm, with pain and sensory disturbances in the arm.

DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 1834.

He likewise noted "good flexion and extension of the arms," as well as good grip on both hands with some discomfort in the fourth and fifth finger of the right hand. He raises and discounts Thoracic Outlet Syndrome ("TOS") based on Dr. Truong's EMG/NCS interpretation but raises again "the possibility of RSD after tetanus injection and may need to send to pain clinic." Pet. Ex. 39 at 14.

On 22 July 2003, Dr. Miller penned a letter of referral to Dr. Alan Togut, a specialist in Thoracic Outlet Syndrome with offices in Philadelphia. Pet. Ex. 66 at 60.

On 11 August 2003, Petitioner saw Dr. Donald Cory of the Central Illinois Pain Management Center ("CIPMC"). At that time he noted that she would soon be seeing Dr. Togut for evaluation of possible TOS. He also noted on exam some indication of TOS. Pet. Ex. 6 at 63.

Dr. Togut saw Petitioner on 21 August 2003. Pet. Ex. 11 at 19. At that time, he diagnosed her with "an entrapment neuropathy of the right brachial plexus known as Neurogenic, Thoracic Outlet Syndrome." Id. The etiology was a bit perplexing to Dr. Togut, but "it seems to have started after a tetanus injection on 3 February 2003." Id. He explains that women like Petitioner, short in stature with "long necks," are at particular risk for developing TOS. Id. at 25. According to Dr. Togut, all of Petitioner's symptoms including the numbness, cold sensations, shooting pain and other sensitivities to heat and cold are indicative of a Complex Regional Pain Syndrome-2 ("CRPS Type II") which is secondary to the brachial plexus entrapment. Id.⁹ However, he could not say whether or how this condition, which he appears to believe was the original underlying etiology of Petitioner's symptoms, relates to the tetanus vaccination. Id. at 26.

Following her appointment with Dr. Togut, Petitioner returned to the CIPMC as she would numerous times thereafter for treatment, counseling concerning pain management, and for prescription pain relief. On 25 August 2003 a "Right stellate ganglion block"¹⁰ was performed with some success in affecting her symptomatology. Pet. Ex. 6 at 67. However, relief lasted only a few days. Another ganglion block was performed on 28 August 2005 and again on 5 September 2003. Id. at 67-69. Following these procedures it was felt that her symptoms were controlled enough so that the next step would be surgical repair of her TOS and/or cubital tunnel syndrome. Also, on the recommendation of Dr. Togut, CIPMC began a series of "trigger point injections." Pet. Ex. 13 at 32.

⁹ Dr. Togut explains, ostensibly for Dr. Miller's edification, that CRPS Type II is like RSD but worse and entails central sensitization of the central nervous system, in this case due to the brachial plexus entrapment:

The modern understanding of this is that with constant stimulation coming in from peripheral nerves into the spinal cord there is a change in the spinal cord particularly the wide dynamic ranging neurons will change. The way they change is that they are caused to depolarize and to stimulate the other neurons and those changes occur. The other thing that happens with CRPS-2 is allodynia that is the stimulus of touch is appreciated as painful.

Pet. Ex. 11 at 20

¹⁰ A stellate ganglion block involves "regional anesthesia produced by blocking of the stellate (cervicothoracic) ganglion" which inhibits nerve impulse transmission. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 229.

On 24 September 2003, Petitioner returned to see Dr. Miller who, based on her clinical course, altered his diagnosis to read "most likely consistent with neurogenic thoracic outlet syndrome" and/or neuritis. Pet. Ex. 39 at 14-15. During that visit, Petitioner also informed Dr. Miller that she was "interested in 'tapping into' the adverse reaction immunization fund." Pet. Ex. 39 at 14. On examination, he noted no ostensible change in her condition.

On 9 October 2003, Petitioner was seen by Dr. Dennis McManus at the CIPMC. His impression at the time was "thoracic outlet syndrome versus brachioplexitis with allydonia."¹¹ Pet. Ex. 12 at 28.

Later that month, on 23 October 2003, Petitioner again saw Dr. Togut in Pennsylvania. He expressed concern that her condition had declined. Pet. Ex. 11 at 28.

According to notes from the team at CIPMC, Petitioner began taking OxyContin some time in December 2003. Pet. Ex. 13 at 41. Overall, however, the team was pleased with the progress she was making but encouraged her to seek out specialists on Thoracic Outlet Syndrome in consultation with her physician, Dr. Miller. They did note, however, that the Petitioner "continues to demonstrate frustration and search by internet for information and answers . . . and she explains that if she had not done the research, she would still be waiting to get care." Id. at 43. It was also noted that Petitioner's prescription of OxyContin had been changed to two doses a day as she had begun taking the pain killer in the morning rather than the evening in order to "get ahead of the pain." Id. at 41. Regardless, Petitioner also informed the CIPMC of her intention to seek counsel from Dr. Stephen Annest, a neuro-surgeon in Denver, Colorado. Id. at 43.

These findings were echoed in a visit to Dr. Miller on 8 January 2004. During that visit, he noted some additional atrophy in the right trapezius muscle. He concludes, "I do not have anything else to offer this patient due to this unusual presentation that has now been going on for almost a year since immunization with the Tetanus booster was given. . . . all other modalities of treatment have been attempted without any definite improvement." Pet. Ex. 13 at 6.

Petitioner saw Dr. Annest on 23 February 2004 for a surgical consultation after which she elected to have surgery for TOS decompression. Pet. Ex. 15 at 6.

In preparation for surgery, an EMG and was conducted by Dr. Bennett Machanic. The results were suggestive of a "locus of pathology over the minor brachial plexus." Pet. Ex. 15 at 10. However, Dr. Machanic could not say whether this was due to a brachial plexopathy secondary to a tetanus vaccination or due to compression from thoracic outlet syndrome. Id.

On 26 February 2004, Petitioner underwent surgery that involved shortening a rib and the removal of various scalene muscles along the spinal column. Pet. Ex. 15 at 11-14. The surgery was

¹¹ Allodynia is "pain resulting from a non-noxious stimulus to normal skin." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 51.

without apparent incident and, in fact, resulted in "dramataic improvement" in Petitioner's condition. Pet. Ex. 19 at 3.

Of particular interest, during the surgery Dr. Annest observed and removed certain scalene muscles that were "intertwined and wrapped around the brachial plexus." Pet. Ex. 15 at 12; 13 at 6. Dr. Annest also told Dr. Miller that "he has never heard of a Tetanus booster ever giving any type of symptoms like this." Pet. Ex. 13 at 6 (emphasis added).

However, despite the recognized benefit afforded her by the TOS compression surgery, Petitioner reportedly continued to experience pain and expressed concern about possible carpal tunnel and cubital tunnel syndromes and expressed suspicion that she might have Thoracic Outlet Syndrome in her left side. Hence, she sought an EMG on 31 March 2004 for further evaluation. That EMG, conducted again by Dr. Machanic showed no sign of "cubital tunnel syndrome or peripheral compressive neuropathy of alternative nature" and showed "spectacular improvement" in conduction rates over the inferior brachial plexus. Pet. Ex. 19 at 3. Meanwhile, the right upper extremity remained "quite normal." Id.

On 2 April 2004, Dr. Richard Lee, clinical assistant professor of neurology at the UIC-college of Medicine at Peoria, a neurologist secured in anticipation of legal proceedings, see Pet. Ex. 14, authored a report concerning Petitioner's condition which concluded, "It is difficult to say how much of her symptomatology is secondary to the thoracic outlet syndrome which has been surgically treated and how much is related to the reaction she appeared to have had to the tetanus injection." Pet. Ex. 18 at 1. On his assessment, "The patient appears to have had an adverse reaction to a tetanus injection. She did have other problems including some signs of a reflex sympathetic dystrophy and a plexopathy which may or may not have been directly related, She also had some findings of a carpal tunnel syndrome and thoracic outlet syndrome." Id. at 1-2. Yet, concerning the findings of the doctors in Denver including the EMG/NCS, "It was not clear whether this could be related to an immunologic cause secondary to the tetanus injection or caused by compression such as a thoracic outlet syndrome." Id. at 2.

On 3 May 2004, Petitioner again saw Dr. Miller. At that visit she raised the spectre of an entrapment syndrome in her right elbow and carpal tunnel. During this visit, Dr. Miller expresses some veiled concern about Petitioner's preoccupation with obtaining OxyContin and advises her from then on to refer such matters to Dr. McManus at the CIPMC. He goes on to say:

Patient claims that she will never get better unless she gets the surgeries to make herself better, but I came around and told her that there is a trap that every time she has a surgery that this could flare-up other problems and that no surgery is 100% safe. I question the possibility that patient will never be satisfied and continue to have surgeries until she feels she is 100%.

Pet. Ex. 13 at 8. The Petitioner again raised the issue of whether the tetanus vaccination cause her maladies; however, Dr. Miller responded:

If anything, her entrapment syndrome from the brachial plexus was a congenital abnormality at her scalene muscles and that this would never have occurred just because of a Tetanus booster, and may have been just coincidence and/or the tetanus

booster itself may have caused just enough swelling to flare the brachial plexus syndrome.

Id. at 8-9.

In a subsequent letter to Dr. McManus concerning petitioner's pain prescription issues, Dr. Miller notes that her treatment "has become somewhat confusing." Pet. Ex. 13 at 10. He goes on to explain, "[A]fter the release from surgery for her right brachial plexus that her symptoms should be improving though she seems to want to hold on to the pain for I do not know what type of gain. Noted that she feels that she needs carpal tunnel release, which I am unsure if that is really necessary or not, but apparently Dr. Annest has told her that that might be the next step." Id. He continues:

As you know, she has blamed the tetanus booster for all these problems ever since even though there is no documentation anywhere that tetanus may cause this problem. Noted that even with my discussion with Dr. Annest in the past, noted that he could not relate any problems with the tetanus booster and increase in tos."

Id. at 11 (emphasis added).

On 3 June 2004, Petitioner again saw occupational therapist Mr. Alan Drummer. His examination noted atrophy in the right hand along with "diminished protective sensation along the palmer surface of the right hand." Pet. Ex. 26 at 10. On hearing the diagnosis, Petitioner became increasingly emotional and eventually exited the exam. Mr. Drummer notes that Petitioner "expressed that she just wanted her carpal and cubital tunnel surgery performed ... it almost appears to the point that she would prefer to just undergo surgery believing that would relieve all of her symptoms." Id. He suggested follow up with the pain clinic and possibly a psychologist. Id.

During this time, Petitioner was seeing a number of different doctors and therapists. For instance, 17 May 2004, she began to see a Dr. Reid Hansen concerning possible surgery. Dr. Hansen ordered an additional EMG/NCS. It was performed on 11 August 2004 by a Dr. Kumar. His interpretation of the results was "chronic denervation in right medial cord (brachial plexus) distribution." Pet. Ex. 24 at 13. Dissatisfied with Dr. Kumar's methodology, Petitioner self-referred for another EMG on 23 August 2004 which was performed Dr. Omprakash Sureka of the Institute of Physical Medicine and Rehabilitation. That EMG/NCS showed no denervation to the right upper extremity and cervical paraspinal muscles. Pet. Ex. 24 at 8. However, it did indicate a "lesion of medial cord of right brachial plexus." Id. at 9. Moreover, "There was no electrodiagnostic evidence of right carpal tunnel syndrome or cubital tunnel syndrome." Id. In the end, Dr. Hansen performed no surgery and warned Petitioner of the possible negative side effects of surgery.

During this same time frame, Petitioner was seeing Dr. Lisa Snyder of the Institute of Physical Medicine and Rehabilitation who, during a 6 July 2004 consultation, expressed some concern that Petitioner seemed prepared only to listen to Dr. Annest. Pet. Ex. 26 at 14.

Petitioner spoke with Dr. Annest on 10 September 2004 about her complaints and concerns. At that time she indicated a diagnosis of "hypermobility soft tissue genetic abnormality that is

unspecified." Pet. Ex. 31 at 5.¹² Dr. Annest, anticipating that Petitioner would again travel to Denver, arranged visits with several colleagues including Dr. Machanic and Dr. Raz Bazaz.

Dr. Raz Bazaz of Western Orthopedics concluded that Petitioner's symptoms were compatible with a medial cord lesion but, as a separate matter, could not recommend surgical intervention for the suspected carpal tunnel and cubital tunnel syndromes. Pet. Ex. 30 at 5.

Petitioner saw Dr. Bennett Machanic again on 28 September 2004. She had previously seen him for EMG/NCS on 24 February and 31 March 2004 prior to and following TOS decompression surgery. Dr. Machanic notes that, as regards the abnormalities noted on the 24 February 2004 EMG, "It was felt this was likely secondary to a brachial plexitis secondary to the tetanus toxin, but it is to be noted that the patient basically could have also had thoracic outlet syndrome." Pet. Ex. 29 at 3. He again notes that, as demonstrated on his 31 March 2004 EMG, the Petitioner experienced "dramatic benefits" from TOS decompression. *Id.* However, in the 28 September 2004 examination, Dr. Machanic expresses some concern about a possible "overuse syndrome" developing on the left side and possible thoracic outlet syndrome there as well secondary to the issues on the right. Pet. Ex. 29 at 6. Therefore, he opted to conduct an EMG/NCS on the left side. That EMG showed no abnormalities, no sign of thoracic outlet syndrome and no sign of cervical radicular dysfunction. The only issue was "a mild emerging left carpal tunnel syndrome," but he notes "the findings are far from definite." Pet. Ex. 29 at 12.

According to Dr. Machanic, however:

The clinical history is clear. She had a tetanus injection followed by a postimmunization brachial plexitis on the right side. As a result of inflammation and congenital abnormalities in the thoracic outlet region, she developed a thoracic outlet compression which was corrected by surgery. However, this did not fully correct the brachial plexus pathology, and she has persistent causalgia¹³ at this point secondary to the onset of the original episode. . . . She is now developing an overuse syndrome on the left arm, and one wonders whether she is developing TOS on that side secondary to problems on the right.

Pet. Ex. 29 at 6.

On 1 October 2004, based his examination and on Petitioner's clinical history in conjunction with the recent EMG/NCS and Petitioner's positive reaction to a stellate ganglion block ordered by Dr. Machanic and a report of a positive reaction to a pectoralis minor injection, Dr. Annest diagnosed, "an entrapment of the brachial plexus at the medial cord." Pet. Ex. 11 at 7-8. Petitioner again opted for surgical intervention which then took place on 4 October 2004, at which time

¹² It is unclear to the Court from whence that diagnosis derived.

¹³ Causalgia is defined as "a burning pain, often accompanied by trophic skin changes, due to injury of a peripheral nerve, particularly the median nerve. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (30th ed. 2003) (SAUNDERS) at 311.

Petitioner underwent "infraclavicular disinsertion of the right pectoralis minor muscle." Pet. Ex. 31 at 10-11.

Three days later, on 7 October 2004, Petitioner saw neurologist Dr. Robert Schwartzman, an associate of Dr. Togut and an expert in CRPS. Dr. Schwartzman opines that Petitioner experienced an "Autoimmune reaction from tetanus toxoid of her brachial plexus particularly on the right side, but this has spread as well to the left side." Pet. Ex. 32 at 5. However, he adds no explication to that conclusion. Moreover, the Court is a bit concerned that his results on examination in certain key respects different than those of other doctors who examined Petitioner and even of Dr. Anest who had examined her not more than a week prior.

In addition, on 7 October 2004, Petitioner once again saw Dr. Togut who indicated that, while the two surgeries had been of great value to Petitioner, there remained concern that the process that occurred on the right was now occurring on the left as well. Petitioner indicated that she would like to seek someone to operate on the left side. According to Dr. Togut, "Clearly I think she has an entrapment neurology of the left brachial plexus and since the major thing time wise that we can relate it to is the tetanus toxoid injection. It must have been due to some immune response with subsequent change in the relationship between the plexus and the structures around it to trap the plexus, particularly the lower trunk." Pet. Ex. 44 at 3 (emphasis added). It is unclear whether Dr. Togut had the benefit of Dr. Machanic's 29 September 2004 EMG/NCS which found no evidence of entrapment of the left brachial plexus.

To date it is the Court's understanding that Petitioner continues to be treated for "chronic pain bilateral upper extremities." Pet. Ex. 45 at 2.

B. Medical Opinion

In addition to those opinions offered as part of the medical records, cited supra, Petitioner proffered additionally the testimony of her family physician, Dr. Miller, a treating neurologist, Dr. Blume and that of another neurologist Dr. Lee.

Dr. Blume testified that the abrupt onset of Petitioner's pain, in conjunction with the "patchy" sensory loss issues and weakness in her right hand coupled with his findings on the 4 March 2004 EMG/NCS "suggest that this was more likely a process involving the brachial plexus." Tr. I at 92, 93, 96. Also of note to him was the significant diminution of pain in the 3 April 2003 follow-up visit, which is characteristic of brachial neuritis. Tr. I at 99. As indicated, supra, Dr. Blume has maintained since the beginning that the brachial neuritis claim is separate from a long standing injury to the right trapezius muscle perhaps secondary to an issue involving the spinal accessory nerve that enervates the trapezius. Tr. I at 97.

However, on cross examination, Dr. Blume indicates that the 4 March 2003 EMG/NCS was not conclusive of brachial neuritis and could potentially be representative of Thoracic Outlet Syndrome. Tr. I at 107. He further testified that muscle atrophy, such as he observed in Petitioner's right trapezius is not typically seen for weeks or even months after an insult to the nerve. Tr. I at 112.

This conclusion, of course, takes the shoulder atrophy first clinically observed on 12 February 2006 out of the timing as being associated with the brachial neuritis.

Petitioner next called Dr. Miller who opined that Petitioner did indeed suffer a brachial neuritis secondary to the tetanus vaccination. However, it should be noted at the outset that Dr. Miller is not a neurologist but a specialist in internal medicine and pediatrics. Yet, he took an obvious interest in his patient and tracked her progress across time and multitudinous treating doctors as best he could and helped coordinate much of her treatment.

As Dr. Miller indicated, this is a very confusing case. And it appears from the records that Dr. Miller's diagnosis altered from visit to visit in conjunction with the experts who were consulted, first to reflect Dr. Blume's diagnosis of brachial neuritis, then as a spinal accessory nerve neuritis, and then to reflect Dr. Togut's diagnosis of Thoracic Outlet Syndrome. Pet. Ex. 39 at 10, 11, 14. As Dr. Miller explained on the witness stand, "Well, the problem here is that I have a patient that has multiple physicians that are coming up with different -- different theories and -- and different diagnoses, and I'm trying to the best of my ability being, you know, an internist to try to bring all those theories to come up with a diagnosis to help this patient." Transcript, 25 August 2006, ("Tr. II") at 53.

From the records, it is obvious that Dr. Miller holds his opinion with something far less than certainty. To wit, "If anything, her entrapment syndrome from the brachial plexus was a congenital abnormality at her scalene muscles and that this would never have occurred just because of a Tetanus booster, and may have been just coincidence and/or the tetanus booster itself may have caused just enough swelling to flare the brachial plexus syndrome." Pet. Ex. 13 at 8-9.

Dr. Miller, however, stood by his theory on the witness stand – namely, that a brachial neuritis caused by the tetanus vaccine irritated a congenital abnormality thereby triggering Petitioner's thoracic outlet syndrome. Tr. II at 52. And this theory is derived from his efforts at "trying to put all these different doctors' diagnoses together thinking that it was a plausible precondition that was flared up by the tetanus booster." Tr. II at 58.

Yet, Petitioner's own records indicate: "[Petitioner] has blamed the tetanus booster for all these problems ever since even though there is no documentation anywhere that tetanus may cause this problem. Noted that even with my discussion with Dr. Annest in the past, noted that he could not relate any problems with the tetanus booster and increase in tos." Pet. Ex. 13 at 10 (emphasis added).

Moreover, the Court is particularly mindful of the following conversation with Dr. Miller at trial concerning his aforementioned theory:

SPECIAL MASTER ABELL: -- is that a -- a theoretical hypothesis or do you feel --

THE WITNESS: Theoretical hypothesis.

SPECIAL MASTER ABELL: Do you feel that -- do you feel that that is what you're confronted with here, or is that less than 50 percent?

THE WITNESS: Well, the problem here is that I have a patient that has multiple physicians

that are coming up with different -- different theories and -- and different diagnoses, and I'm trying to the best of my ability being, you know, an internist to try to bring all those theories to come up with a diagnosis to help this patient.

Yes, it's extremely confusing. It's very confusing, and like I said, I've never seen this type of reaction due to -- to a tetanus booster, though it is very rare. I mean, it is very rare.

SPECIAL MASTER ABELL: So, therefore, the theory you've just postulated is really conjectural?

THE WITNESS: Yes. Correct.

SPECIAL MASTER ABELL: All right. So, therefore, that's less than 50 -- you would hold that to less than 50 percent as a -- as a possibility? It's just one of a constellation of options?

THE WITNESS: Correct.

SPECIAL MASTER ABELL: And I don't want to put words in your mouth. I'm trying to under -- I'm trying to articulate it.

THE WITNESS: Correct.

Tr. II at 53-54.

Dr. Miller then, while considering this the most-likely scenario and biologically plausible – despite the absolute dearth of supporting evidence – in fact ranks this theory as the highest out of a constellation of other possibilities or plausible medical theories perhaps to include Thoracic Outlet Syndrome. However, in his written opinion, Dr. Miller expressly declined to comment on the question as to whether the TOS could be related to the tetanus booster, deferring instead to those with particular expertise on such matters. Pet. Ex. 39 at 4.

Key to Dr. Miller's hypothesis is the fact that Petitioner's injury occurred in such close proximity to the tetanus vaccination. As Dr. Miller states:

[T]here's not a lot of evidence in this particular situation for me to pinpoint, so yeah, it is a lot of speculation, but it's based on information I'm getting from all these specialists who many of them are, you know, in some disagreement, too, but it all seems to -- you know, we have to, you know, look through all this stuff, all these papers and get down to that she did not have any of these symptoms prior to the tetanus booster, and then after the tetanus booster, all this stuff occurred.

One soon recognizes the temporal relationship as the idée fixe of Petitioner's argument. Essentially this is the sort of post hoc ergo propter hoc argument¹⁴ that had, until quite recently, been consistently rejected under the Vaccine Act. But see, e.g., Capizzano v. Secretary of HHS, 440 F.3d 1317, 1326 (Fed. Cir. 2006) ("The fact that these physicians' diagnoses may have relied in part on the temporal proximity of Ms. Capizzano's injuries to the administration of the vaccine is not disqualifying. We see no reason why evidence used to satisfy one of the Althen III prongs cannot

¹⁴ Post hoc ergo propter hoc, Latin for "after this, therefore because of this" is defined by dictionary.com simply as "the logical fallacy of believing that temporal succession implies a causal relation." See also, Fricano v. U.S., 22 Cl. Ct. 796, 800 (1991) ("Although petitioner denies it, her causation argument is based on a type of reasoning generally referred to as 'post hoc ergo propter hoc' reasoning (after this, therefore on account of this), which is regarded as neither good logic nor good law.").

overlap to satisfy another prong. In other words, if close temporal proximity, combined with the finding that hepatitis B vaccine can cause RA, demonstrates that it is logical to conclude that the vaccine was the cause of the RA (the effect), then medical opinions to this effect are quite probative." (citations omitted)).

Petitioner next presented testimony from Dr. Lee, a board-certified neurologist and an assistant professor at the University of Illinois College of Medicine at Peoria and on staff with St. Francis, Methodist, and Proctor Hospitals.

Dr. Lee is of the opinion that Petitioner's injury is indicative of a brachial neuritis. He bases his opinion on the symptomatology evinced on examination in February 2003 to include pain, weakness, discomfort and, as noted on 20 February 2003, some atrophy. He opines that that her RSD could have been secondary to the brachial neuritis and further opines as to the possibility that, while the tetanus shot could not have caused the Thoracic Outlet Syndrome "it is possible that having the inflammation and irritation of the brachial plexus could cause some secondary changes, especially considering that with the chronic pain and dysfunction in the brachial plexus, this could aggravate the anatomic condition which is called thoracic outlet syndrome." Tr. II at 71. Or to restate,

[T]he most likely explanation for her symptoms are related to the tetanus injection which caused the plexitis and then caused the reflex sympathetic dystrophy and then caused anatomic changes and variation with regard to her physiological function of the shoulder and the muscles in that area, which then aggravated the anatomic variation which she had and gave rise to irritation to the cervical rib, leading to the thoracic outlet syndrome.

Tr. I at 74-75.

However, on closer scrutiny Dr. Lee later characterized this theory as a "possibility" and admitted on cross examination that this theory is not based on any sort of objective scientific data and is not described, at least to his knowledge, in any medical literature ever scribed by anyone anywhere – that is, that a brachial neuritis, an inflammatory condition, can lead to the congenital compressive syndrome known as TOS. Tr. II at 80-82. Neither could Dr. Lee explain the findings of Dr. Annest on surgery that the muscles comprising the thoracic outlet were intertwined and wrapped around the lower trunk of the brachial plexus – the exact part of the brachial plexus that affects one's hand. Tr. II at 78-79. Dr. Lee does not explain how a brachial neuritis could have caused such a marked structural issue.

Per contra, Respondent presented the testimony of Dr. Vinay Chaudhry, a board certified neurologist, professor of neurology at Johns Hopkins University School of Medicine, and a widely published author on the topic of brachial neuritis.

Dr. Chaudhry opines that this case, while complex, was more likely than not caused by Thoracic Outlet Syndrome. Dr. Chaudhry expresses some concern that Petitioner's symptomatology did not track with a typical case of brachial neuritis. Tr. II at 101. First, objective evidence of weakness and atrophy is somewhat lacking. Tr. II at 103. While noted by Dr. Miller in the 20 February 2003 office visit, such findings are glaringly absent from the 28 February 2003 visit to neurologist, Dr. Blume, and on numerous other contemporaneous exams. In fine, weakness and

atrophy, which are key factors in diagnosing brachial neuritis, are not prominent in Petitioner's case. Tr. II at 102-104. Moreover, Dr. Chaudhry indicates that neither of the EMGs conducted contemporaneous to Petitioner's condition show any evidence of denervation of the brachial plexus, which one would expect to see if this were a case of brachial neuritis. Dr. Chaudhry did recognize that Dr. Blume interpreted his 4 March 2003 EMG as being corroborative of some irritability of the brachial plexus, but this is not the same as denervation. Tr. II at 107-08.

According to Dr. Chaudhry, the first test to properly look for thoracic outlet syndrome was not conducted until the 24 February 2004 EMG/NCS by Dr. Machanic. While the intervening EMG/NCS are more or less consistent with thoracic outlet "compression of the lower trunk of the brachial plexus," Tr. at 110-11, Dr. Machanic actually discover evidence of Thoracic Outlet Syndrome which led shortly thereafter to surgery to decompress the TOS. During the surgery, Dr. Annet discovered that certain scalene muscles comprising the thoracic outlet, through which the lower trunk of the brachial plexus passes, were in fact wrapped around the lower trunk of Petitioner's brachial plexus. Pet. Ex. 15 at 12. Dr. Chaudhry avers that this is a congenital condition wholly unrelated to any possible brachial neuritis. Tr. at 113-14. And, in fact, following that surgery, Petitioner experienced a dramatic improvement.

Dr. Chaudhry indicated that 50% of his practice at Johns Hopkins involves patients with brachial neuritis, and that in his 18 years there he has never heard of a case where a brachial neuritis later led to the development of the congenital structural abnormality that is TOS. Tr. II at 119-20. Rather, according to Dr. Chaudhry, thoracic outlet syndrome is a chronic, long-standing condition "that is developed over a long period of time." Tr. II at 108-09. Moreover, Dr. Chaudhry testified that only rarely does brachial neuritis even affect the lower trunk of the brachial plexus. It almost exclusively affects the upper trunk. Tr. II at 122. Similarly, says Chaudhry, it is the rarest of occasions that a brachial neuritis would affect the trapezius muscle. Id. at 112.

However, Dr. Chaudhry has no good explanation for the timing of the onset and in particular with relation to the tetanus vaccine. Consider the following set of exchanges:

SPECIAL MASTER ABELL: What about the timing of vaccination?

THE WITNESS: Well, there are -- there are symptoms that are developing in this patient post-vaccination, and I would say even post an accident two days prior to the vaccination. I don't know. Again, it would be hard to say how and when the thoracic outlet developed and why it thinks -- why did she start complaining of these symptoms immediately after the vaccination or a few days or week after, and I -- I -- but what I'm going by is the examination and the EMG findings where we are not able to document anything else except minor changes in the hand.

Now could that have come from brachial neuritis? Well, first of all, the -- the -- the evidence for this being another etiology is much stronger than the time relation. Whatever is present in the hand and the pain in the pinch are clearly far more common to be coming from thoracic outlet compression than brachial neuritis.

If you take away her thoracic outlet completely and say the surgeons didn't find anything or that there was no EMG changes, could this hand numbness and weakness which was not there prior to surgery come from brachial neuritis? Well,

the answer is sure, it could.

SPECIAL MASTER ABELL: All right.

Mr. Reistrup, you said you have no further questions.

MR. REISTRUP: I do not, sir.

SPECIAL MASTER ABELL: Mr. Morrison, cross?

MR. MORRISON: Yes.

CROSS-EXAMINATION

BY MR. MORRISON:

Q Doctor, the remaining hand symptoms then could be a result of brachial neuritis?

A Sorry. I didn't catch that.

Q Pardon?

A I -- I did not get your question. I'm sorry.

Q The remaining hand symptoms that she has now could be a result of the brachial neuritis?

A The remaining hand symptoms could be a result of brachial neuritis, thoracic outlet syndrome, or the -- from the ulnar neuropathy of the elbow that's been documented, or could be RSD and complex regional pain syndrome. I'm not able to -- I'm not even calling this a brachial neuritis because the evidence for brachial neuritis to me is nothing.

But could anyone have if you take away half the facts, like I said, the surgery and all that and say none of that happened, and this was just brachial neuritis, could she still have hand symptoms? Yes.

Tr. II at 123-25.

II. CONCLUSIONS OF LAW

A petitioner may prevail under the Vaccine Injury in one of two ways. First, a petitioner may show that an injury recognized by the Vaccine Injury Table, 42 C.F.R. § 100.3, ("Vaccine Table" or "Table") occurred within the statutorily prescribed time period. § 11(c)(1)(C)(i). If a petitioner demonstrates such an injury by a preponderance of the evidence, she is entitled to a presumption of causation. § 13(a)(1)(A). If a petitioner qualifies under this presumption, she will be said to have suffered a "Table Injury." The burden would then shift to the Respondent to prove that the injury or condition "is due to factors unrelated to the administration of the vaccine described in the petition." § 13(a)(1)(B). Second, if a petitioner fails to satisfy the requirements under the Act for demonstrating a Table Injury, he may yet prevail by proving by preponderant evidence that the vaccination in question, more likely than not, caused the alleged injury. §§ 11(c)(1)(C)(ii)(I) and (II). This causation-in-fact standard, according to the Federal Circuit, requires that petitioner demonstrate by preponderant evidence:

- (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). Once again, if a petitioner is successful in that showing, the burden shifts to Respondent to prove that the injury or condition "is due to factors unrelated to the administration of the vaccine described in the petition." § 13(a)(1)(B).

To reiterate, according to the Vaccine Act, "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).

Concerning §11(c)(1) and certain other preliminary requirements, it is undisputed that (1) Petitioner is a valid legal representative; (2) the vaccine at issue is set forth in the Vaccine Injury Table; (3) the vaccine was administered in the United States; (4) no one has previously collected an award or settlement of a civil action for damages arising from the alleged vaccine-related injury; and, (5) no previous civil action has been filed in this matter. §§ 300aa-11(b) and (c). Additionally, the § 300aa-16(a) requirement that the petition be timely filed has been met.

Instead, the present case involves at its nexus a dispute as to whether this Petitioner: [S]ustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with the vaccine referred to in subparagraph (A) or died from the administration of such vaccine, and the first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Vaccine Injury Table.

Section 11(c)(1)(C)(i).

A. Table Injury

Petitioner is alleging herein that she suffered the Table Injury known as "brachial neuritis" following the administration of a vaccine containing tetanus toxoid. The Vaccine Injury Table, which can be found in its present iteration at 42 C.F.R. § 100.3, provides that a Petitioner is entitled to compensation if she suffered a "brachial neuritis" from two to twenty-eight days following the administration of a vaccine containing tetanus toxoid.

In addition, the term "brachial neuritis" is defined by the Qualification and Aids to Interpretation ("QAI") accompanying the Vaccine Injury table in the following manner:

- (6) 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).

The medical records provided by Petitioner, as per the factual recitation supra, indicate that she received a tetanus vaccination on 3 February 2003. Within the 2-28 day window specified by the Vaccine Injury Table, Petitioner suffered the onset of pain accompanied by weakness and atrophy of the deltoid which was noted on objective examination by her family physician, Dr. Miller. Sensory loss was noted in the inner arm and in the hand. Moreover, an EMG/NCS conducted by neurologist, Dr. Blume, on 4 March 2003 was interpreted as being indicative of a possible brachial neuritis. In addition, a diagnosis of brachial neuritis is proffered by numerous treating physicians over the course of Petitioner's illness.

Respondent contends quite adamantly that this petition must be denied as Petitioner's experts view the temporal relationship as the principal factor or lynchpin of their medical analysis. Were this case proceeding under causation-in-fact, Respondent's point would be well met. It has long 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). Yet, this is a Table Injury case. And the Table indicates quite clearly that a brachial neuritis evinced as per the QAI within 2 to 28 days is afforded a presumption of causation.

As the Federal Circuit has noted, "The Vaccine Act established a federal 'compensation program' under which awards are to be 'made to vaccine-injured persons quickly, easily, and with certainty and generosity.'" Knudsen v. Secretary of HHS, 35 F.3d 543, 549 (1994) (quoting from House Report 99-908, supra, at 3, 1986 U.S.C.C.A.N. at 6344). Moreover, it was anticipated that awards would sometimes be made where an individual was not in actuality harmed by the vaccine in question but nevertheless fit the Vaccine Injury Table.

Considering the record as a whole, the Court finds that Petitioner has indeed met the requirements of §13(a)(1)(A) and has demonstrated, via medical records and the opinion of medical experts, by preponderant evidence the matters required by §11(c)(1).

However, that is not the end of the matter. The Court, under §13(a)(1)(B), must also find that the injury alleged is not due to a factor unrelated to the vaccination.

B. Factor Unrelated

The statutory presumption of causation afforded to the Petitioner, supra, may be affirmatively defeated if a preponderance of the evidence indicates that the condition was caused by a factor unrelated to the vaccine. §13(a)(1)(B). The Vaccine Act states that, for petitioners to receive compensation under the act, the special master must find:

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.

Section 13(a)(1)(B).

Furthermore, § 13(a)(2) further explains that the term “factors unrelated to the administration of the vaccine”

(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and

(B) may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

In this particular case, Respondent argues that Petitioner's injuries, more likely than not, were caused by Thoracic Outlet Syndrome. The legal standard applied to Respondent's burden of proof in this regard is the same that applied previously to Petitioner. Knudsen v. Secretary of HHS, 35 F.3d 543, 549 (Fed.Cir. 1994). Similarly, Respondent has the affirmative obligation in certain instances to demonstrate that the alleged factor unrelated was the agent “principally responsible for causing” a petitioner's injuries. §13(a)(2).

The factual records and medical opinions, as indicated supra, are ambivalent at best when it comes to certain questions. However, it is generally agreed upon by those on Petitioner's side of the fence that her condition could not have been caused by a brachial neuritis alone, but that the brachial neuritis must have exacerbated an underlying, dormant congenital structural defect that then manifested in the cascade of unfortunate issues suffered by Petitioner. In Petitioner's favor, certain symptoms at the outset are consistent with a brachial neuritis while those symptoms which are somewhat inexplicable are nevertheless not inconsistent with said diagnosis. For instance, there was the onset of pain, weakness and deltoid atrophy noted on 20 February 2003 within the 2 to 28 day timeframe articulated on the Table. However, it is rare event indeed for a brachial neuritis to manifest with pain, weakness and atrophy concurrently. The pain is typically derived from the immunological aberration that is laying waste to the nerves of the brachial plexus. Tr. II at 115. The subsequent weakness is an indication that a connection has in fact been severed between the related muscles and the brachial plexus or what is otherwise known as "denervation." Hence, the QAI notes that, with brachial neuritis, typically one will see an acute onset of pain which diminishes and finally recedes once the damage is done followed thereafter by weakness and atrophy. In the case at bar, Petitioner did experience some diminution of her pain which is noted in several records in the latter

part of March 2003. This was viewed, and understandably so, as a confirmation of the diagnosis of a brachial neuritis. However, it is also fairly evident from the records that the treating physicians are at a loss to explain the continuing pain that then once again increases somewhat over time or in the least does not resolve. Hence, Dr. Miller starts to question, as early as 24 February 2003, whether Petitioner is suffering from reflex sympathetic dystrophy or RSD caused by a brachial neuritis. Additional opacity is created by the neurological findings of Dr. Blume which indicate that the atrophy noted in the trapezius muscle is not part of the same clinical picture but represents a long standing injury of some sort. Further, his original EMG/NCS on 4 March 2003, while showing evidence of multiple compromised nerve roots and "patchiness" that "could be compatible with a long standing spinal accessory nerve lesion and a superimposed patchy neural irritant of the [right] brachial plexus" such as brachial neuritis, at the same time revealed "normal nerve conduction studies of [right] upper extremity including ulnar nerve"; and, as Respondent points out, these findings, while corroborative of a possible "superimposed" brachial neuritis as Dr. Blume found, might also be indicative of Thoracic Outlet Syndrome, as Dr. Blume admits. Pet. Ex. 7 at 17.

Moving away from the vaccination and onset of Petitioner's injuries, on 21 August 2003, only six months later, Petitioner is diagnosed by Dr. Togut, an expert in the field, with Thoracic Outlet Syndrome an entrapment of the brachial plexus coupled with Complex Regional Pain Syndrome-2. As Dr. Togut communicated to Dr. Miller:

I think it is very important to totally assess these patients and this is my own bias. I have seen, as I have said, a thousand of these patients over the last twenty years and avoid suggesting in any way and I know you did not do this but others have that maybe this is in her head. It is not in her head. It is a real situation and the only thing that is needed is somebody with the curiosity, as you have Dr. Miller, to explore what this could be and the people who have seen the patient need to have that same curiosity. If they do not have an explanation they need to send the patient on to somebody else so that she has a sense that we are all interested in her problem and we are all trying to figure this out. Some of us have a little specialized bit of information and experience like I have in this area and others do not and it is just a matter of trying to find the people who have this.

Pet. Ex. 11 at 27.

Therefore, it could easily be seen, as Respondent posits, that this Petitioner finally saw the right doctor who accurately diagnosed her condition.

But the proof, as they say, is in the pudding. As Dr. Togut indicates, the wrong sort of cures in physical therapy can actually injure a patient further. *Id.* at 23. And it is relatively clear that the physical exercises prescribed to the patient to assist her in recovering from the alleged brachial neuritis were in no way helpful. So that is an issue in the Court's mind but not a glaring one. What is more problematical from Petitioner's perspective are the following: the lack of evidence of denervation to the brachial plexus on contemporaneous EMGs; the atypical clinical course of the alleged brachial neuritis; Dr. Togut's diagnosis of TOS; the EMG correlation by Dr. Machanic of TOS entrapment; the subsequent discovery during surgery of the muscles composing the thoracic outlet actually wrapped around the brachial plexus; and the tremendous benefit of that surgery.

In short, perhaps the only thing going for Petitioner in this case is the timing of the injury. And Respondent has not adequately addressed that issue except to say it was something of a coincidence. Is that possible, yes. But a brachial neuritis within 2 to 28 days was added to the Vaccine Injury table presumably because the experts agreed that there is an increased statistical risk above background that such an injury can occur within that time frame from a vaccine containing tetanus toxoid. That is not to say it cannot occur in conjunction with a tetanus vaccination outside the Table time frame. The Table explicitly provides for such eventualities. § 11(c)(1)(C)(ii)(II). However, presumably such instances are statistically merged into the background and can therefore not be accorded a legal presumption or, as a lay person might understand it, be given the "benefit of the doubt." However, it should be noted that the Federal Circuit recently held it was not improper per se that treating physicians rely on a temporal relationship in articulating a sequence of cause and effect; and further, "[T]reating 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, 440 F.3d at 1317 (quoting Althen, 418 F.3d at 1280).

That being said, Respondent's strongest suit is the lack of a medically reliable theory as to how an inflammatory process like brachial neuritis could cause a congenital structural abnormality, as was discovered in Petitioner to be thoracic outlet syndrome or, in other words, an entrapment of the brachial plexus. While various experts and treating physicians speculate as to a potential theory, it remains just that: a theory and one that finds no corroboration within the medical or scientific community. Furthermore, while this Court is adjured to consider any diagnosis, conclusion, medical report or impression contained in the record, the Vaccine Act is quite clear 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 treating physicians and other medical experts, that is not to say that such are binding on the Court, particularly should the record and course of the condition on the whole prove contradictory. 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. See, Terran v. Secretary of HHS, 195 F.3d 1302, 1316 (Fed. Cir. 1999).

After much careful consideration and deliberation concerning the veritable labyrinth of facts and medical opinion on record in this case and according each aspect an appropriate weight given the record as a whole and the entire course of Petitioner's condition, the crux of the case hangs on the question of whether there is preponderant evidence that another factor, identified in the medical records, and unrelated to the vaccination in question, was responsible for the injuries alleged.

While Respondent presents a compelling argument in favor of TOS, it must needs give way to the evidence contained in the medical record and espoused by Petitioner's many experts and treating physicians all of whom considered the primary cause to have been brachial neuritis which in some way exacerbated certain underlying issues. There is certainly a question, particularly in light of recent Federal Circuit decisions, as to whether Petitioner's medical theory would pass muster were

this a question of causation-in-fact analysis as it seemingly fails to establish, via reliable medical or scientific evidence, a logical sequence of cause and effect connecting the vaccine to the injury alleged. However, as this is a Table Injury claim, Petitioner need only demonstrate by preponderant evidence that a Table Injury, as described in the QAI and corroborated by medical records and medical opinion, more likely than not occurred in order to be eligible for program compensation. In the end, Petitioner's idée fixe concerning the temporal relationship is the equivalent of the Sirens' song leading to an inevitable legal conclusion.

That being said, Respondent comes close to lashing the Court to the mast of its argument in favor of Thoracic Outlet Syndrome as a factor unrelated. On that note, Dr. Chaudhry offered a particularly compelling medical analysis and theory as regards TOS. And the Court, in consideration of the evidence presented can see, yes, this could have been TOS; however, at the same time her symptomatology is compatible with brachial neuritis, EMG/NCS are not inconsistent, and there is a cloud of witnesses evinced in the medical records and medical opinion offered that advance this conclusion. Therefore, while it is a possibility that Petitioner's condition was principally caused by the thoracic outlet syndrome, the Court cannot make such a finding based on a preponderance of the evidence. While Respondent proffers a plausible medical theory articulating a logical sequence of events between the cause alleged, TOS, and the course of Petitioner's injury, in the end the quantum of evidence in its favor is something less than a preponderance.

CONCLUSION

For the reasons articulated supra, the Court finds that Petitioner is entitled to Program compensation. In so doing, the Court would like to remind the parties of its long standing policy on fair and amicable resolution.

The parties shall contact the Court to discuss further proceedings in this case on the topic of damages but are encouraged to begin discussions amongst themselves.

IT IS SO ORDERED.

Richard B. Abell
Special Master