OFFICE OF SPECIAL MASTERS

No. 01-413V

(Filed: May 15, 2003)

JAN DeGRANDCHAMP, Petitioner, v. SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, Respondent.	TO BE PUBLISHED

Andrew W. Dodd, Esq., Torrance, California, for Petitioner.

Ann K. Donohue, Esq., United States Department of Justice, Washington, D.C., for Respondent.

ENTITLEMENT DECISION

ABELL, Special Master:

I. Issue

The issue in this case is whether the injuries alleged by Petitioner, Miss Jan DeGrandchamp, occurred as a result of her tetanus-diphtheria ("Td") vaccination administered on 24 November 2000. Specifically, Petitioner alleged brachial neuritis, anaphylaxis and peripheral neuropathy as sequlae to the Td vaccine. The Court finds that Petitioner did not meet her burden by a preponderance of the evidence concerning her claims of brachial neuritis and anaphylaxis. However, the Court finds that it is more likely than not that Miss DeGrandchamp did suffer peripheral neuropathy as a result of the Td vaccine.

II. PROCEDURAL BACKGROUND

On 16 July 2001, Petitioner, Miss Jan DeGrandchamp, filed a claim under the National Childhood Vaccine Injury Compensation Act (Vaccine Act or Act)[1] alleging vaccine-related injury. As put forth at the 10 October 2002 entitlement hearing, Petitioner claims that as a result of receiving a Td vaccination on 24 November 2000, the tetanus component of the vaccination caused her to suffer an "on-Table" brachial neuritis and anaphylaxis. In the alternative, if the Court finds such do not meet the Vaccine table definitions, Petitioner alleges that the Td shot in fact caused the brachial neuritis and anaphylaxis. Transcript at 46 (hereinafter "Trans."); Petitioner Exhibit 29 at 1.[2] Also, Petitioner claims that the Td vaccination caused her to suffer peripheral neuropathy. Pet. Ex. 29 at 1.

Petitioner has satisfied the requirements for a *prima facie* case pursuant to § 300aa-11(b) and (c) by showing that: (1) Petitioner is a valid legal representative; (2) the vaccine at issue, Td, is a vaccine set forth in the Vaccine Injury Table; (3) the Td vaccination was administered to Miss DeGrandchamp 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 injury; and, (5) no previous civil action has been filed in this matter. Additionally, the § 300aa-16(a) requirement that the petition be timely filed has been met.

On 25 February 2002, Petitioner filed the medical expert's report of Victor S. Hogen, Jr., M.D.,[3] a board certified neurologist. Pet. Ex. 30. In his report, Dr. Hogen stated that the Petitioner "developed a number of acute severe symptoms," Pet. Ex. 29 at 1, related to the 24 November 2000 "tetanus shot." *Id.* "[T]he patient experienced anaphylaxis after the tetanus reaction, brachial neuritis after the tetanus reaction and a systematic autoimmune peripheral neuropathy after the injection. The sequelae of which are still with her as of this date." *Id.*

On 7 May 2002, Respondent, the Secretary of Health and Human Services, filed an expert's report from Steven Herskovitz, M.D.,[4] also a board certified neurologist. Res. Ex. A. Dr.

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[1] The statutory provisions governing the Vaccine Act are found at 42 U.S.C. §§ 300aa-1 to 300aa-34 (1991 & Supp. 2002). Hereinafter, for ease of citation, all references will be to the relevant subsection of 42 U.S.C. § 300aa.

[2] References to the Petitioner's Exhibits and Respondent's Exhibits, shall be hereinafter truncated to "Pet. Ex.", and "Res. Ex." respectively.

[3] Dr. Hogen is board certified in neurology. He currently runs his own private practice in neurology, is an Assistant Clinical Professor in Neurology at UCL.A Medical Center, is the Medical Director at Providence Holy Cross Medical Center, and is the Director, Neurology Laboratory at Providence Holy Cross Medical Center. He formerly served as the Chief of Staff at Providence Holy Cross Medical Center (1995-1997).

[4] Dr. Herskovitz is board certified in neurology and electromyography (EMG). He is currently the Director of the EMG Lab at Montefore Medical Center, the Director of EMG Fellowship Training at Albert Einstein College of Medicine and an Associate Professor of Neurology at Albert Einstein College of Medicine. Previously, he occupied numerous positions specializing in neurology including: Chief-Division of Neurology, North Central Bronx Hospital (1987-1988); Residency Director, Department of Neurology Montifiore Medical Center (1992-1997); and, Deputy Chief of Service, Department of Nuerology Montifiore Medical Center (1995-1997). To his

Herskoivitz stated that "[t]here is nothing in [the] record to objectively support that this patient had anaphylaxis, brachial neuritis or peripheral neuropathy." Res. Ex. A at 1. Dr. Herskovitz stated that the symptomology was "entirely subjective and non-specific," *Id*. at 2, with "[n]o attempt to document objective abnormalities as in nerve conduction studies." *Id*.

Petitioner submitted the results of a nerve conduction study performed by Dr. Hogen on 11 June 2002. Pet. Ex. 32. The findings of the nerve conduction study were "consistent with a mild moderate axonal[5] neuropathy." *Id*. Respondent's expert, Dr. Herskovitz, responded to the findings of the nerve conduction study with a supplemental report dated 12 June 2002 but submitted to the Court on 11 September 2002. Res. Ex. D. Dr. Herskovitz questioned the veracity of the study and suggested that another nerve conduction study be done at a "reliable, preferably academic setting." *Id.* Petitioner followed Dr. Herskovitz's suggestion and had a nerve conduction study performed by John D. Keesey, M.D.[6] at the UCLA Department of Neurology EMG Laboratory. Dr. Keesey stated that the results of the study's findings "are interpreted as indicating the presence of a sensory polyneuropathy in the left lower extremity." Pet. Ex. 40 at 149. Respondent filed a supplemental report by Dr. Herskovitz in which Dr. Herskovitz stated that "[a]t face value, we may have to accept, based on [Dr. Keesey's] report, that [Miss DeGrandchamp] may have a mild sensory peripheral neuropathy of the axonal type." Res. Ex. E at 1.

On 10 October 2002, the Court conducted an evidentiary hearing in this matter. The Court heard testimony from Petitioner's medical expert, Dr. Hogen, and Respondent's medical expert, Dr. Herskovitz. The hearing transcript was filed on 12 November 2002.

Thereafter, the parties filed post-hearing briefs. On 20 November 2002, Petitioner filed her post-hearing brief. On 5 December 2002, Respondent filed a post-hearing brief. Petitioner filed her *sur-response* on 16 December 2002. Subsequently, the parties had discussions in an effort to settle the matter. Such discussions were unsuccessful. Thus, the record is complete and ripe for decision.

II. FACTS

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credit, Dr. Herskovitz has written over twenty-five articles in peer reviewed journals and authored, edited or contributed to numerous books on neurology.

[5] Axonal, pertaining to or effecting an axon. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 176 (27th ed. 1988). Axon is "the long, spider-thin, tail-like structure of a neuron. The axon carries signals (electric voltages) between the dendrites (the neuron's input sites) and the terminal buttons (the neuron's output sites that are at the very end of the axon). The signal always travels in the same direction - the signal comes into the neuron through the dendrites, through the cell body (soma), to the axon, and then out the terminal buttons to the dendrites of the next neuron." http://www.alleydog.com/glossary/definition.cfm?term=Axon.

[6] John Keesey, M.D. is a "world-renowned expert in electromyography," Trans. at 42, is a Professor of Neurology at UCLA School of Medicine, and is a Co-Director of UCLA Medical School's Nuerology-Neuroscience, Neuromuscular Program. He is a member of the National Medical Advisory Board and Chairman of the Medical Advisory Board of the California Chapter of the Myasthenia Gravis Foundation, Inc. He is the Director of the Myasthenia Gravis Clinic at Memorial Medical Center of Long Beach California.

Petitioner, Miss Jan DeGrandchamp, was born on 17 April 1947. Petition For Vaccine Compensation at 2 (hereinafter "Petition"). The earliest medical record submitted by Petitioner states that on 14 November 2000, Miss DeGrandchamp visited the Frazier Mountain Community Health Center complaining of "shooting pain in her right groin area, frequency, and fatigue [for the past two] days. Pet. Ex. 1 at 1. The doctor indicated that it could be a possible urinary tract infection. *Id.* Ten days later, on 24 November 2000, as part of a routine gynecological examination, Petitioner received a Td vaccine administered to her upper left arm. Pet. Ex. 1 at 2.

Soon thereafter, Petitioner stated that she experienced a surging tingle on the left side of her neck moving upward toward her head. Petition at 2. On 25 November 2000, the day after receiving the Td vaccine, Petitioner stated that she "experienced a whole body ache, fatigue and pain near the injection site." *Id.* On 26 November 2000, Petitioner stated she was "very stiff and ached all over, accompanied by pain, particularly in the left arm." *Id.* By 27 November 2000, Petitioner said that she experienced "a deep, very intense burning/stinging sensation throughout her body, but primarily in her thighs, chest and arms area accompanied by difficulty in walking, shortness in breath, extreme difficulty in driving a motor vehicle, overall fatigue, a state of mental confusion and pain and trembling in both hands." *Id.* On 5 December 2000, Petitioner went to see the doctor and complained of myalgias[7] in her upper and lower extremities, general body ache, burning-like sensation, sore left arm and fatigue since the 24 November 2000 Td vaccination. Pet. Ex. 1 at 3. The doctor noted that Petitioner was normal under all categories of the physical examination and stated that she had full range of motion in her extremities and no effusion.[8]

On 13 December 2000, Petitioner was seen by Charles Trammel, M.D. at an urgent care center. Pet. Ex. 12. On presentation, Petitioner told the doctor that she "was in pain all over, has been under a quite a bit of stress at work and at home, and feels that maybe something went wrong with her tetanus shot." Pet Ex. 12 at 76. Dr. Trammel's examination of Petitioner's upper extremities revealed "no erythema,[9] edema,[10] or any abnormality of the deltoid area[11]. . . . She has no diffuse myalgias and there are no discrete joint effusions. Neuromotor, sensory and vascular are intact." *Id.* Petitioner's neurologic examination was also "intact." *Id.* Dr. Trammel noted that Miss DeGrandchamp previously had labs drawn to "make sure that nothing else was wrong with her. . .

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[7] Myalgia is "pain in a muscle or muscles." DORLAND'S *supra* at 1083.

[8] Effusion is "the escape of fluid into a part or tissue, as an exudation or a transudation." DORLAND'S *supra* at 532. Exudation is " the escape of fluid, cells, and cellular debris from blood vessels and their deposition in or on the tissues, usually as the result of inflammation. *Id.* at 600. Transudation is the " passage of serum or other body fluid through the membrane or tissue surface, which may or may not be the result of inflammation." *Id.* at 1745.

[9] Erythema is "redness of the skin produced by congestion of the capillaries, which may result from a variety of causes . . . ." DORLAND'S *supra* at 577.

[10] Edema is "the presence of abnormally large amounts of fluid in the intercellular tissue spaces of the body . . . ." DORLAND'S *supra* at 530.

[11] Shoulder area. DORLAND'S *supra* at 1066-67.

. [Her] labs reveal[ed] normal CBC,[12] Chem-7,[13] liver function tests and TSH[14] with no abnormalities." *Id*. Dr. Trammel tested Petitioner's sedimentation rate,[15] which was normal, *Id.* at 76-77, and her test for infectious disease markers came back negative. *Id*. at 78. Dr. Trammel assessed Petitioner with "[d]iffuse myalgias with weakness, nonspecific" and "[s]tress and anxiety." *Id*. at 77.

Petitioner presented to David Morrow, M.D., of the Facey Medical Group on 4 January 2001. Pet. Ex. 8 at 24. Under subjective findings, Dr. Morrow recorded that Petitioner "complains of multiple problems" since her 24 November 2000 Td booster, *Id.*, including "weakness and burning sensation in the muscles, fatigue, difficulty sleeping at night, and generalized malaise. . . . These symptoms are not becoming progressively worse." *Id*. Under objective findings, Dr. Morrow recorded that there was "[n]o clubbing,[16] cyanosis[17] or edema of the extremities." *Id.* Under neurologic findings, Petitioner's motor function was recorded as "5/5 (normal) throughout," *Id.*, "[d]eep tendon reflexes are 2+ (normal) and symmetric in the biceps, brachialis,[18] patellar[19] and Achilles tendon. Cerebellar is intact." *Id.* Dr. Morrow ran a test to check Petitioner's tetanus toxoid IgG[20] and the result was an elevated level at 6.26. *Id*. at 24, 25.

On 5 February 2001, Petitioner presented to Mark C. Schultz, M.D. a neurologist. Pet. Ex. 2. Following a comprehensive neurological exam, Dr. Schultz recorded that Petitioner was

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[12] Complete blood count (CBC): a common blood test to determine general health status and to screen for a variety of disorders, such as anemia and infection, as well as nutritional status and exposure to toxic substances. http://www.labtestsonline.org/understanding/analytes/cbc/glance.html.

[13] Laboratory tests for glucose, blood urine nitrogen, creatinine, potassium, sodium, chloride, and carbon dioxide. NEIL M. DAVIS, MEDICAL ABBREVIATIONS : 8600 CONVENIENCES AT THE EXPENSE OF COMMUNICATIONS AND SAFETY 35 (6th ed. 1993).

[14] Thyroid-stimulating hormone. MEDICAL ABBREVIATIONS *supra at* 175.

[15] Sedimentation rate is a test that "measures the rate at which red blood cells separate from plasma (the liquid part of blood) and fall to the bottom of a test tube to form a sediment. High levels may indicate heart attack, rheumatic fever, giant cell arteritis, severe anemia, cancer relapse or other conditions. Low levels may indicate congestive heart failure, sickle cell anemia or other conditions." HSLabs BloodworksUSA.com *at* http://www.bloodworksusa.com/cs_productpages/28.html.

[16] Clubbing is "a proliferative change in the soft tissues about the terminal phalanges of the fingers or toes." DORLAND'S *supra* at 348.

[17] Cyanosis is "a bluish discoloration, applied especially to such discoloration of the skin and mucous membranes due to excessive concentration of reduced hemoglobin in the blood." DORLAND'S *supra* at 415.

[18] Pertaining to the arm. DORLAND'S *supra* at 229.

[19] Patellar means "of or pertaining to the patella." DORLAND'S *supra* at 1241. Patella is a "triangular sesamoid bone, about 5 cm. in diameter, situated at the front of the knee in the tendon of insertion of the quadriceps extensor femoris muscle. Called also *knee cap*." *Id.* at 1241.

[20] IgG is a medical abbreviation for immunoglobulin G. MEDICAL ABBREVIATIONS *supra* at 85.

"objectively intact." Pet. Ex. 2 at 15. Dr. Schultz assessed that it is "certainly possible to get a post-vaccination reaction with systematic symptoms including an inflammatory myopathy[21] . . . . It is also possible to get similar symptoms from viral infections but it is important to rule out other more systematic illnesses or conditions that might cause similar symptoms." *Id*. Dr. Schultz ordered an MRI scan of the brain with and without contrast, which was conducted on 22 February 2001, which was normal. Pet. Ex. 2 at 16; Pet. Ex. 3 at 19. On 5 March 2001, Petitioner returned for neurological follow-up with Dr. Schultz. During that visit, Dr. Schultz observed a "mild postural tremor" and assessed Petitioner's condition as "tremor, myoclonus."[22] Petitioner was prescribed Neurontin,[23] and Dr. Schultz noted improvement of this condition on 2 April 2001. Pet. Ex. 2 at 18.

During the period of time that Dr. Schultz treated petitioner, she also remained under the care of Dr. Morrow. Dr. Morrow's records dated 16 March 2001, state that Petitioner was "still having migratory pains, but the cramping in her hands has mostly resolved. She is still not working and continues to complain of fatigue." Pet. Ex. 8 at 27. Dr. Morrow recorded a "[f]ine hand tremor" under objective neurologic findings, *Id*., all other findings were normal or intact. *Id.*

On 8 June 2001, Petitioner evaluated by a second neurologist, Victor S. Hogen, M.D. Dr. Hogen stated that Petitioner presented with a "probable immune related peripheral neuropathy[24] based on a 24-hour reaction after a tetanus vaccination . . . ." *Id.* Dr. Hogen's subjective findings included "burning all over, diffuse weakness, ataxia,[25] and residual loss of ankle jerks,[26] especially on the right but not the left." Pet. Ex. 9 at 34. A neurological examination revealed abnormal sensation with a mild reduction in the lower extremities. Pet. Ex. 13 at 82. Dr. Hogen stated that there was really no treatment for Petitioner's condition and that "[t]here [was] no need for further work up." *Id*

On 25 February 2002, Petitioner filed a supplemental report by Dr. Hogen. Pet. Ex. 29. Dr. Hogen opined that the constellation of symptoms that Petitioner experienced and still experiences lead him to believe that Petitioner suffered anaphylaxis, brachial neuritis and a systematic autoimmune peripheral neuropathy as a result of the tetanus vaccination. *Id*. at 1. On 10 May 2002, Respondent filed a report by Dr. Herskovitz in which he opined that Petitioner's "symptomatology was entirely subjective and non-specific, with no exam ever documenting convincing, consistent or

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[21] Myopathy is "any disease of a muscle." DORLAND'S *supra* at 1092.

[22] Myoclonus is "shocklike contractions of a portion of a muscle, an entire muscle, or a group of muscles, restricted to one area of the body or appearing synchronously in several areas." DORLAND'S *supra* at 1090.

[23] Neurontin is an anti-epileptic drug and is widely used for neuropathic pain. http://www.loftusmd.com/Articles/AED/neurontin.html.

[24] Peripheral - "pertaining to or situated at or near the periphery; situated away from a center or central structure. DORLAND'S *supra* at 1262. Neuropathy is "a general term denoting functional disturbances and/or pathological changes in the peripheral nervous system. DORLAND'S *supra* at 1131. Immune related denotes a response related to the immune system. DORLAND'S *supra* at 818.

[25] Ataxia is "failure of muscle coordination; irregularity of muscular action." DORLAND'S *supra* at 161.

[26] The ankle jerk reflex is synonymous with the Achilles reflexes. Trans. at 84.

relevant findings." Res. Ex. A at 2. Dr. Herskovitz went on to state that "[n]o attempt was made to document objective abnormalities as in nerve conduction studies." *Id.*

Petitioner presented to Dr. Hogen on 22 May 2002 for a nerve conduction study.[27] Dr. Hogen's impressions from the results of the study were: "Abnormal nerve conduction study with moderate axonal neuropathy in the legs as evidenced by low amplitudes for the peroneal[28] motor conduction latency and also conduction block affecting the left median and left ulnar[29] motor nerves with absence of the sural[30] sensory on the left side. These findings would be consistent with a mild to moderate axonal neuropathy." Pet. Ex. 32 at 117. Respondent filed a response by Dr. Herskovitz to Dr. Hogen's study on 11 September 2002. Res. Ex. D. Dr. Herskovitz stated that he had "some difficulties with the veracity of [the] study," *Id.* at 1, and he suggested that the "findings be verified with an appropriate study in a reliable, preferably academic setting." *Id.*

On 18 September 2002, Petitioner presented to the UCLA Department of Neurology EMG Laboratory for an additional nerve conduction study to be performed by John Keesey, M.D. Pet. Ex. 40. Results of the UCLA study were as follows: "Abnormal nerve conduction studies of the lower extremity because of low amplitude sensory evoked responses and slowed sural sensory nerve conduction velocity." Dr. Keesey concluded that "[t]hese electrical findings are interpreted as indicating the presence of a sensory polyneuropathy in the left lower extremity." Pet. Ex. 40 at 149. Respondent filed a supplemental report by Dr. Herskovitz in which he responded to the UCLA nerve conduction study. Pet. Ex. E. Dr. Herskovitz stated that "[a]t face value, we may have to accept, based on this report, that [Petitioner] may have a mild sensory peripheral neuropathy of the axonal type." *Id.* However, Dr. Herskovitz went on to say that the results of the nerve conduction study "do[es] not provide for a specific etiology," *Id.*, he did not see an effort to eliminate other causes, *Id.*, and "the medical record does not provide any convincing clinical evidence of a neurologic deficit." *Id.*

III. DISCUSSION AND ANALYSIS

Petitioner can prove she is entitled to compensation under the Program in one of two ways. She can prove entitlement through a statutorily prescribed presumption of causation or, by proving causation-in-fact. First, Petitioner may prove that she suffered an injury or condition listed in the Vaccine Injury Table within the statutorily prescribed time period. § 11(c)(1)(C)(i). If Petitioner establishes that she suffered such injury by a preponderance of the evidence, Petitioner is entitled to a presumption of causation. § 13(a)(1)(A). If Petitioner qualifies under this presumption, she will

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[27] "A Nerve Conduction Study is a useful diagnostic tool that measures the rate at which an electrical impulse moves along a nerve. It is used to diagnose disorders of the peripheral nerves and muscles." http://www.neurologyhealth.com/ncs.htm.

[28] Peroneal, "pertaining to the fibula or to the outer side of the leg." DORLAND'S *supra* at 1265.

[29] Ulnar, "pertaining to the ulna (the inner or larger bone of the forearm) or to the ulnar (medial) aspect of the arm." DORLAND'S *supra* at 1784.

[30] Sural, "pertaining to the calf of the leg." DORLAND'S *supra* at 1616.

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).

If Petitioner fails to satisfy the requirements under the Act for demonstrating a Table injury, Petitioner may prove by a preponderance of the 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 proof of a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Grant v. Secretary of HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). A reputable medical or scientific explanation must support this logical sequence of cause and effect. Id. at 1148; Strother v. Secretary of Dep't of Health and Human Servs., 21 Cl. Ct. 365, 370 (1990), aff'd, 950 F.2d 731 (Fed. Cir. 1991). Temporal association of the onset of the injury with the vaccination, although probative, is not sufficient in and of itself to establish causation-in-fact. Grant, 956 F.2d at 1148; Strother, 21 Cl. Ct. at 369. Additionally, simply showing an absence of an alternative cause of injury does not meet petitioner's affirmative duty to show causation, however, this too is probative. Grant, 956 F.2d at 1149. Once again, if 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).

In the present case, Petitioner alleges that she suffered two Table injuries as a result of the 24 November 2000 Td vaccination: "anaphylactic shock and brachial neuritis." Trans. 45-46. In the alternative, if the Court finds that the two table injuries do not meet the definitions set out by the Vaccine Table, Petitioner proffers that those would also fall into the "off-table category too," Trans. at 46, otherwise known as causation-in-fact. Finally, Petitioner alleges an autoimmune peripheral neuropathy resulting from the Td vaccination. Petitioner's Pre-Trial Memorandum at 5 (hereinafter "Pet. Pre-Tri."). Autoimmune peripheral neuropathy is not listed as a Table injury, thus, Petitioner must prove such under this Court's causation-in-fact strictures.

A. On-Table Anaphylactic Shock (or Anaphylaxis)[31] and Brachial Neuritis[32]

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[31] "Anaphylaxis and anaphylactic shock. For purposes of paragraph (a) of this section, Anaphylaxis and anaphylactic shock mean an acute, severe, and potentially lethal systemic allergic reaction. Most cases resolve without sequelae. Signs and symptoms begin minutes to a few hours after exposure. Death, if it occurs, usually results from airway obstruction caused by laryngeal edema or bronchospasm and may be associated with cardiovascular collapse. Other significant clinical signs and symptoms may include the following: Cyanosis, hypotension, bradycardia, tachycardia, arrhythmia, edema of the pharynx and/or trachea and/or larynx with stridor and dyspnea. Autopsy findings may include acute emphysema which results from lower respiratory tract obstruction, edema of the hypopharynx, epiglottis, larynx, or trachea and minimal findings of eosinophilia in the liver, spleen and lungs. When death occurs within minutes of exposure and without signs of respiratory distress, there may not be significant pathologic findings." 42 C.F.R. § 100.3(b)(1).

[32] An on-table brachial neuritis: "(i) This term 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

The Court finds that Miss DeGrandchamp did not suffer on-table anaphylactic shock (or anaphylaxis) or brachial neuritis as a result of the 24 November 2000 Td vaccination. The Court's analysis on this issue will be brief. Petitioner's medical expert, Dr. Hogen, testified that Petitioner "didn't have shock, but she had a severe immune reaction to the tetanus vaccination" Trans. at 21, and the reaction "comes very close" to the table definition of anaphylaxis but "it doesn't quite cross the line." Trans. at 21 (agreeing with the Court that that is a correct interpretation of his testimony). In his testimony concerning on-table brachial neuritis, Dr. Hogen stated that "[Miss DeGrandchamp] doesn't meet the strict definition of brachial neuritis used in this program." Trans. at 24. Additionally he stated that Ms. DeGrandchamp did not suffer from brachial neuritis as defined by the table. Trans. at 49-50. Thus, the Court accepts the testimony of Petitioner's expert as dispositive in these two matters.

Causation-In-Fact

In order to demonstrate entitlement to compensation in a causation-in-fact claim, a 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) and (II); *Grant,* 956 F.2d 1144; *Strother,* 21 Cl. Ct. at 369-70, *aff'd*, 950 F.2d 731 (Fed. Cir. 1991). The Federal Circuit, which summarized the legal criteria required to prove causation-in-fact under the Vaccine Act, requires that every petitioner:

> 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.

This Court has organized the legal criteria in *Grant* by means of a two-part test. *First*, a petitioner must provide a reputable medical theory causally connecting the vaccination and the injury. In fine, can Td cause the type of injury alleged? *Second*, a petitioner must also prove that the vaccine actually caused the alleged symptoms in her particular case.

Under the first prong, a petitioner must demonstrate the biologic plausibility of their theory. This may be accomplished in a number of ways. First, a petitioner must proffer a scientific pathogenesis underlying the alleged causal relationship. Reliability and plausibility are found by providing evidence that a sufficient minority of physicians have accepted the theory. In addition,

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opposite side of the injection; it is sometimes bilateral, affecting both upper extremities.
(ii) 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 monoeuropathies), as well as other peripheral and central nervous system structures (e.g., cranial neuropathies and myelopathies)." 42 C.F.R. § 100.3(b)(7).

epidemiological studies and an expert's experience, while not dispositive,[33] lend significant credence to the claim of plausibility. Articles published in respected medical journals, which have been subjected to peer review, are also persuasive.

The second prong of the causation-in-fact test is difficult but not impossible. Petitioner must show, by a preponderance of the evidence--as this Court is wont to say, a test based on 50% and a feather--that the vaccine caused the symptoms that manifested in this case. A petitioner does not meet this affirmative obligation by merely showing a temporal association between the vaccination and the injury. Rather, a petitioner must explain *how* and *why* the injury occurred. *Strother*, 21 Cl. Ct. at 370; *see also Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1993), *cert. denied*, 469 U.S. 817 (1984) (inoculation is not the cause of every event that occurs within a ten day period following it).

B. Applicability of the Two Part test in Miss Jan DeGrandchamp's Case

In Petitioner's case, the Court follows the two pronged causation in fact analysis tailored as: (1) Can Td, specifically the tetanus toxoid, cause anaphylactic shock (or anaphylaxis), brachial neuritis and peripheral neuropathy?; and, (2) Did Miss DeGrandchamp's Td vaccination result in these injuries?

1. Can the tetanus toxoid in Td cause an (a)anaphylactic shock (or anaphylaxis); (b) brachial neuritis; and, (c) peripheral neuropathy?

(a) Anaphylactic shock (or anaphylaxis)

Quite simply, the answer is yes. The Institute of Medicine concluded that there is a causal relationship between tetanus toxoid and anaphylaxis. INSTITUTE OF MEDICINE, ADVERSE EFFECTS OF PERTUSSIS AND RUBELLA VACCINES, 108 (1994). Respondent usually relies on the Institute of Medicine's (IOM) publications to confirm Respondent's own positions, generally that there is a lack of causation between a particular vaccine and an alleged injury. Here, the IOM confirms the relationship.

(b) Brachial Neuritis

Again, the answer is yes. The IOM concluded that the evidence favors acceptance of a causal relationship between tetanus toxoid and brachial neuritis. *Id.* at 94.

(c) Peripheral Neuropathy

Although arriving at this answer was much more vexing, the Court finds that the Petitioner has demonstrated that this condition is possible. The IOM has not definitively come to conclusion

[33] This first prong of the Court's test meets easily with cases where epidemiological or case study reports are already available. Beginning with this prong is practical when there is epidemiological evidence, for it avoids the tautalogical reasoning that would result when one attempts to answer *Can It?* without having reports and studies that previously would have answered *Did It?*

on this issue. "The evidence is inadequate to accept or reject a causal relationship between tetanus toxoid . . . and peripheral mononeuropathy." *Id.* However, the testimony of both experts, the medical literature filed by the Petitioner, and the letter from the pharmaceutical manufacturer of the Td vaccine in question proved convincing.

Respondent's expert, Dr. Herskovitz testified that "it's entirely biologically plausible that certain kinds of neuropathies can be induced by certain vaccinations and by certain immunization." Trans. at 94. However, Dr. Herskoivitz opined that such neuropathies fit into clearly, clinically defined broad syndromes, such as brachial neuritis or Guillian Barre Syndrome, and there is no such entity as a vague immune neuropathy as is described here. *Id.* at 94-95. Further, Dr. Herskovitz stated that "*most* immune neuropathies are a demyelinating type" and typically not the axonal type as is the case here. *Id*. at 95 (emphasis added).

Dr. Hogen testified that tetanus toxoid can sometimes, "for whatever reason," trigger an immune response which attacks the peripheral nervous system. Trans. at 22-24. The immune response may result in the "body's own immune system attacking the peripheral nervous system . . . [and] either infiltrate or directly attack with antibodies the peripheral nerves . . . ." Trans. at 26.

Petitioner's filed several articles concerning neurologic complication precipitated by tetanus toxoid administration. One article, a case study of a 23 year old medical student, concludes that the student suffered a heretofore unseen and "unusual reaction, peripheral neuropathy, to tetanus toxoid. . . ."[34] Pet. Ex. 22 at 5. In an article that reviewed the neurologic side effects of commonly used vaccines, the authors reported that "[t]he most common reported neurologic complication of tetanus toxoid is polyneuropathy."[35] Pet. Ex. 35 at 123.

Petitioners also submitted two articles that concluded a link between tetanus toxoid and neuritis, either mononeuritis or polyneuritis. One of the articles proclaimed "[t]he most common reaction to tetanus toxoid alone [is] . . . polyneuritis. . . ."[36] Pet. Ex. 37 at 136. The second article "conclude[s] that there is a connection between tetanus vaccination and . . . mono- and polyneuritis, [however] . . . these complications are extremely rare."[37] Pet. Ex. 24 at 12. There is one important caveat that in fairness must be mentioned concerning these two articles. Neuritis is the "inflammation of a nerve,"[38] whereas neuropathy is "used to designate noninflammatory lesions in

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[34] George I. Blumstein, M.D. and Harold Kreithen, M.D., *Peripheral Neuropathy Following Tetanus Toxoid Administration*, 198 JAMA 1030, 1031 (1966).

[35] S. Lane Rutledge, M.D. and O. Carter Snead III, M.D., *Neurological Complications of Immunizations*, 109 J. OF PEDIATRICS 917, 918 (Dec. 1986).

[36] Patti L. Holliday, M.D. and Raymond B. Bauer, M.D., *Polyradiculoneuritis Secondary to Immunization With Tetanus and Diphtheria Toxoids*, 40 ARCH NEUROL 56, 57 (Jan. 1983).

[37] Ute Quest, W. Hennessen and R. M. Widmark, *Mono- and Polynueritis After Tetanus Vaccination (1970-1977)*, 43 DEVELOP. BIOL. STANDARD 25-32 (1979).

[38] DORLAND'S *supra* at 1127.

the peripheral nervous system . . . ."[39] However, "in practice, [neuritis] is also used to denote noninflammatory lesions in the peripheral nervous system."[40] Thus, although neuritis and neuropathy technically have different definitions, the medical community often interchanges neuritis for neuropathy.

Petitioner sent an e-mail to Aventis Pasteur explaining her symptoms and querying the company about whether the company had any knowledge of past reactions to their Td vaccinations similar to that experienced by Miss DeGrandchamp. Pet. Ex. 6. In response the company's Director, Scientific Affairs stated that "the types of symptoms [Miss DeGrandchamp] report[ed] experiencing following [her] vaccination with tetanus vaccine have been reported in the past, and this is contained in the package insert under adverse reactions." Pet. Ex. 8.

Although Dr. Herskovitz does not believe that Petitioner's symptoms fit into a category of neuropathy that can be induced by the tetanus vaccine, he does testify that neuropathies may result from the vaccine. Dr. Hogen provides the possible mechanism for such a reaction and the medical literature filed by Petitioner includes cases and studies concluding a link to the tetanus vaccine. Finally, the pharmaceutical manufacturer of the vaccine admits that Miss DeGrandchamp's symptoms have been reported in the past in relation to their Td vaccine. Thus, the Court finds that the Petitioner has demonstrated that peripheral neuropathy precipitated by tetanus toxoid is possible.

2. Did the tetanus toxoid in the Td vaccine cause an (a)anaphylactic shock (or anaphylaxis); (b) brachial neuritis; and, (c) peripheral neuropathy?

(a) Anaphylactic shock (or anaphylaxis)

Dr. Hogen testified that Petitioner "suffered a very severe, extremely symptomatic reaction to the vaccination." Trans. at 22. Dr. Hogen also testified that in his opinion Petitioner's symptoms immediately after receiving the Td vaccination did not meet a technical definition of anaphylaxis because the reaction " wasn't a catastrophic, life threatening, immediate need for medical care." *Id.* However, Dr. Hogen did agree that her symptoms could be called an anaphylactic reaction in the general way that physicians use the term. *Id*.

In order to receive compensation under the Vaccine Act, the injured party must suffer the residual effects or complications of the injury, in this case anaphylaxis, for more than six months, must die, or the injury must have resulted in inpatient hospitalization and surgical intervention.[41] Here, Miss DeGrandchamp thankfully did not die from her injuries nor did such result in hospitalization. Additionally, Petitioner's expert testified that the anaphylaxis is not the cause of Miss DeGrandchamp's on-going injury. Dr. Hogen stated that usually anaphylaxis is "self-limited" and that it was "the immune stimulation that caused [the sequela]." Trans. at 46-47. Thus, *arguendo*, even if Miss DeGrandchamp did meet the medical community's technical definition of anaphylaxis,

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[39] DORLAND'S *supra* at 1131.

[40] DORLAND'S *supra* at 1127.

[41] *See* 42 U.S.C.A. § 300aa-11(c)(1)(D) (West 2002).

the anaphylaxis did not, according to Petitioner's expert, result in residual effects or complications lasting for six months or more following the Td vaccination and, therefore, is not compensable under the Vaccine Act.

(b) Brachial Neuritis

The Court has found as a result of its own research that the onset of brachial neuritis is most often accompanied with severe shoulder pain. "Brachial neuritis usually is characterized by the acute onset of excruciating unilateral shoulder pain."[42] Also, the Vaccine Injury Table states that "[a] deep, steady, often severe aching pain in the shoulder and upper arm usually heralds onset of the brachial neuritis."[43] Nowhere in the contemporaneous medical records, the petition or in Miss DeGrandchamp's affidavit is there a description of severe or excruciating shoulder pain. Petitioner does state that approximately four months after the Td vaccination that the stiffness and pain she had been experiencing migrated to her shoulders. Pet. Ex. 20 at 112. However, Petitioner never describes the pain as severe or excruciating. Thus, the Court finds that it was more likely than not that Petitioner did not suffer the onset of brachial neuritis.

(c) Peripheral Neuropathy

Petitioner's medical expert, Dr. Hogen, proffers the following sequence of events leading to Miss DeGrandchamp's alleged injuries:

> [S]he had an antibody or immune response by her own body directed against her peripheral nervous system, amongst other things, which caused damage or disfunction to her peripheral nerves. . . . It [was] the body's own immune system attacking the peripheral nervous system. That is, the body's immune system would actually either infiltrate or directly attack with antibodies the peripheral nerves as they reside in the torso or arms or legs.

Trans. at 24, 26. An autoimmune response is a response of the immune system directed against one's own body.[44] In essence, it is an immune response that has misfired. Instead of attacking an intruder to the body, it attacks the body itself. Autoimmune responses can be triggered by an outside

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[42] Brachial neuritis (BN) is a rare syndrome of unknown etiology affecting mainly the lower motor neurons of the brachial plexus and/or individual nerves or nerve branches. BN usually is characterized by the *acute onset of excruciating unilateral shoulder pain*, followed by flaccid paralysis of shoulder and parascapular (near the shoulder blade) muscles several days later. The syndrome can vary greatly in presentation and nerve involvement. The pathophysiology is unknown, but the condition generally is thought to be an immune-mediated inflammatory reaction against nerve fibers of the brachial plexus. http://www.emedicine.com/pmr/topic58.htm (emphasis added).

[43] 42 C.F.R. § 100.3(b)(7).

[44] Noel R. Rose, M.D., Ph.D., *The Autoimmune Diseases: A Discussion of the Causes and Treatments of Autoimmune Diseases*, at http://www.aarda.org/article12.html. Dr. Rose is the Chairperson, American Autoimmune Related Diseases Association's (AARDA) Scientific Advisory Board; Professor of Pathology and of Molecular Microbiology and Immunology and Director of Autoimmune Research Center, The Johns Hopkins University.

agent, one of which can be a toxin.[45] Tetanus toxoid is a toxin. Thus, there is a reputable medical or scientific explanation supporting Dr. Hogen's proffered logical sequence of cause and effect.[46]

Petitioner's constellation of symptoms originated soon after her 24 November 2000 Td vaccination. The contemporary medical records are replete with symptomology of body ache, myalgia in the upper and lower extremities, decreased energy levels, generalized malaise, numbness, tingling, difficulty walking, burning, stiffness, etc. *See* Pet. Ex. 1 through Pet. Ex. 8. Although this temporal relationship is not dispositive, the Court does find it probative. Additionally, the doctors that Petitioner saw to diagnose her malady looked for other causes. Dr. Hogen testified that

> other physicians and in records that I reviewed . . . made a reasonable attempt to rule out any other cause of peripheral nerve disease that might be there. That included extensive laboratory testing, MRI scans of her head, determinations of B12 levels, at least a preliminary look for underlying auto-immune diseases, such as rheumatoid arthritis and lupus and other causes such as diabetes, toxic alcohol, ect. So, there was at least a -- what I thought was a reasonable first pass by many physicians to look for other causes of peripheral neuropathy that might be related to this.

Trans. at 43. Further, "[the other doctors] looked really hard for other things. They may not have looked exhaustively for other things, but they looked very hard, and they did not find it. *Id.* at 45-46. Again, eliminating other causes, while not dispositive, is probative.

While Dr. Hogen opined as Petitioner's expert he was also a treating physician of Miss DeGranchamp. Dr. Hogen testified that a face-to-face clinical evaluation is one of the most important tools in making a neurologic diagnosis:

> [I]t's a long-established principal in neurology that you have to have a face-to-face evaluation of the patient to be able to determine many different variables about what the patient is complaining of. Not the least of which are the veracity of her complaints, the validity of her complaints, the seriousness of her complaints, in addition to assessments about whether there could be any overlying or superimposed psychiatric conditions which she might have at the time, which might bear on the complaint. A lot of that is important in a face-to-face evaluation. It can only be determined there. . . . I think the clinical evaluation on the face-to-face basis is essential to making a correct evaluation in this particular case, but in general, in making evaluations of most neurologic cases.

Trans. at 17-18. Dr. Herskovitiz agreed that face-to-face evaluation of a patient is a very important part of neurology. *Id.* at 114-15. Dr. Herskovitz testified "there are plenty of times that the clinical features are more critical. You'll step back and even though you don't find

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[45] *Id.*

[46] Additionally, "peripheral neuropathy . . . can originate from numerous causes [including] . . . toxin exposure." Athena Diagnostics, *Diagnostic Education: Peripheral Neuropathy, located at* http://www.athenadiagnostics.com/site/ content/diagnostic_ed/neuro_disorders/peripheral_neuropathy.asp.

something on study, you'll say the clinical features nonetheless support and you go with that." *Id.* at 116.

Here, Dr. Hogen, as a treating physician, was able to make a face-to-face clinical evaluation of Miss DeGrandchamp. Dr. Herskovitz did not. Both agree that such an evaluation is very important with Dr. Herskovitz even testifying that clinical features can be more critical. *Id*.

In his 7 May 2002 medical expert's report, Dr. Herskovitz opined that the symptomology in the medical records was entirely subjective and "[n]o attempt was made to document objective abnormalities as in *nerve conduction studies*." Res. Ex. A at 2 (emphasis added). In response to Dr. Herskovitz's claim, Petitioner presented to Dr. Hogen for a nerve conduction study on 11 June 2002. Pet. Ex. 32. Dr. Hogen found that the findings of the nerve conduction study were "consistent with a mild moderate axonal neuropathy." *Id*. Dr. Herskovitz responded to the findings of the nerve conduction study with a supplemental report questioning the veracity of the study and suggested that another nerve conduction study be done at a "reliable, preferably academic setting." Res. Ex. D. Petitioner took Dr. Herskovitz up on his suggestion and presented to John D. Keesey, M.D. at the UCLA Department of Neurology EMG Laboratory for another nerve conduction study. Dr. Keesey stated that the results of that study's findings "are interpreted as indicating the presence of a sensory polyneuropathy in the left lower extremity." Pet. Ex. 40 at 149. In response to the UCLA study, Dr. Herskovitz, in a supplemental report, stated that "[a]t face value, we may have to accept, based on [Dr. Keesey's] report, that [Miss DeGrandchamp] may have a mild sensory peripheral neuropathy of the axonal type."Res. Ex. E at 1. Thus, an objective finding of neurologic abnormality that Dr. Herskovitz said was missing from the medical records now, by Dr. Herskovitz's own admission, is present.

Petitioner provides a medically plausible mechanism, an autoimmune response, for Miss DeGrandchamp's injuries. The onset of her maladies was temporal to the administration of the Td vaccine. The medical records indicate that doctors searched for other causes for Petitioner's symptoms but found none. Although both medical experts are eminently qualified, only Dr. Hogen, Petitioner's expert, performed a face-to-face evaluation of Miss DeGrandchamp. Finally, Dr. Herskovitz's concern that the medical records indicated only subjective findings was allayed by the objective findings of the two nerve conduction studies. Thus, the Court finds that Petitioner has proven by a preponderance of the evidence that the Td vaccine that she received on 24 November 2000 was more likely than not the cause of the peripheral neuropathy she suffers until this day.

IV. FURTHER PROCEEDINGS

For the reasons stated above, the Court finds that the Petitioner is entitled to an award under the Vaccine Act for the peripheral neuropathy she suffered as a result of the Td vaccination she received on 24 November 2000. The Court strongly encourages the parties to come to a meeting of the minds in determining the amount of the award. Thus, the Court requests Petitioner's counsel to initiate efforts in this regard. Petitioner's counsel is also requested to contact this Court to schedule a status conference.

IT IS SO ORDERED.

Richard B. Abell
Special Master