OFFICE OF SPECIAL MASTERS
No. 01-417V
August 4, 2006

| | | |
|---|---|---|
| ROSEANNE BORRERO, | * | |
| | * | |
| Petitioner, | * | |
| | * | |
| v. | * | Pre-existing MS developed |
| | * | over nine years; did hepatitis |
| SECRETARY OF THE DEPARTMENT OF | * | B vaccine in the fourth year |
| HEALTH AND HUMAN SERVICES, | * | significantly aggravate it? |
| | * | |
| Respondent. | * | |

**ORDER TO SHOW CAUSE**[1]

Petitioner filed a petition dated July 18, 2001, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that her first hepatitis B vaccine administered on March 26, 1999 significantly aggravated her pre-existing demyelinating disease, beginning with numbness in her hand four days later.

[1] Because this order contains a reasoned explanation for the special master's action in this case, the special master intends to post this order on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and move to delete such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

Petitioner is ORDERED TO SHOW CAUSE by September 22, 2006 why this case should not be dismissed.

**FACTS**

Petitioner was born on October 16, 1954.

On July 18, 1995, petitioner went to Royal Oaks Medical Center. Med. recs. at Ex. 2, p. 14. She had an auto accident on Sunday, July 16, 1995. *Id.* She had pain across the chest where the shoulder strap crossed. *Id.*

On July 24, 1995, petitioner filled out a patient history form for the Orthopedic Clinic of Titusville. Med. recs. at Ex. 3, p. 31. The onset of her pain was an auto accident. In answer to what activities made the pain worse, petitioner listed exercise/movement, rest, sitting, standing, walking, bending, and twisting. *Id.* For areas where she felt numbness and burning, she indicated both shoulders, her right hip, her right wrist, and her right leg. *Id.* For areas where she felt pins and needles and stabbing, she indicated her upper back, her right hip, and both hands. *Id.* She stated that her general health was "tired, discomfort, fatigued, soreness, stiffness, dizzy spells, sharp pain in hip." Med. recs. at Ex. 3, p. 32. She checked off that she had frequent or severe headaches, dizziness or fainting spells, chest pain, shortness of breath, swollen or painful joints, and depression or excessive worry. *Id.*

On September 11, 1995, petitioner saw Dr. Joseph E. Rojas. Med. recs. at Ex. 3, p. 3. She had been injured in an auto accident on July 16, 1995 and was seen at Royal Oak Medical Center. Her pain was over her shoulders, anteriorly and posteriorly. She had some tingling in her right hand. She had pain over her right hip area and lateral area with some clicking in it. Exercise, rest, sitting, standing, walking, bending, or twisting aggravated the pain. *Id.* Petitioner stated she had frequent

headaches, dizziness, chest pain, shortness of breath, swollen joints, and depression. *Id.* Petitioner had been having some weakness in the left hand and some pain developed. Med. recs. at Ex. 3, p. 4. On physical examination, petitioner was losing the use of her left hand and had difficulty with weakness in it. There was weakness of the interossei of the long finger flexors and of the thenar. The biceps and triceps were strong. This seemed to be something progressive. *Id.*

On October 12, 1995, petitioner saw Dr. Rojas. Med. recs. at Ex. 3, p. 1. Petitioner still had some problems with her right hip, but her neck felt better. *Id.*

On November 10, 1995, petitioner saw Dr. Rojas with continuing back pain. *Id.*

On February 3, 1997, petitioner saw Dr. Rojas with continuing neck, back, right hip, and shoulder pain. She had continuing nausea with headaches. *Id.*

On February 6, 1997, petitioner saw Dr. Roberto Mixco, a neurologist, complaining of headaches since she had been in an automobile accident on July 16, 1995. Med. recs. at Ex. 4, p. 5. Initially, she had pain in her neck with headaches and pain radiating to her shoulder. Over the prior several weeks, the headaches worsened in frequency and intensity. *Id.*

On February 8, 1997, petitioner had a brain MRI done. It was unremarkable. Med. recs. at Ex. 5, p. 7.

Also on February 8, 1997, petitioner had an MRI of her cervical spine. Med. recs. at Ex. 3, p. 22. Dr. J. Swalchick's impression was congenital central canal stenosis of a minimal degree, and mild cervical spondylitic changes at C5-C6 and C6-C7. *Id.*

On March 6, 1997, petitioner saw Dr. Mixco again. He reviewed an MRI of her brain, which was normal. A cervical MRI was slightly abnormal, suggesting congenital stenosis that was

minimal. There were also spondylitic changes mainly at C5-C6 and C6-C7. At C5-C6, petitioner had a small central disc protrusion with some osteophytes. Med. recs. at Ex. 4, p. 4.

On March 7, 1997, petitioner saw Dr. Rojas. She still had pain in her neck and some stiffness and tenderness. Med. recs. at Ex. 3, p. 2.

On April 23, 1997, petitioner saw Dr. Rojas. She still had shoulder spasms. Med. recs. at Ex. 3, p. 6.

On May 21, 1997, petitioner saw Dr. Rojas. She had severe pain in her neck the day before. *Id.*

On August 10, 1997, petitioner went to Royal Oaks Medical Center, having fallen in the shower, traumatizing her left arm. Med. recs. at Ex. 2, p. 13. She had multiple contusions. *Id.*

On November 10, 1997, petitioner saw Dr. Rojas. Med. recs. at Ex. 3, p. 5. She was still having some spasms and problems with pain. Med. recs. at Ex. 3, p. 5.

On November 11, 1997, petitioner went to Royal Oaks Medical Center, complaining of tingling in her fingers and pain in her forearm. She had a positive Tinel's sign.[2] She also noted weight gain and fluid retention. Med. recs. at Ex. 2, p. 12. She was diagnosed with carpal tunnel syndrome, obesity, fluid retention, and left shoulder pain. *Id.*

On December 8, 1997, petitioner saw Dr. Rojas. Her left shoulder was much better. She had some limitation in abduction of the left shoulder. Med. recs. at Ex. 3, p. 5.

On December 12, 1998, petitioner went to Royal Oaks Medical Center, complaining of tingling in her leg since November, and a twisted neck. Med. recs. at Ex. 2, p. 11.

---

[2] Tinel's sign is "a tingling sensation in the distal end of a limb when percussion is made over the site of a divided nerve. It indicates a partial lesion or the beginning regeneration of a nerve." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1703.

On December 27, 1998, petitioner saw Dr. Robert Bartemus. She complained of tingling and slight weakness in the right leg ongoing for some time, radiating down to approximately knee level posteriorly and some anterior irritation as well. Med. recs. at Ex. 2, p. 10. The discomfort appeared to originate from her low back area, right side. This had been a recurring problem since twisting her neck in November. She stated her neck felt fine, but she had some low back muscle spasm, trouble moving around with sitting for a period creating the discomfort in her right leg. She now felt it also crept over the medial portion of the upper portion of the left lower extremity as well. The leg was not specifically weak, however. *Id.* Dr. Bartemus' impression was acute low back pain, right-sided, with sciatica and no specific neurological dysfunction in the right lower extremity. *Id.*

On December 31, 1998, petitioner went to Royal Oak Medical Center, complaining of having difficulty moving her right leg. Med. recs. at Ex. 2, p. 9. Dr. Bartemus saw petitioner. Her lower back had improved somewhat with manipulation since he last saw her. She continued to notice unsteadiness in the right leg. She weighed 218 pounds, which possibly contributed to the current complaint. She felt a loss of sensory function on the anterior thighs even down to the posterior calf area, right greater than left, for the past four weeks. She had no particular weakness in the left leg. *Id.* On physical examination, petitioner had difficulty standing from a sitting position and used her hands for assistance. She was slightly unsteady on her feet, but showed no cerebellar signs. No weakness was noted on flexion or extension of the lower extremities. She had good quadriceps tone and no atrophy. Her deep tendon reflexes (DTRs) were hypoactive in the patella area and in the Achilles tendon area. *Id.*

On January 19, 1999, petitioner saw Dr. Len Van Eaton for back pain which was dull and aching. She had severe intensity of symptoms. Pain was in the right lumbar area with radiation to

the right ankle. Associated neurological symptoms included positive right leg weakness, and whole leg numbness. Med. recs. at Ex. 2, p. 7. Any kind of movement aggravated the pain which was getting worse. On examination, petitioner had decreased range of motion. Her strength and tone were normal. Dr. Van Eaton diagnosed lumbosacral strain/sprain and low back pain and sciatica. *Id.*

On March 26, 1999, petitioner received her first hepatitis B vaccination. Med. recs. at Ex. 1, p. 10.

On April 12, 1999, petitioner saw Dr. Miguel Rivera Rivera, a neurologist, complaining of tingling involving both legs, numbness and weakness of her left arm and unusual abdominal muscle contractions. Med. recs. at Ex. 4, p. 2. She stated she first had problems with her legs around November 19, 1998. These problems were weakness, and persistent burning sensations in both feet and both legs distally. The problems with her left arm began on March 30, 1999. She initially experienced numbness in the tips of the fingers of her left hand which later radiated upward. She also had skin hypersensitivity and tingling involving the entire left upper extremity. More recently, she experienced weakness and lack of coordination of the left arm. She could not control her left arm when she combed her hair. *Id.*

On physical examination, there was no atrophy, abnormal movement, fibrillation, or fasciculation. There was weakness of the left arm and a significantly weak grip. Her left hand exhibited hypertension and involuntary, irregular movements of her fingers both in flexion and extension. Astereognosis[3] was present in the left hand. Med. recs. at Ex. 4, p. 3. DTRs were brisk and present in the right upper extremity, hyperactive in the left biceps and triceps, and absent in the

[3] Astereognosis is "loss or lack of the ability to understand the form and nature of objects that are touched...." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 167.

left lower extremity and right ankle. Hoffman's sign[4] was present on the left and there was a transient upgoing toe on each foot. *Id.* Sensation was decreased bilaterally in both lower extremities distally with some degree of dissociation of deep and superficial sensation. Petitioner had ataxia on finger to nose and heel to shin on the left, particularly finger to nose. Dysmetria[5] was also present on the left. Petitioner could not perform alternating movements with her left hand. *Id.* Dr. Rivera Rivera's impression was a possible low intracranial lesion or a high spinal cord lesion. *Id.*

On April 14, 1999, petitioner had an MRI of her brain done. It showed mild supratentorial atrophy but was otherwise unremarkable. Med. recs. at Ex. 5, p. 5.

Also on April 14, 1999, petitioner had an MRI of her cervical spine done which Dr. Catherine L. Gardner stated showed a 22 x 10 x 8 mm enhancing central to left lateral cervical cord mass which developed since a prior MRI of the cervical spine done February 8, 1997. This could be a cord astrocytoma or glioma. Med. recs. at Ex. 5, p. 6.

On April 15, 1999, petitioner saw Dr. Rivera. They discussed her MRIs. The MRI of the brain was unremarkable. Med. recs. at Ex. 4, p. 1. The MRI of the cervical spine showed the presence of a 22 x 10 x 8 mm enhancing central to left lateral cervical cord mass which has developed since the prior MRI scan of Feb.8, 1997. Possible diagnoses were cord astrocytoma and/or glioma. Cystic changes were present. The region of enhancement was associated with focal cord enlargement. Objectively, her neurological examination was unchanged. *Id.*

---

[4] In Hoffman's sign, "a sudden nipping of the nail of the index, middle, or ring finger will produce flexion of the terminal phalanx of the thumb and of the second and third phalanges of some other finger...." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1699.

[5] Dysmetria is "a condition in which there is improper estimation of distance in muscular acts, with disturbance of the power to control the range of muscular movements, often resulting in overreaching." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 575.

On April 21, 1999, petitioner saw Dr. Barth A. Green, a neurosurgeon. Med. recs. at Ex. 5, p. 11. She had neck and left upper extremity paresthesias in March 1999. Her first symptoms occurred in November 1998 when she twisted her neck and had pain. She also had it the next day and felt tightening of her legs around her knee caps. In March 1999, she had tingling of her fingertips and left hand which gradually progressed to mild clumsiness which progressed over the last two weeks. An MRI showed a mass in the left side of the cervical cord from C2-C4. She now complained of numbness in her left hand extending up her arm into the left axilla and down her whole left hemibody. She had bilateral numbness in her legs to her feet. Her fingertips became weak that week. She reported increased impairment of her hand dexterity, inability to write and hold a pen, and difficulty dressing herself. She had progressive left upper extremity weakness and numbness. She noticed increased tightness in the legs, thighs, and knee caps. She had no leg pain. She had an electrical shock-type pain in her anterior axillary area, radiating to the scapula. She had a banding tightness over her left breast and below the breast bilaterally, left more than right. She had loss of balance and a tendency to run into things. Occasionally, she was dizzy when standing up. *Id.*

Petitioner had headache due to post-concussion secondary to her auto accident in 1997. [Petitioner's auto accident occurred in 1995.] The headaches were occipital to the forehead and better with therapy and magnets. Med. recs. at Ex. 5, p. 12. On examination, her cerebral, cerebellar, and cranial nerve examinations were normal, except for some flattening of her left nasal labial fold with some decreased rapid fine movements and rapid alternative movements in the left hand. She had a lag on the left on arm roll and pronator drift. She had atrophy of her left forearm about 3/4 inch smaller than the right. She had numbness down the whole left side of her body from the chin down, numbness in both thighs and on the left side anteriorly and posteriorly. She had

numbness in both feet and ankles and in a stocking-glove distribution in both hands. She had mainly numbness in all sensory modalities and less so to the dorsal column than the right; bad proprioceptive problems and vibratory compromise of the left upper extremity. Her reflexes were hyperactive in the left upper extremity compared to the right. She had a slight increase in her ankle jerk on the left compared to the right. She had a positive Romberg.[6] She had tenderness in the left medial scapular area with fairly good range of motion of her head and neck. *Id.*

Petitioner's x-rays were not remarkable. Med. recs. at Ex. 5, p. 13. Her MRI of the brain and cervical spine from 1997 were not remarkable. The MRI of the brain from 1999 has some slight increased signal, but that might be artifact. The cervical MRI showed a lesion in the left side of the cord at C2, C3, and C4, centered at C3. The differential diagnosis would be inflammatory (such as MS) versus tumor (such as astrocytoma). *Id.*

On April 26, 1999, petitioner received her second hepatitis B vaccination. Med. recs. at Ex. 1, p. 10.

On April 28, 1999, petitioner saw Dr. Van Eaton for presurgical evaluation. She had a history of weakness. A diagnosis of cervical spinal cord tumor was made. Med. recs. at Ex. 2, p. 2.

On May 3, 1999, Dr. Green had an MRI conference. Med. recs. at Ex. 5, p. 10. Petitioner's MRI showed a large herniated disc at C2-C3 compressing the cord on the right. At C3 was a large intramedullary mass which enhanced with gadolinium and was bright on T2. The differential diagnosis was tumor such as astrocytoma versus inflammatory lesions. So far, the workup for MS was negative, including electrophysioloy, brain MRI, and CSF analysis. The somatosensory evoked

---

[6] Romberg's sign is a "swaying of the body or falling when standing with the feet close together and the eyes closed; the result of loss of joint position sense...." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1702.

potentials (SSEP) were abnormal. The brainstem and visual evoked potentials (VEP) were normal. *Id.*

On May 6, 1999, Dr. Green performed a partial laminectomy of the C2 and C4 and a toal laminectomy of C3 on petitioner. Med. recs. at Ex. 6, p. 45.

On May 19, 1999, Dr. Carol K. Petito wrote a pathology report that there was no tumor. The biopsy suggested a demyelinating lesion. Med. recs. at Ex. 16, p. 4. (The pages in P. Exs. 14-22 are unnumbered; the undersigned numbered the pages herself and expects counsel to do the same for their copies.) In an addendum, Dr. Petito notes that myelin and axon stains showed demyelination with loss of myelin and preservation of axons. Med. recs. at Ex. 16, p. 5.

On May 21, 1999, Dr. Green noted that the final pathology result was demyelinating disease, MS. Med. recs. at Ex. 5, p. 9.

On June 28, 1999, petitioner saw Dr. Thomas G. Hoffman for follow-up of cervical myelopathy. Med. recs. at Ex. 7, p. 7. Petitioner developed some symptoms of leg numbness in November 1998 followed by some left-handed weakness in April 1999. She related the onset of her left-handed weakness to hepatitis B vaccine. Since April, she has had not only left-handed weakness and numbness, but also some numbness over the entire left side of her body and a tight feeling around her chest and underneath her breasts. *Id.*

She underwent partial laminectomy and exploration of myelotomy on May 6, 1999. Pathology revealed no evidence of tumor. MRI of the brain spinal fluid exam, visual brainstem, and somatosensory evoked potential tests were all negative. Since the surgery, petitioner had been stable, bothered mostly by symptoms of tightness in her legs and chest, numbness on the left side, and profound numbness and incoordination with some swelling in the left hand. *Id.*

On physical examination, petitioner had good strength in her extremities. Rapid alternating movements were impaired in the left hand. The legs had minimal increased tone. Left arm reflexes were slightly hyperactive. There was some subjective sensory loss over the left side of her body. There was profound position sense loss in the left hand up to the shoulder. She had no visual symptoms and no problem with bladder or bowel. *Id.* Dr. Hoffman's impression was cervical myelopathy, etiology uncertain. *Id.*

On August 10, 1999, petitioner saw Dr. Hoffman for follow-up. Petitioner had completed physical therapy paid for by insurance and wanted to continue paying for herself. Her left hand function was improving slowly. She was able to walk three miles to school and back with her daughter on August 9, 1999. Med. recs. at Ex. 7, p. 5. She continued to have weakness in the left shoulder and some paresthesias and itching in the left upper chest and shoulder region. Dr. Hoffman told petitioner he could not differentiate whether she had an exacerbation of MS or a single mild temporal illness such as cervical myelitis. On examination, she had minimal spasticity in her legs, mild hyperreflexia in the left arm, and some mild left-sided subjective sensory loss. *Id.*

On September 26, 1999, petitioner received her third hepatitis B vaccination. Med. recs. at Ex. 1, p. 10.

On September 27, 1999, petitioner returned to Dr. Hoffman. Med. recs. at Ex. 7, p. 1. She complained of tightness as if she were wearing a girdle. The left side still felt numb and swollen and she still had difficulty using the left hand with fine coordination. She had difficulty using a computer keyboard because of this. Sometimes, when she moved her neck, she felt it crunching. She had a mild left pronator drift and moderate slowing and impairment of fine coordination in the left hand. She walked fairly well independently but had significant increased tone in both legs. *Id.*

On November 15, 1999, petitioner saw Dr. F. Expinoza at Titusville Family Practice for a referral to neurology. She had severe spasticity and severe hyperreflexia in her left upper extremity. Med. recs. at Ex. 8, p. 1.

On November 22, 1999, Dr. Wasim Niazi, a neurologist, wrote that petitioner had normal distal motor latencies, normal CMAP (compound muscle action potential) amplitudes, and motor conduction velocities in the left median nerves and both ulnar nerves. Med. recs. at Ex. 8, p. 2. Petitioner had normal F wave latencies in the left median and both ulnar nerves. She had normal SNAPs (sensory nerve action potentials) and NAPs (nerve action potentials) amplitudes and sensory conduction velocities in the left median nerves and in both ulnar nerves. *Id.* Petitioner had normal needle EMG (electromyography) of the muscles of the left upper extremity including median innervated muscles and right first dorsal interosseous. Dr. Niazi's impression was that petitioner's study was normal. "There is no evidence of left cervical radiculopathy, brachial plexopathy, or ulnar or median neuropathy in the left extremity." *Id.*

Dr. Niazi wrote a longer report on November 22, 1999. Med. recs. at Ex. 9, p. 3. Petitioner was seen for evaluation of loss of motor skills associated with atrophy of the muscles, paresthesias, burning pains and swelling of the left upper extremity of eight months duration. There was numbness and tingling involving the inner three fingers on the right side and pain and stiffness on both sides of the neck. *Id.* Petitioner reported that, in March 1999, she was at work and attempted to pick up a bottle of water which dropped from her hand. A few days later, she was unable to put her hand in a latex glove because her fingers would not stop moving. She saw Dr. Rojas who referred her to Dr. Rivera. She underwent laminectomy of C2-C4 on May 6, 1999. Unless she concentrated, she could not control the motor skills in her left hand. She could not wash her hair, wash dishes,

cook without help, iron, dress herself, or tie her shoelaces. She had a constant burning sensation in the posterior aspect of the forearm and hand. She had pressure in the tips of all fingers. She had constant swelling in the entire hand. She experienced numbness and tingling, particularly at night, that often interfered with sleep. She was unable to hang the arm or hand over the bed.. She also felt that the hand, fingers, and muscles of the forearm were shrinking and her left hand fingernails had curved markedly during the last two months. She gained significant weight on Prednisone for four months. *Id.*

Petitioner stated that two months before the onset of these symptoms (presumably January 1999), she experienced tightness throughout both legs associated with a feeling of sand on the soles of her feet. These symptoms of numbness, tingling, and stiffness remain unchanged. She also reported numbness and tingling in the inner three fingers of her right hand. She reported no new events during the last seven months. Dr. Hoffman saw her in June 1999. She reported marked stiffness involving both sides of the cervical region. She does not report problems with vision, speech, or swallowing. *Id.*

On physical examination, petitioner had appropriate strength in all four extremities except marked spasticity and loss of dexterity involving the left hand with almost complete inability to open the hand after closure except manually with the other hand. There was no pronator drift. Muscle bulk was normal with suggestion of spasticity in the lower extremities, more on the left than on the right side. There were no abnormal movements. Med. recs. at Ex. 8, p. 5.

Her DTRs were 1-2+ in the brachioradialis, 1-2+ in the biceps, 2+ in the triceps bilaterally, 2+ in the knee jerks, 1-2+ in the ankle jerks bilaterally. She did not have Hoffman's or Babinski's sign and there was no ankle clonus. *Id.* Touch, pinprick, proprioception, and vibratory sense was

intact throughout. Double simultaneous stimulation was intact. There was no sensory level in the trunk. She was able to perform tip-toe and heel walking and her gait was normal. The range of motion of her neck was somewhat limited. There were some spasms of the paraspinal muscles. Her range of motion was normal in all joints. Her lumbar spine had normal range of motion. *Id.* A biopsy report of the cervical lesion dated May 19, 1999 was reviewed: it was a demyelinating lesion. *Id.*

Dr. Niazi's impression was TM, manifesting as left-sided sensory motor manifestation, monophasic disease versus polyphasic demyelinating disease, with no clinical evidence of progression during the last six months. Med. recs. at Ex. 8, p. 6. Other diagnoses were symptomatology suggestive of right ulnar neuropathy, and bilateral cervical stiffness and pain most likely related to cervical spondylosis. *Id.*

On December 28, 1999, petitioner returned to Dr. Niazi, complaining that the tightness around her chest had gotten worse and she had associated pain in the bend, pain in the left forearm and hand, and a worsened gait (although she walked unaided). Med. recs. at Ex. 9, p. 5. A report of petitioner's MRI done December 1, 1999 showed nonspecific foci of deep white matter T2 hyperintensity. One of the right frontal deep white matter areas of T2 hyperintensity was new compared to a prior examination. This was worrisome, given the prominent spinal cord lesion previously, because of white matter disease with lesions evolving in space and time, such as MS. Med. recs. at Ex. 9, p. 6.

On January 26, 2000, petitioner saw Dr. Niazi. Med. recs. at Ex. 9, p. 7. Since petitioner had been on Neurontin, she has about 50% improvement in her painful symptoms and can do things she could not do before. She still had problems with intermittent tightness around the chest and trunk

associated with pain in the bend. There was pain in the left forearm and hand as well as pressure feeling in the fingers and arms. She still felt spasticity in the legs. *Id.*

On May 23, 2001, petitioner saw Dr. Niazi. Med. recs. at Ex. 14, p. 7. Petitioner still had pains and spasms in the upper and lower extremities, mostly in the right leg from the knee down. She felt heat, cold, and lack of feeling in the left arm. Her marked spasms in the muscles of the extremities were worse at night. She had no problem with bladder or bowel control. She reported some blurring of vision. *Id.*

On June 26, 2001, petitioner had a brain MRI done which was normal except for subtle white matter lesions in the frontal lobes that appeared non-specific. Med. recs. at Ex. 19, p. 1.

On July 5, 2001, petitioner took a visual evoked response test which Dr. Niazi said was normal. Med. recs. at Ex. 14, p. 13. Also on July 5, 2001, petitioner took a somatosensory evoked response test, which Dr. Niazi found abnormal, suggesting dysfunction involving the dorsal column associated to central sensory pathways. Med. recs. at Ex. 14, p. 14.

On July 25, 2001, petitioner saw Dr. Niazi. Med. recs. at Ex. 14, p. 5. She remained bothered by tightness from the neck down with bend at the waist. She had problems swallowing without any epigastric burning sensation. Her fingers had spasms, causing anxiety when they were severe. She had stress, anxiety, and impaired sleep. *Id.*

On October 25, 2001, petitioner saw Dr. Niazi. Med. recs. at Ex. 14, p. 3. She reported she had gained 12 pounds. Her muscles felt tighter than ever though she did not have as many spasm attacks as previously. She had difficulty maintaining balance for long periods of time. *Id.* On December 6, 2001, petitioner saw Dr. Niazi. Med. recs. at Ex. 14, p. 1. Petitioner complained of aching pains in the extremities that worsened since last seen October 25, 2001. She had leg pains

primarily in the areas above the knees. *Id.* There was no hyperreflexia in the lower extremities and the spasticity in the left leg was better. Med. recs. at Ex. 14, p. 2.

On June 26, 2002, petitioner had an MRI done of her cervical spine, which Dr. Niazi interpreted as showing signal changes in the mid-portion of the cervical spinal cord consistent with old TM and spinal cord biopsy without suggestion of recurrent or acute myelitis; cervical spondylosis with multi-level disc disease and protrusions at C4-C5 and C5-C6; and evidence of previous laminectomy in upper cervical region. Med. recs. at Ex. 23, p. 3. She had recent worsening of her symptoms in consideration of a reoccurrence of cervical myelopathy. *Id.*

On November 12, 2002, petitioner saw Dr. Niazi, complaining that her gait had worsened as well as the spasticity of her lower extremities. Med. recs. at Ex. 23, p. 1. It took her ten minutes to exit a car. She could not wear closed shoes. *Id.*

On June 24, 2004, petitioner saw Dr. Niazi. Med. recs. at Ex. 26, p. 7. She complained her gait had worsened as well as her lower extremities spasticity. She cannot walk any distance because of leg tightening. She had gained 20 pounds. Her headaches, fatigue, neck pain, and head heaviness had worsened. *Id.*

On July 1, 2004, petitioner underwent a brain MRI which Dr. Niazi interpreted. Med. recs. at Ex. 26, p. 13. She had signal changes involving the corpus callosum and periventricular white matter suggestive of MS. The study showed interval development of white matter disease compared to the MRI done June 26, 2001. *Id.*

On July 21, 2004, petitioner saw Dr. Niazi, with worsened pain, vision, and spasticity. Med. recs. at Ex. 26, p. 4. She had moderate asymmetrical spasticity in the lower extremities. Her gait was stable. Med. recs. at Ex. 26, p. 5.

On August 4, 2004, petitioner had a median somatosensory evoked response test, which Dr. Niazi interpreted as being abnormal because of depressed amplitudes of N20 bilaterally, more on the left than on the right, suggesting dysfunction of the median nerve associated with central sensory pathways. Med. recs. at Ex. 26, p. 12. An auditory evoked potential test on the same date was normal. Med. recs. at Ex. 26, p. 11.

Also on August 4, 2004, petitioner underwent a tibial somatosensory evoked response test which Dr. Niazi interpreted as showing prolongation of P37 bilaterally. This suggested either primary demyelinating disease or L5-S1 radiculopathy. Med. recs. at Ex. 26, p. 10. Also on the same date, petitioner had a visual evoked response which showed mild prolongation of the P100 bilaterally, suggesting a dysfunction of the optic nerve associated pathways as may be seen in association with a primary demyelinating disorder. Med. recs. at Ex. 26, p. 9.

On September 29, 2004, petitioner saw Dr. Niazi with continued pain and spasticity with episodes of shortness of breath. Med. recs. at Ex. 26, p. 1.

**DISCUSSION**

This is a causation in fact case. To satisfy her burden of proving causation in fact, petitioner must offer "(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). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

> A persuasive medical theory is demonstrated by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]" the logical

> sequence being supported by "reputable medical or scientific explanation[,]" *i.e.*, "evidence in the form of scientific studies or expert medical testimony[.]"

In Capizzano v. Secretary of HHS, 440 F.3d 1274, 1325 (Fed. Cir. 2006), the Federal Circuit said "we conclude that requiring either epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect is contrary to what we said in Althen...."

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, at 1149. Mere temporal association is not sufficient to prove causation in fact. Hasler v. US, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984).

Petitioner must show not only that but for the vaccine, she would not have had significant aggravation of her pre-existing MS, but also that the vaccine was a substantial factor in bringing about significant aggravation of her pre-existing MS. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

The Vaccine Act defines "significant aggravation" as follow:

> The term "significant aggravation" means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.

42 U.S.C. §300aa-33(4).

In Stevens v. Secretary of HHS, No. 99-594V, 2006 WL 659525 (Fed. Cl. Spec. Mstr. Feb. 24, 2006), the undersigned ruled that hepatitis B vaccine can cause TM and did so in that case. The onset intervals after Ms. Stevens' two hepatitis B vaccinations were eight and nine days, appropriate

temporal periods for an immune reaction. Respondent's expert, Dr. Roland Martin, testified that the appropriate onset interval, if a vaccination were to cause an acute reaction, would be a few days to three to four weeks. *Id.* at *18.

In Werderitsh v. Secretary of HHS, No. 99-310V, 2006 WL 1672884 (Fed. Cl. Spec. Mstr. May 26, 2006), the undersigned ruled that hepatitis B vaccine can cause MS and did so in that case. Onset of visual difficulties was a few days to one week post-vaccination.

In the instant action, petitioner was initially (perhaps one should say eventually) diagnosed with TM and, as her demyelinating condition progressed and she developed lesions in the brain and visual difficulties, with MS. This process took nine years, from 1995 to 2004.

It is practically impossible to pinpoint one time that petitioner experienced a significant aggravation of petitioner's pre-existing MS. Instead, one sees a progression of worsening symptoms. Her symptomatology was clearly neurologic in September 1995, four and one-half years before her first hepatitis B vaccination, when she complained of losing the use of her left hand and having difficulty with weakness in it. There was weakness of the interossei of the long finger flexors and of the thenar. Her doctor viewed this as something progressive, occurring two months after an automobile accident. During the rest of that year and the nine subsequent years (the latest medical records petitioner filed are dated 2004), petitioner had bouts of pain, weakness, numbness, tingling, burning, reflex changes, and sensory changes in her legs, arms, and back, as well as headaches and visual disturbances, leading ultimately to a diagnosis of MS.

Petitioner had three hepatitis B vaccinations, and even though a complaint of left-handed numbness four days after her first hepatitis B vaccination is a proper medical time frame for some

effect from the vaccine, the fact is that she was losing use of her left hand (just as on March 30, 1999) and complaining of weakness in the left hand in September 1995.

Petitioner needs to prove that her gradually worsening neurologic condition, which began in 1995, was significantly aggravated by hepatitis B vaccine in 1999, so that the vaccine is responsible for petitioner's markedly greater disability, pain, or illness accompanied by substantial deterioration of health over the nine years from 1995 to 2004.

Petitioner must file an expert report by **September 22, 2006** or this case will be dismissed. Petitioner is ORDERED TO SHOW CAUSE why this case should not be dismissed by **September 22, 2006**.

**IT IS SO ORDERED.**

_____ _____

DATE Laura D. Millman
Special Master