OFFICE OF SPECIAL MASTERS
No. 00-782V
July 28, 2006

ELAINE MONACO,	*	
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Petitioner,	*	
	*	
v.	*	Hepatitis B vaccination followed by TM three months later; not appropriate temporal time frame
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SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

ORDER TO SHOW CAUSE[1]

Petitioner filed a petition dated December 26, 2000, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., on her own behalf, alleging that hepatitis B vaccine administered on December 15, 1998 caused her unspecified injury. In an amended petition, filed April 2, 2001, petitioner alleges that her injury was an autoimmune disorder. In P. Ex. 20, ¶ 1, petitioner's affidavit, dated December 14, 2000, petitioner alleges that hepatitis B

[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.

vaccine caused her transverse myelitis (TM). She also states, at ¶ 7, that she has been told she has sarcoidosis, Guillain-Barré Syndrome (GBS), vasculitis, and multiple sclerosis (MS). In ¶ 8, she states she now has chronic fatigue syndrome (CFS), and, in ¶ 11, that she has chronic uveitis directly related to her TM.

Petitioner is ORDERED TO SHOW CAUSE by September 15, 2006 why this case should not be dismissed.

FACTS

Petitioner was born on April 8, 1944.

Petitioner saw Dr. Kim King on April 11, 1994, complaining of back pain. Med. recs. at Ex. 18, p. 5.

Petitioner saw Dr. King on February 14, 1995, complaining of neck and back pain. *Id.*

She had her first hepatitis B vaccination on October 27, 1998. Med. recs. at Ex. 1, p. 2. She had her second hepatitis B vaccination on December 15, 1998. *Id.*

Over two months later, on February 26, 1999, petitioner (under the name Elaine Stroud), was attempting to guide an autistic student by walking with him and redirecting him, when he stepped on her foot, causing her to lose her balance and fall on her tailbone. On February 26, 1999, Dr. Stephen Gilliland took a history from petitioner. She had pain in her lower back along her tailbone since the incident. She stated that she had generally been in good health. She had a back strain at age 17 which resolved. She stated she had no other job-related injuries and had not had any problems with her back. Med. recs. at Ex. 2, p. 1.

On physical examination, Dr. Gilliland noted that petitioner had exquisite tenderness over the sacrum extending to the mid-coccyx. Her deep tendon reflexes (DTRs) in her lower

extremities were 2+ symmetrically and her straight leg raise was negative bilaterally. Tactile sensation in the lower extremities was intact. *Id.* X-rays of the lumbar spine and coccyx revealed some spondylolisthesis[2] of the L3 on L4 with marked degenerative disc disease at that level. There was some lateral shifting of the spine and some osteophyte[3] formation. There were some scattered arthritic changes in the lumbar area. Dr. Gilliland's diagnosis was contusion of sacrum with associated lumbar and sacral strains. *Id.* He prescribed Ibuprofen. *Id.*

On March 5, 1999, petitioner returned to Dr. Gilliland, having had three physical therapy treatments, but still having pain in her lower back and now complaining of neck discomfort and pain when she attempted to turn her head. She also stated she had been having some headaches. Med. recs. at Ex. 2, p. 3.

On examination, petitioner was not in acute distress. She could flex the lumbar spine to 55 degrees and extend to 15 degrees. X-ray reports revealed some chronic degenerative interspace narrowing at the L3-L4 level with hypertrophic end plate spurring and sclerosis, as well as the anterior and leftward listhesis of L3 relative to L4 with some suspect right-sided pars interarticularis[4] defect. Petitioner also had some degenerative changes of the lower lumbar

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[2] Spondylolisthesis is the "forward displacement (olisthy) of one vertebra over another, usually of the fifth lumbar over the body of the sacrum, or the fourth lumbar over the fifth, usually due to a developmental defect in the pars interarticularis." Degenerative spondylolisthesis is "that caused by long-standing instability due to progressive degeneration of the spinal joints, usually accompanied by rotation of the affected disk." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1743.

[3] An osteophyte is "a bony excrescence or osseous outgrowth." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1336.

[4] Pars interarticularis is "the part of the lamina between the superior and inferior articular processes of a lumbar vertebra." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1375.

facets.[5] Dr. Gilliland's diagnosis was contusion of sacrum with lumbar and sacral strain, with limited improvement to date. *Id.* He prescribed Ibuprofen and an ice pack. *Id.*

On March 10, 1999, petitioner saw Dr. Gilliland again. She stated she had been having slow, but steady, progress. She complained about her lower back and tailbone, and right shoulder strain. On examination, her DTRs in the lower extremities were 2+ symmetrically and straight leg raise remained negative bilaterally. Neurological examination in the lower extremities remained within normal limits. Range of motion in the right shoulder was full. Her entire right upper extremity was neurologically normal, including motor function and tactile sensation. Med. recs. at Ex. 2, p. 5. Dr. Gilliland's diagnosis was multiple contusions and strains with remaining active problems of lumbar strain and contusion of sacrum. *Id.* He prescribed Ibuprofen and physical therapy. *Id.*

On March 22, 1999, petitioner saw Dr. Gilliland again. She stated she was ready to return to work. On physical examination, she had no palpable spasm in her lumbar area and the tenderness in the sacrum had resolved. She had full range of motion in the lumbar spine. Tactile sensation and motor function in the lower extremities were fully intact bilaterally. DTRs were 2+ symmetrically and the straight leg raise was negative bilaterally. Dr. Gilliland's diagnosis was contusion of sacrum with associated lumbar sprain which had resolved. Med. recs. at Ex. 2, p. 7. She could return to work on the next day without restrictions. *Id.*

On April 2, 1999, petitioner returned to Dr. Gilliland, complaining of developing a burning sensation along with associated numbness in her left hip extending downward into her

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[5] A facet is "a small plane surface on a hard body, as on a bone." Dorland's Illustrated Medical Dictionary, 30th ed (2003) at 663.

leg. On physical examination, she had very pronounced tenderness over the sciatic notch and extending downward across the buttocks. She had a positive stretch test regarding the left sciatic nerve. DTRs remained 2+ symmetrically in the lower extremities. She had some remaining tenderness to palpation over the sacrum. Dr. Gilliland's diagnosis was contusion of sacrum with lumbar strain and symptoms and signs consistent with residual left sciatica. Med. recs. at Ex. 2, p. 8. He prescribed a short course of additional physical therapy and Ibuprofen and Flexeril. *Id.* She could return to work. *Id.*

On April 7, 1999, petitioner returned to Dr. Gilliland. Med. recs. at Ex. 2, p. 10. She stated she had no significant change in her pain which she described as a burning sensation in the left low back and hip area extending down the left leg. She had been exercising and doing physical therapy a total of eight times. *Id.* On physical examination, she still had limited range of motion in the lumbar spine which decreased since her prior visit. There was no significant ongoing spasm in the lumbar area, but she had persistent tenderness over the left sciatic notch extending down the buttocks to the proximal calf. *Id.* Range of motion in the left hip was full. DTRs were 2+ symmetrically in the lower extremities and straight leg raise remained negative bilaterally. Tactile sensation in the left lower extremity was grossly intact. *Id.* Dr. Gilliland diagnosed contusion of the sacrum with lumbar strain and residual sciatica which had plateaued. *Id.* He decided to discontinue physical therapy and have petitioner continue her home exercise program. He would refer her to an orthopedic surgeon because of her ongoing left lower leg radicular symptomatology versus classic sciatica. *Id.*

On April 8, 1999, petitioner had an MRI of her lumbar spine. Med. recs. at Ex. 12, p. 7. Dr. Michael A. Pollack wrote that she had bilateral L3 spondylolysis with a 10 mm L3-L4

anterolisthesis as well as a right lateral subluxation. There was also disc narrowing and spondylosis resulting in foraminal stenosis which was worse on the right because of the concavity of a scoliotic curve. The right foraminal stenosis was severe and could be compressing the right L3 nerve. She had mild diffuse annular bulging at L1-L2 and L4-L5. She had mild lumbar levoscoliosis. There was a transitional lumbosacral vertebra which was designated as a partially sacralized L5 with hypoplastic, asymmetric L5-S1 facets. Med. recs. at Ex. 12, p. 8.

On April 12, 1999, petitioner saw Dr. Gilliland to discuss her MRI findings. She had no significant change in her condition. Med. recs. at Ex. 2, p. 12. She stated she had numbness and aching in her back with intermittent radiating pain into the legs primarily on the left side. *Id.* On physical examination, she had normal range of motion in her back. Her DTRs were unchanged at 2+ symmetrically in the lower extremities and tactile sensation was intact. *Id.* Dr. Pollack performed the lumbar MRI on April 8, 1999, which showed disc narrowing and spondylosis resulting in foraminal stenosis which was worse on the right because of concavity of petitioner's scoliotic curve. This resulted in right foraminal stenosis which was severe and could be compressing the right L3 nerve. Petitioner also had a mild, diffuse annular bulging at L1-L2 and L4-L5. She had mild lumbar levoscoliosis and a partially sacralized L5 with hypoplastic asymmetric L5-S1 facets. *Id.* Dr. Gilliland recommended referral to a neurosurgeon or possibly an orthopedic surgeon, and she should continue with Ibuprofen and Flexeril. Med. recs. at Ex. 2, p. 13.

On April 16, 1999, petitioner saw Dr. Gilliland. She had an appointment with Dr. Brent Hisey on April 26th, but she was in considerable pain and had developed some headaches (a new complaint). She had returned to work, but was under a lot of pressure and had to do a lot of

moving around and substitute teaching which exacerbated her back symptoms. Med. recs. at Ex. 2, p. 14. On physical examination, she was basically unchanged. She was under obvious stress. Dr. Gilliland believed she was having tension headaches, and that the headaches were not related to her lower back problem. *Id.* Dr. Gilliland recommended petitioner stop work and continue her home exercises. She should continue taking Ibuprofen and Flexeril. *Id.*

On April 26, 1999, petitioner saw Dr. Brent Hisey, who concluded petitioner's symptoms were caused by her L3-L4 spondylolisthesis. Med. recs. at Ex. 3, p. 2. He recommended that she see Dr. Jim Odor for a second opinion regarding surgical correction. *Id.*

On May 19, 1999, petitioner saw Dr. James M. Odor, a spinal surgeon. Med. recs. at Ex. 17, p. 8. Her MRI showed a Grade II spondylolisthesis at L3-L4. Petitioner stated her pain was present all the time and getting worse. On physical examination, she had limited lumbar motion, especially lumbar extension, secondary to pain. Motor and reflex testing was normal in the lower extremities. Sensation was diminished in the left lower extremity in the L3-L4 dermatomes. Hip rotation was symmetric. X-rays of the lumbar spine showed spondylitic defects at L3-L4 with a left lateral translation and asymmetric collapse on the right at L3-L4. She had a Grade II spondylolisthesis at that level. Dr. Odor recommended a lumbar epidural steroid injection as an alternative to surgery. *Id.*

Petitioner filled out a form on May 19, 1999 for Dr. Odor stating her symptoms (burning sensation in the low back region, aching in the low back region, pain in the lower back and left leg, pain in the lower back and right leg, pain in the lower back and bilateral leg pain, pain in the lower back, left buttock and leg). Med. recs. at Ex. 17, p. 10. For date of injury or onset of symptoms, she listed February 26, 1999. *Id.* When asked if she had back injury in the past,

petitioner responded no. *Id.* In answer to how she would describe her health, petitioner circled the word "good." Med. recs. at Ex. 17, p. 13.

On May 28, 1999, petitioner returned to Dr. Halsey. Med. recs. at Ex. 3, p. 3. The lumbar epidural steroid injection was scheduled for the next Tuesday. Dr. Halsey did not think it would significantly change petitioner's symptomatology. She complained of weakness in the right upper extremity. On examination, her motor function was diffusely 5/5 in the hand extrinsics with a slight amount of wasting. He recommended she have an EMG and nerve conduction study with Dr. Jarrell. *Id.*

On June 8, 1999, petitioner saw Dr. H.R. Jarrell for an EMG and nerve conduction study. Med. recs. at Ex. 12, p. 1. The right ulnar nerve had relative slowing of motor nerve conduction velocity in the segment crossing the elbow when compared with the distal ulnar conduction velocity. Sensory conduction velocity was normal and needle EMG did not reveal any denervation activity in the ulnar or other muscles of the hand or forearm. The isolated slowing of the ulnar nerve segment at the elbow supports a clinical diagnosis of ulnar compressive neuropathy. There was no indication of active cervical radiculopathy or of polyneuropathy. Med. 12, p. 2.

On June 9, 1999, petitioner saw Dr. Hisey. Med. recs. at Ex. 3, p. 4. She complained of increasing weakness in the lower extremities with pain. She would probably require an L3-L4 fusion. *Id.*

On June 10, 1999, petitioner returned to Dr. Odor. Med. recs. at Ex. 17, p. 4. She had not received an epidural injection because, in the last five days (or June 5, 1999), she had a dramatic deterioration so that she could hardly walk. She was now totally dependent on the use

of a cane in one hand and holding onto a friend with the other hand. *Id.* She noticed some increased feeling of weakness and numbness in her legs, and denied any injury or fall. She had been constipated and lost bladder control twice. On examination, she had difficulty walking secondary to pain and quad weakness. She had 4/5 quad weakness on the right, but was otherwise neurologically intact to motor, reflex, and sensory testing. She had a lot of pain on movement. Dr. Odor ordered a new MRI. *Id.*

Also on June 10, 1999, an MRI of petitioner's lumbar spine was performed. Med. recs. at Ex. 17, p. 5. Dr. Walter J. Milton wrote that petitioner had a Grade I anterolisthesis as well as left lateral listhesis at this level. Med. recs. at Ex. 17, p. 6. She had severe right foraminal stenosis, moderate left foraminal narrowing, and mild central canal stenosis. *Id.* He recommended an MRI of the thoracic and/or cervical spines if there were clinical concern for a myelopathy. Med. recs. at Ex. 17, p. 5.

On June 15, 1999, petitioner had an MRI of her cervical spine with gadolinium. Med. recs. at Ex. 17, p. 2. Dr. Oliver Cvitanic wrote she had multiple intrinsic cord lesions associated with swelling and heterogenous contrast enhancement. The primary consideration was acute transverse myelitis (TM). Other important considerations included acute disseminated encephalomyelitis (ADEM), nonthrombosed cavernous angiomas, and sarcoidosis. *Id.*

Also on June 15, 1999, petitioner had an MRI of her thoracic spine with gadolinium. Med. recs. at Ex. 17, p. 3. Dr. Cvitanic wrote that she had patchy enhancing intrinsic cord lesions associated with cord swelling from T9-T12. The primary consideration was acute TM. Other considerations were ADEM, sarcoidosis, and nonthrombosed cavernous angiomas. *Id.*

On June 18, 1999, petitioner saw Dr. Hisey, who reviewed her cervical and thoracic MRIs, demonstrating multiple high intensity lesions in the cervical and thoracic regions with the differential diagnosis of myelitis, sarcoiditis, MS, etc. He recommended she see a neurologist. Med. recs. at Ex. 3, p. 5.

On June 30, 1999, petitioner saw Dr. Hugh G. McClure, a chiropractic orthopedist. Med. recs. at Ex. 13, p. 1. His diagnostic impression was L3-L4 Grade I/Grade II spondylolysis with nerve compression at this level and probable MS. Med. recs. at Ex. 13, p. 7. As a result of her job injury on February 26, 1999, she sustained injury to her lumbar spine with resulting pain radiating into the sciatic nerve bilaterally, left greater than right. The subsequent upper tract symptoms, more probably MS, were a latent problem activated, accelerated, or exacerbated by the trauma to her spine on February 26, 1999. *Id.*

On July 1, 1999, petitioner saw Dr. Andrew C. Gin, a neurologist. Med. recs. at Ex. 18, p. 22. After falling on February 26, 1999, she initially had pain in her buttocks region and, over time, difficulty with walking. She denied any visual disturbance including double vision or loss of vision. She had some degree of numbness around her lower thorax and two episodes of urinary incontinence. Her most consistent complaint was of weakness on the right, pain in the low back and buttocks, and numbness around her lower thorax. Her past medical history was otherwise unremarkable. *Id.* Physical examination showed her back was mildly, diffusely tender to palpation. Straight leg raising was difficult to judge because of back discomfort. She had mild wasting of the intrinsic hand muscles on the right compared to the left. She had right quadriceps weakness but could stand and ambulate. Flexion, abduction, and external rotation caused pain in her low back. Reflexes were 2+ in the upper extremities, 2+ in the knee jerks, 1+

crossed adductor response, and trace ankle jerks bilaterally. Med. recs .at Ex. 18, p. 23. A questionable right Babinski[6] was present. Dr. Gin's impression was this was a complicated case. She might have elements of myopathy but it did not appear she had MS. It would be difficult to correlate her condition with her fall. *Id.*

On July 14, 1999, petitioner had an MRI done of her brain. Med. recs. at Ex. 6, p. 54. She had a focal enhancing lesion in the left posterior parietal area which might represent a small vascular malformation or possibly a vascular insult. She had a probable old infarction of the right superior cerebellum. Med. recs. at Ex. 6, p. 55.

On August 12, 1999, petitioner saw Dr. Mark A. Fisher, a neurologist. Med. recs. at Ex. 9, p. 1. He saw petitioner at Dr. King's request for unsteadiness, weakness, abnormal imaging studies, and back pain. "The patient is an extremely poor historian and is focused on her back and leg pain to the extent that it is very difficult to direct a history." *Id.* Petitioner stated she fell on her lower back and buttocks on February 26, 1999. She claimed "that all of her problems started after that." *Id.* In March 1999, she began to experience upper extremity weakness. This progressed somewhat in April, on the right greater than the left. Now, with resolution of some right upper extremity weakness, primarily distal, petitioner appeared to be worsening in her left hand. She described Lhermitte's phenomenon[7] in both upper extremities for the prior two weeks.

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[6] Babinski's reflex is "dorsiflexion of the big toe on stimulating the sole of the foot; ...a sign of a lesion in the central nervous system, particularly in the pyramidal tract." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1600.

[7] Lhermitte's sign is "the development of sudden, transient, electric-like shocks spreading down the body when the patient flexes the head forward; seen mainly in multiple sclerosis but also in compression and other disorders of the cervical cord." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1700.

Id. She noticed a bandlike sensation around her midthoracic area in late March and early April which was now mostly gone. For the last couple of months, her legs had been jumping. This worsened over a period of about a month, but then stabilized. For the last three to four weeks, she was a little better. She described burning in her lower back and severe dysesthetic sensations in her distal lower extremities. Med. recs. at Ex. 9, pp. 1-2. She denied visual changes, cognitive changes, diplopia, dysarthria, clumsiness, or loss of consciousness. Med. recs. at Ex. 9, p. 2.

On physical examination, her recent and remote memory were intact. Med. recs. at Ex. 9, p. 3. Spontaneous speech and comprehension were intact. *Id.* She had slightly decreased handgrip bilaterally and perhaps 5-/5 strength in the right upper extremity. The left lower extremity was perhaps 5-/5. Strength was 5/5 elsewhere. There was patchy sensory loss with multiple level to pinprick over the back bilaterally with some possible right-sided mild hemisensory loss. She complained of prominent dysesthesias in the distal lower extremities and had loss of pain and temperature below the knees. Romberg's sign[8] was present to the right. Petitioner had a clear sensory component to her unsteadiness of stance. She used a quad cane and staggered slightly to the right. DTRs were 3+ to 4+ at the knees, 3+ in the upper extremities, and 2+ at the ankles. Hoffmann's sign[9] was present bilaterally, right greater than left. Babinski's sign was present bilaterally. *Id.*

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

[9] Hoffman's phenomenon is "increased excitability to electrical stimulation in the sensory nerves; the ulnar nerve is usually tested." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1419.

The MRI of petitioner's cervical spine dated June 15, 1999 showed multiple lesions which looked plainly edematous, consisting of areas of high signal from C3-C7. There was a small area of enhancement at C1. The lesions were eccentric, parenchymal, and heterogeneously enhancing. Because the lesions were numerous and usually confined to one side, the consideration of acute TM was possible but questionable. Med. recs. at Ex. 9, p. 4. Differential diagnosis included ADEM, sarcoidosis (unlikely in petitioner), and a nonthrombosed cavernous angioma. There was a low probability of metastatic disease. *Id.* The MRI of petitioner's thoracic spine showed another cluster of lesions from T9-T12. There was vascular enhancement of the cord and at least four or five intrinsic cord lesions that again enhanced heterogeneously. An MRI of the brain showed a large old cystic area in the right cerebellum, and a small linear area of high signal in the lateral part of the white matter underlying the parietal cortex. There was no evidence of enhancement of this lesion. *Id.*

Dr. Fisher's impression was progressive onset of symptoms and signs consistent with central nervous system (CNS) disease, with a multifocal disease process, inflammatory versus neoplastic, in the cervical and thoracic spinal cord, with no evidence of cerebral parenchymal involvement. While multifocal demyelinating disease, such as MS, was possible, a variant of TM, ADEM, vascular structures, or malignancy must be considered. *Id.*

On September 3, 1999, petitioner returned to Dr. Fisher. Med. recs. at Ex. 9, p. 6. Petitioner was worse with slightly more burning and paresthesias in her hands, right greater than left, and slightly more unsteadiness. *Id.* On physical examination, she was oriented to time, place, and person. Recent and remote memory were intact. Attention and concentration were normal. She had a slightly decreased handgrip bilaterally and perhaps 4+/5 strength in the right

upper extremity. The left upper extremity was perhaps 5-/5. Strength was 5/5 elsewhere. Med. recs. at Ex. 9, p. 7. She had a clear sensory component to her unsteadiness of gait. *Id.* Repeat MRIs of the cervical and thoracic cord were available for review. There were multiple lesions in the cervical spine which looked frankly edematous, consisting of areas of high signal from C3-C7. There was also a small area of enhancement at C1. The lesions were eccentric, parenchymal, and heterogeneously enhancing. They were noticeably larger than on the previous MRI of June 15, 1999. An MRI of the thoracic spine was also available for review which showed another cluster of lesions from T9-T12. There was vascular enhancement of the cord and at least four or five intrinsic cord lesions that enhanced heterogeneously. They might be larger as well. The differential diagnosis included Lyme's disease, vasculitis, MS, arteritis, and other inflammatory causes. CSF analysis from September 1, 1999 was notable for 9 white blood cells with a cytopsin differential of 98% lymphocytes and a protein of 57, which was mildly elevated. Med. recs. at Ex. 9, p. 8. Dr. Fisher's impression was progressive onset of symptoms and signs consistent with CNS disease with a multifocal disease process, apparently inflammatory versus neoplastic, in the cervical and thoracic spinal cord, with no evidence of cerebral parenchymal involvement. The disease was progressing. He recommended five days of high-dose IV steroids. *Id.*

On September 17, 1999, petitioner again saw Dr. Fisher. Med. recs. at Ex. 9, p. 9. Petitioner had significant improvement of her weakness and symptoms after five days of high-dose IV steroids. Lumbar puncture was done and no oligoclonal bands were found. She was discharged on Prednisone one week earlier. *Id.* She still complained of burning and paresthesias in her hands, right greater than left, slight unsteadiness, and urge incontinence, indicative of a

neurogenic bladder with some sparing of sensation. *Id.* Her stance was much better. Med. recs. at Ex. 9, pp. 10-11. Dr. Fisher's impression was inflammatory or vascular myelitis. Med. recs. at Ex. 9, p. 11.

On October 19, 1999, petitioner again saw Dr. Fisher. Med. recs. at Ex. 9, p. 12. Her walking was much more stable and she had much more upper extremity strength. *Id.*

On November 9, 1999, petitioner saw Dr. Fisher. Med. recs. at Ex. 9, p. 15. Prednisone was tapered and discontinued. Petitioner told Dr. Fisher that "a couple of weeks prior to the onset of her weakness, she received immunization for hepatitis B. She wonders whether that is the cause of her problems."[10] *Id.*

On February 23, 2000, petitioner saw Dr. Stephen E. Smedlund. Med. recs. at Ex. 6, p. 4. Petitioner said she received hepatitis B vaccine in October and December 1998. In February 1999, she was at work when a student stepped on her foot. She fell backwards, landing on her back and shoulder, with pain radiating to her legs and feet. In March 1999, she began to have more difficulty with weakness, burning, and a tingling sensation in her left hip radiating to her left leg. In April 1999, she had more difficulty walking as both legs seemed weak, and could hardly walk. She began to have weakness in her upper arm. Because of progressive pain, she had a cervical MRI on June 16, 1999 which showed multiple abnormal signal areas. A repeat

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[10] Petitioner states in her affidavit, which is undated, unsigned, and obviously not notarized, at paragraph 1 that she received hepatitis B vaccinations, and "[s]hortly thereafter," got TM. P. Ex. 20, p. 1. The undersigned does not consider three months to be shortly thereafter. In paragraph 2, she states that after her vaccinations, she did not feel well and felt achy, as if she had been run over by a truck. She did not sign papers on the line. P. Ex. 20, p. 2. Petitioner told every one of the doctors to whom she gave a history that she was in good health before February 26, 1999. None of these symptoms has ever appeared in any medical history. Moreover, they are not indicative of neurologic disease.

study on August 31, 1999 as well as an MRI of her thoracic spine showed apparent progression of abnormal signals in the cervical spine from C3-C4 to T1. The thoracic MRI also showed abnormal signal areas from T9-T12 and at T7-T8. *Id.* By September 1999, she had a positive Lhermitte's sign that bothered her if she flexed and extended her neck. She had difficulties with bowel and bladder and had significant weakness and loss of feeling and fine use of her hands. She had treatment starting on September 3, 1999 with methyl prednisolone for five days and was discharged on a tapering course of Prednisone over the next two months. She stated she was a lot better in that she could now walk independently and had only minor bladder and bowel problems. *Id.* Follow-up MRIs of the cervical and thoracic spines on November 2, 1999 showed patchy areas of increased signal extending from T9-T12 and T7-T8 as well as C3-C4 to T1. Med. recs. at Ex. 6, p. 5. There was an area of apparent encephalomalacia involving the superior aspect of the right cerebellar hemisphere. *Id.* Dr. Fisher's diagnosis was multifocal myelitis or vasculitis involving the cervical and thoracic spinal cord suggestive of a systemic autoimmune disorder. Petitioner was concerned that hepatitis B could have caused this or possibly her fall in February 1999. *Id.*

On examination, her DTRs were 2+ in the upper and lower extremities and she did not have Babinski signs. Her Romberg was also negative. Muscle group strength was reasonably good and symmetric in the upper and lower extremities. Med. recs. at Ex. 6, p. 6. Dr. Smedlund's impression was multifocal myelitis, likely secondary to a systemic autoimmune disorder, etiology unknown. The cause was more likely her fall in February 1999 than the hepatitis B vaccination. *Id.*

On May 19, 2000, petitioner saw Dr. Bradley K. Farris, a neuro-ophthalmologist. Med. recs. at Ex. 4, p. 1. She had chronic granulomanous uveitis in both the anterior and posterior portions of the eye. This could well be related to her previous episode of TM. There was a remote possibility of sarcoid, lupus, or MS. *Id.*

On June 26, 2000, Dr. Loftus performed a cervical laminectomy of the C5, C6, C7, partial C4, and partial T1 levels of petitioner's cervical and thoracic spines. Med. recs. at Ex. 25, p. 2. This decompression was to alleviate her cervical stenosis. *Id.*

On January 28, 2002, petitioner saw Dr. Chris E. Codding, an orthopedist. Med. recs. at Ex. 34, p. 7. Petitioner told Dr. Codding she had had pain in her neck, back, and shoulders, and had TM and MS under evaluation since January 1999. *Id.* Her pain in her knees, hands, elbows, shoulders, hips, and spine began when she had hepatitis vaccine in 1998. Med. recs. at Ex. 34, p. 8. Then, in February 1999, a student stepped on her foot and she fell on her back. Id.

Petitioner filed her testimony for workmen's compensation, dated December 21, 1999. Med. recs. at Ex. 25, p. 613. She states that, on February 26, 1999, a student named Marco stepped on her foot and she fell on her tailbone. The next day, her shoulder and whole spine started to hurt. Later her right arm was bad. Med. recs. at Ex. 25, p. 641. When she saw the workmen's comp doctor, March 2, 1999, her shoulder was hurting. Med. recs. at Ex. 25, p. 644. Then it went to her left arm so that she could not even write. *Id.* The legs were so bad in April that she could not walk. She had numbness and burning from her hips down. Med. recs. at Ex. 25, p. 645. In April or late March 1999, she had a funny feeling along her side and burning from her left hip down. She had hot and cold sensations in her legs. Then she had incontinence and loss of bowel control. *Id.* She stopped working April 20, 1999. Med. recs. at Ex. 25, p. 648.

Petitioner saw Dr. Douglas Kerr, the head of the Myelitis Center at Johns Hopkins Medical Center, and he told her that trauma, such as a fall, can cause myelitis. Med. recs. at Ex. 25, pp. 649, 650.

Petitioner filed a deposition, dated April 18, 2000, of Dr. J. Mike Banowetz. Med. recs. at Ex. 24, p. 685. He examined petitioner on February 18, 2000. His opinion is that the fall caused her low back pain and right shoulder pain, but not her myelitis. Med. recs. at Ex. 24, p. 688. He does not believe that falls cause myelitis. Med. recs. at Ex. 24, p. 692. No cause was ever determined for petitioner's myelitis. Med. recs. at Ex. 24, p. 693.

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 TM (if that is what she had), but also that the vaccine was a substantial factor in bringing about her TM. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

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. 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 the instant action, petitioner's onset of neurologic disease was three months after her second hepatitis B vaccination, and one month after a student stepped on her foot causing her to fall back on her coccyx. When giving a history to Dr. Gilliland on February 26, 1999 (the date of the accident), she stated she had generally been in good health. The doctor's examination revealed no neurologic problems. Her DTRs in her lower extremities were 2+ and symmetrical, her straight leg raise was negative bilaterally, and her tactile sensation in both lower extremities was intact. All the histories petitioner gave to numerous doctors, including her neurologist Dr. Fisher, stated that she did not experience burning or weakness until March 1999, three months

after vaccination. In the form she filled out for Dr. Odor on May 19, 1999, she stated the onset of her pains was February 26, 1999, that she had not had back pain before that, and that her prior medical condition was good.

On November 9, 1999, petitioner changed her history. On that day, she said her symptoms began just weeks after her hepatitis B vaccination. Petitioner changed her history again on January 28, 2002, telling Dr. Codding that all her pains and her diagnosis of TM began in January 1999, one month before she fell. She also told Dr. Codding during the same visit that all her joint pains began after her hepatitis B vaccination in 1998. Petitioner's changes of her history are not credible, being totally inconsistent with the numerous histories she gave to numerous doctors contemporaneous with the onset of her symptoms, starting on the day of her fall. Importantly, there are no medical records between her second hepatitis B vaccination on December 15, 1998 and her fall on February 26, 1999 to support her changed medical history.

Contemporaneous medical records are considered trustworthy because they contain information necessary to make diagnoses and determine appropriate treatment:

> Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.

Cucuras v. Secretary, HHS, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

The onset of petitioner's neurologic symptoms was in March 1999, three months after her second hepatitis B vaccination. According to the testimony in the Omnibus proceeding, three months exceeds the temporal time frame for concluding causation from the vaccine. Petitioner was not neurologically ill within a medically-appropriate temporal time frame after her second

hepatitis B vaccination. The undersigned does not believe that petitioner will find an expert to testify that hepatitis B vaccine can cause an inflammatory or vascular myelitis three months later. Dr. Smedlund states that the cause of petitioner's illness was more likely her fall in February 1999 than her hepatitis B vaccination. Dr. Douglas Kerr, the renowned head of the Transverse Myelitis Center at Johns Hopkins Medical Center, told petitioner that trauma, such as a fall, can cause myelitis. (Petitioner has not filed any record from Dr. Kerr although she testified that she sent him all her records and spoke to him.) The Federal Circuit in Capizzano, supra, states that the opinions of treating physicians must be considered in evaluating causation. 440 F.3d at 1326.

. Petitioner is ORDERED TO SHOW CAUSE why this case should not be dismissed by **September 15, 2006.**

IT IS SO ORDERED.

_____ _____

DATE Laura D. Millman
Special Master