OFFICE OF SPECIAL MASTERS
No. 99-608V
June 20, 2006

HARILYN ADLER,	*	
Petitioner,	*	
v.	*	Hepatitis B vaccine in someone with preexisting neuropathy that may have been MS and whose symptoms continued in degree and kind; how prove causation or significant aggravation
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

ORDER TO SHOW CAUSE[1]

Petitioner filed a petition on August 4, 1999, under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10 et seq., on her own behalf, ultimately alleging that hepatitis B

[1] Because this order to show cause contains a reasoned explanation for the special master's action in this case, the special master intends to post this order to show cause 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 administered on August 6, 1990, caused or significantly aggravated her MS. Although her treating neurologist diagnosed her with peripheral neuropathy prior to her vaccination, the symptoms that petitioner had strongly suggest she had a central nervous system problem. Petitioner was diagnosed with retrobulbar neuritis six days after vaccination. However, an MRI of petitioner's brain on August 13, 1990 (7 days after vaccination) was normal as were numerous spinal MRIs. The first abnormal MRI of petitioner's brain occurred in 1994, four years post-vaccination. She was diagnosed with MS June 17, 1994, four years after vaccination.

This case was suspended with over 60 other cases while the hepatitis B vaccine-demyelinating diseases Omnibus proceeding was concluded. The undersigned has recently concluded those proceedings, ruling that hepatitis B vaccine can cause TM, GBS, CIDP, and MS.

The undersigned does not believe that petitioner will find an expert witness to support her allegation that hepatitis B vaccine caused or significantly aggravated her MS because, as the undersigned explained in Werderitsh v. Secretary of HHS, No. 99-319V, 2006 WL _____ (Fed. Cl. Spec. Mstr. May 26, 2006), "to paraphrase petitioner's expert Dr. Vera Byers, if someone with the phenotype of MS that is relapsing/remitting were to allege that hepatitis B vaccine worsened his or her MS, the undersigned might find it impossible to determine whether the vaccine played any role in the course of an illness that, by itself, is episodic." Slip op. at 41-42.

Moreover, for petitioner to prove significant aggravation means proving more than an occurrence of one possible symptom of MS. It means, per the Act's § 300aa-33(4), "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." If petitioner experienced the normal course of her pre-existing MS, that is not significant aggravation. Either because she already had

MS and it waxed and waned over the years, or because she was not diagnosed with MS until four years after her vaccination, the undersigned does not see how petitioner will be able to make a prima facie case of causation in fact. The undersigned notes that almost a decade before her hepatitis B vaccination, she had numbness in her feet (rising to the thigh level) and persistent vision difficulties.

The undersigned ORDERS petitioner to SHOW CAUSE why this case should not be dismissed by July 31, 2006.

FACTS

Petitioner was born on June 25, 1945.

On June 20, 1977, she saw Dr. Martin E. Liebling at the request of Dr. Martin Cohen. She had fatigue and intermittent low grade fever of 101° a year previously. She had some cervical adenopathy which subsided. Several months previously, she had an enlarged inguinal node which was biopsied and found compatible with chronic lymphadenitis. In November 1976, she developed 4+ proteinuria and edema. She was diagnosed with nephrotic syndrome, etiology undetermined. She smoked two packs of cigarettes a day. Her father had severe myelofibrosis and myeloid metaplasia. Dr. Liebling was concerned about underlying lymphoma. Med. recs. at Ex. 6, p. 1.

Dr. Liebling notes on September 16, 1977 that petitioner had occult Hodgkin's disease and was on radiotherapy. Med. recs. at Ex. 6, p. 2.

On November 17, 1977, petitioner returned to Dr. Liebling and complained of back pain. Med. recs. at Ex. 6, p. 3.

Petitioner saw. Dr. Liebling with tachycardia on January 3, 1978. She had been drinking five cups of coffee daily. Dr. Liebling told her to stop drinking coffee. Med. recs. at Ex. 6, p. 4.

Petitioner was admitted to Baptist Hospital on November 6, 1978 because of herpes zoster of the right side of her face. Med. recs. at Ex. 6, p. 6. She was discharged on November 9, 1978. Med. recs. at Ex. 6, p. 7.

On December 19, 1979, petitioner saw Dr. Liebling, complaining of bitemporal and frontal headaches for about three days. Med. recs. at Ex. 6, p. 9.

On April 6, 1981, petitioner saw Dr. Allan Herskowitz, a neurologist. She was well until 1977 when she developed fatigue, headache, and lymphadenopathy. She was diagnosed with nephrotic syndrome, prescribed Prednisone, and improved. Med. recs. at Ex. 3, p. 1. In late 1977 or early 1978, she was diagnosed with Hodgkin's disease, stage II-A, mainly confined to the neck and mediastinum. She had a splenectomy and underwent radiation. Her symptoms did not improve. She had chemotherapy. She did well afterwards without recurrences. *Id.* Petitioner felt well until 12 days prior to the April 6, 1981 visit when she noted some tingling dysesthesias and numbness of both feet. This gradually ascended to the mid-calf region and caused her occasionally to stumble or lose her balance because of inadequate sensation in her feet. *Id.* She had vague symptomatology in her hands on awakening, and her hands felt stiff. She had some right flank pain since a kidney biopsy. *Id.*

A year and one-half previously, she had herpes simplex involving the right side of her face and had intravenous Vira-A therapy and improved. Her dietary habits were poor. *Id.* On examination, she had mildly diminished proprioception and vibration in both feet distally without

loss of light touch or pinprick. *Id.* Dr. Herskowitz diagnosed a mild sensory polyneuropathy whose etiology was unclear. Med. recs. at Ex. 3, p. 2.

On April 20, 1981, Dr. Herskowitz wrote to Dr. Martin Liebling that petitioner still complained of dysesthesias in the lower extremities although she felt it had spread to involve her thighs. Her legs still felt weak and heavy at times. She no longer complained of her hands being stiff. Med. recs. at Ex. 3, p. 3.

On June 8, 1981, Dr. Herskowitz wrote to Dr. Liebling that petitioner was doing better. The dysesthesias remitted except for the soles of her feet. Med. recs. at Ex. 3, p. 4. He wrote a similar letter on July 10, 1981. Med. recs. at Ex. 3, p. 5. However, on September 14, 1981, Dr. Herskowitz wrote to Dr. Liebling that petitioner's symptoms increased over the prior month. She now had a numb sensation from her feet up to the mid-abdominal area. She felt her legs at times were weak as if they were going to collapse. She had difficulty with urination. She had one episode of questionable fecal incontinence. She noted some numbness over the fingertips of her left hand. Med. recs. at Ex. 3, p. 6. On physical examination, petitioner had significant impaired vibration and position sense in both feet distally to the mid-tibial region. Reflexes were clearly increased throughout (hyperreflexia). She had a positive Lhermitte's sign.[2] Dr. Herskowitz stated, "She has continued to display at this point a recurrence and progression of her symptoms which appear to be myelopathic in origin." *Id.* Her bladder problems were apparently recent. *Id.*

---

[2] 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.

Petitioner was admitted to Baptist Hospital of Miami on September 20, 1981 for a complete myography to rule out any central nervous system involvement or recurrence of her primary lesion. Med. recs. at Ex. 6, p. 8. CT scan of the brain showed mild enlargement of the lateral ventricles. Med. recs. at Ex. 6, p. 9. She also had a prominent cisterna magna. Med. recs. at Ex. 3, p. 78. She was diagnosed with possible myelitis and peripheral neuritis of uncertain etiology, and trigonitis (bladder inflammation). Med. recs. at Ex. 3, p. 10. The cystourethroscopy did not reveal a neurogenic bladder. Med. recs. at Ex. 6, pp. 44, 45.

On October 26, 1981, Dr. Herskowitz wrote Dr. Liebling that petitioner was still complaining of numbness in the mid-abdominal region and weakness of her legs. Dr. Herskowitz stated she might be having some time of autoimmune phenomenon. Med. recs. at Ex. 3, p. 11.

On November 2, 1981, petitioner returned, still complaining of tight band-like sensation in the upper thorax and stumbling when she walked due to inadequate sensation in her feet. She has had some dysesthesias in her hand and electric shock down her spine when she flexed her neck. On examination, she had mild to moderate impaired position and vibration sense distally in the feet up to the ankles. Med. recs. at Ex. 3, p. 12. There was a suggestion of bilateral Babinski signs (which would indicate central nervous system involvement). She had difficulty walking on heels or toes. She had a positive Lhermitte's sign. *Id.*

On February 3, 1982, petitioner returned to Dr. Herskowitz, still complaining of headaches which were mainly nocturnal. She also still had significant neck and back pain. Her neck was quite rigid. Med. recs. at Ex. 3, p. 13.

On March 22, 1982, petitioner returned to Dr. Herskowitz still having neck pain and headaches. The pain went from the base of her spine to the top of her head. She got three to four episodes a day. Her neck was quite stiff with hyperextension. Med. recs. at Ex. 3, p. 14.

On March 29, 1982, petitioner returned to Dr. Herskowitz. Over the past three days, she had fatigue, lethargy, double vision, and headaches. For the past several months, she had a generalized pruritis. She was in an automobile accident on January 12, 1982 and had a post-concussive syndrome, but her symptoms then were different than after the accident. The numbness in her feet was unchanged. She had unsteadiness in her walk over the prior several days. On examination, there was some prominence to the globe on the right on inspection of her eyes. He referred her to Dr. Eugene M. Eisner. Med. recs. at Ex. 3, p. 15.

Also on March 29, 1982, she complained to Dr. Eisner of double and blurred vision in her left eye. Med. recs. at Ex. 2, p. 3.

Petitioner saw Dr. Herskowitz on April 2, 1982. For the past week, when her double vision began, she had nausea with some weight loss due to inability to eat, occasional night sweats, dysequilibrium, and increased numbness in her feet. She did not feel well. On examination, she had mild right 6th nerve paresis which was brought out significantly with red glass testing of her extraocular muscles. Dr. Herskowitz felt petitioner might be having recurrent demyelinating episodes. Med. recs. at Ex. 3, p. 16.

On April 7, 1982, Dr. Herskowitz wrote to Dr. Liebling that petitioner developed right 6th nerve paresis and recently complained of some unusual sensation on the right side of her face. She had a very subtle right peripheral 7th weakness as well. She complained of difficulty hearing

localizing sounds on her right side. These symptoms presented more as focal demyelinating episodes. Med. recs. at Ex. 3, p. 18.

On April 15, 1982, petitioner had a CT scan of the brain which detected a possible Arnold-Chiari malformation, type I. Med. recs. at Ex. 3, p. 87.

On April 16, 1982, petitioner returned to Dr. Herskowitz, still complaining of some double vision to right gaze and numbness of the right side of her face. The day before, she had difficulty swallowing solids and felt as though her head were stuffy. On examination, she still had the right 6th paresis but her right eye seemed to be moving laterally better. Med. recs. at Ex. 3, p. 19.

Dr. Herskowitz wrote to Dr. Liebling on April 22, 1982 that petitioner's symptoms were gradually and slowly improving. She still had a right 6th nerve paresis, but this had improved as did her minimal facial weakness. Her appetite had improved and her bowel problems were less significant. Her spinal fluid protein electrophoresis showed an elevated IgG component which is consistent with either an autoimmune or demyelinating process. Med. recs. at Ex. 3, p. 20.

On May 3, 1982, petitioner returned to Dr. Herskowitz, having made considerable improvement. Her right 6th nerve paresis had almost complete cleared after three weeks on Prednisone. Spinal fluid gamma globulins were elevated, indicating this was a demyelinating episode. Med. recs. at Ex. 3, p. 21.

On June 3, 1982, petitioner returned to Dr. Herskowitz with significant improvement. Her double vision looking to the right was only minimal. She still had some complaints of dysesthesias of the feet. Med. recs. at Ex. 3, p. 22.

On October 1, 1982, Dr. Herskowitz wrote Dr. Liebling that petitioner had been doing quite well until about a month previously when she began feeling a sensation of heat in the soles of her feet and increasing numbness. She also had no energy generally and had intermittent leg cramps. Med. recs. at Ex. 3, p. 23.

She still had diplopia on January 23, 1983. Med. recs. at Ex. 2, p. 83. This continued in 1984. Med. recs. at Ex. 2, p. 5.

On August 2, 1990, petitioner saw Dr. Jerry Rosenbaum, a rheumatologist, complaining about discomfort about her right shoulder for the past month with associated diminished range of motion, morning stiffness, nocturnal pain, and referred pain to her upper arm. Med. recs. at Ex. 9, p. 29. She received radiation and chemotherapy for Hodgkin's 12 years previously. *Id.* Physical examination revealed diminished internal rotation about her right shoulder with guarding and a mildly tender subdeltoid bursa. Dr. Rosenbaum's impression was capsulitis. *Id.*

Petitioner alleges she received a hepatitis B vaccination on August 6, 1990 although she has not provided documentation of vaccination.

On August 12, 1990, Dr. Eisner diagnosed her with retrobulbar neuritis. Med. recs. at Ex. 2, p. 7.

On August 13, 1990, petitioner had an MRI done of her brain with gadolinium. It was normal. Med. recs. at Ex. 3, p. 88.

Dr. Herskowitz wrote a letter dated August 13, 1990 to Dr. Eugene Kafka. He stated that 8-10 years previously, he had seen petitioner for peripheral neuropathy secondary to Hodgkins which apparently resolved. She was left with a mild residual of dysesthesias in her feet which had been nonprogressive and stable. She was doing well until one week previously (which

would be August 6, 1990) when she noted a left hemicranial retro-orbital pain which persisted for about five days and then, on August 11, 1990, noticed a big black spot in front of her left visual field. The pain in her eye increased with eye movement. She saw Dr. Eisner and had a full work-up which was normal except for a central scotoma (lost or depressed vision) and a left Marcus Gunn pupil. He put her on Prednisone. There had been no change in her vision. Dr. Herskowitz diagnosed petitioner with left retrobulbar neuritis. About one week prior to this, she received a heptavax injection. (Petitioner alleges vaccination on August 6, 1990, the date her eye problems began, according to Dr. Herskowitz's record.) Med. recs. at Ex. 3, p. 26.

A visual evoked response done on August 15, 1990 was abnormal due to prolonged latency in the left eye. Med. recs. at Ex. 3, p. 89.

On August 20, 1990, Dr. Herskowitz wrote Dr. Kafka that petitioner was much improved. The vision in her left eye was significantly better. She no longer had a Marcus-Gunn pupil in the left eye. Petitioner asked Dr. Herskowitz if hepatitis B vaccine could have precipitated this and he told her she did have an altered immune system. Med. recs. at Ex. 3, p. 28.

On August 27, 1990, Dr. Herskowitz wrote Dr. Kafka that petitioner was doing much better. She noticed some minor paresthesias in her feet. Med. recs. at Ex. 3, p. 29.

On September 7, 1990, Dr. Herskowitz wrote Dr. Kafka that petitioner saw Dr. Eisner the day before and he told her that her vision was normal. She complained of increasing numbness in her feet up to the midcalf. She had this in 1981. On examination, she had impaired vibratory and position sense in both feet and decreased ankle reflexes. She had mild weakness of her right foot. Med. recs. at Ex. 3, p. 30.

Nerve conduction studies conducted on October 2, 1990 were normal. Med. recs. at Ex. 3, p. 90. Visual evoked response done on October 2, 1990 was abnormal due to prolongation of the left optic tracks. Med. recs. at Ex. 3, p. 91. Somatosensory evoked responses were abnormal in both lower extremities on October 2, 1990. Med. recs. at Ex. 3, p. 92.

On March 14, 1991, Dr. Herskowitz wrote Dr. Kafka that petitioner had an automobile accident on March 6, 1991. She immediately started complaining of neck pain, bilateral shoulder pain, and headache. She had a prior automobile accident six years previously with neck injuries that never got completely better. After examining petitioner, Dr. Herskowitz's impression was cervical sprain. She still had a left Marcus-Gunn phenomenon. She did not have any pathologic reflexes. She had normal strength. Med. recs. at Ex. 3, p. 31.

A cervical spine x-ray done on March 14, 1991 showed slight narrowing of the C5-6 and C6-7 discs. Med. recs. at Ex. 3, p. 93.

On April 25, 1991, Dr. Herskowitz wrote Dr. Kafka that physical therapy did not improve petitioner. She still had neck pains, and limited head rotation, flexion, and extension. Med. recs. at Ex. 3, p. 33.

An MRI of the cervical spine done May 1, 1991 showed nothing remarkable except the narrowing of the disc space at C5-6 and C6-7. Med. recs. at Ex. 3, p. 94. There was no evidence of any root encroachment at any level. *Id.*

Dr. Herskowitz noted on June 24, 1991 that an MRI of petitioner's spine did not show any significant herniated disks. Med. recs. at Ex. 3, p. 35.

On January 15, 1992, Dr. Herskowitz wrote an attorney that petitioner was still having significant neck discomfort with limitation of range of motion. She still had spasm of the

paracervical and trapezius muscle. Dr. Herskowitz felt this was a permanent injury, mainly soft tissue. Her disability was in the range of 5-6%. Med. recs. at Ex. 3, p. 42.

On May 27, 1994, petitioner saw Dr. Liebling. She stated she had been depressed for months without any specific reason. Med. recs. at Ex. 6, p. 12. Dr. Liebling wondered if she could have a collagen disorder with her anemia, vague athralgias, vague headaches, and elevated sedimentation rate. Med. recs. at Ex. 6, p. 11.

On June 12, 1994, petitioner saw Dr. Rosenbaum, who had not seen her since 1990. She had a positive antinuclear antibody with a titer of 1:160, and a hemoglobin of 11.6 with an elevated MCV. Med. recs. at Ex. 9, p. 21. She had classical tender areas of fibromyalgia. Med. recs. at Ex. 9, p. 22.

On June 15, 1994, Dr. Herskowitz wrote Dr. Kafka, noting that petitioner had a normal MRI of the brain in August 1990. In September 1990, she had numbness extending to the mid-calf in both feet and a mild grade 4/5 weakness in the right foot. Med. recs. at Ex. 3, p. 43. In October 1990, nerve conduction studies were done of both lower extremities and were normal despite her complaints of numbness. She stated that for about a year (which would be June 1993), she has noticed that her legs felt weak and have slowly been getting weaker. Her balance had not been good over the prior several months. Over the last two weeks, she had increasing lower back pain. She had a mild frontal headache. She has been feeling generally sick, weak and exhausted over the past month. She had night sweats without fever and recurrent herpes lesions of the face. Over the past month, she had joint pains in her knees and less in her shoulders. On examination, fundoscopic exam was normal. Visual fields were full. Med. recs. at Ex. 3, p. 44.

Dr. Herskowitz's conclusion was that petitioner might have a systemic or inflammatory process. Lupus was a possibility. Med. recs. at Ex. 3, p. 45.

On June 21, 1994, petitioner had an MRI done on her lumbar spine. There was no evidence of compression or abnormal enhancement on gadolinium administration. Med. recs. at Ex. 3, p. 95. On June 21, 1994, petitioner had an MRI done on her brain which showed changes consistent with MS of moderate severity. There was associated dilatation of ventricles and sulci. This could be a transient effect of steroid therapy if she were on it. If she were not on it, it would suggest atrophy. Med. recs. at Ex. 3, p. 97.

Dr. Herskowitz wrote Dr. Kafka on June 27, 1994 that petitioner still had a very mild paraparesis 4+/5 in both lower extremities. The MRI of her lumbar spine was normal. The MRI of her brain showed hyperintense periventricular signals consistent with demyelinating disease. She was not a clear cut case of MS. Perhaps she had a mix of lupus and MS. Med. recs. at Ex. 3, p. 46.

On July 13, 1994, Dr. Herskowitz wrote Dr. Kafka that petitioner was unchanged. She complained of being unsteady when she walked with weakness of her legs. He has some mild urinary incontinence. The numbness in her legs to midcalf had been present since 1981. This most likely represented residual neurologic deficit from myelitis at that time. He thought petitioner most likely had MS. He did not think her complaints about her eyes and poor vision were related to MS. She was depressed. Med. recs. at Ex. 3, p. 47.

Dr. Herskowitz wrote Dr. Kafka on August 10, 1994 that petitioner made a nice recovery from her last bout of paraparesis. She had only minimal grade 4+/5 weakness in her proximal muscles in her legs. Dr. Eisner examined her eyes and found only that her prescription was a

little bit worse than before. She had nocturnal cramps in her calves and feet which she had had for many years. Med. recs. at Ex. 3, p. 49.

Dr. Herskowitz wrote Dr. Kafka on November 4, 1994 that petitioner complained of an increase in fatigue, heaviness, and weakness of her legs. Her calf cramps resolved spontaneously. She was neurologically unchanged. She had a positive Lhermitte's sign. Dr. Herskowitz thought she was in relative remission from her MS. She saw Dr. David Racher for a second opinion and he agreed with the diagnosis of MS. Med. recs. at Ex. 3, p. 50.

On November 22, 1994, petitioner saw Dr. Rosenbaum, complaining of morning stiffness lasting one to two hours, pain in both knees and hips, and moderate fatigue. Med. recs. at Ex. 9, p. 4. She was diagnosed with connective tissue disease. *Id.*

In a note dated December 12, 1994, Dr. Herskowitz states that Dr. Rosenbaum did not feel petitioner had lupus but some component of it. She still complained of weakness of her legs and pain in her knees. Med. recs. at Ex. 3, p. 52.

On January 11, 1995, Dr. Herskowitz noted that petitioner was significantly better. She walked better and her legs were stronger. She broke out with herpes simplex on the right side of her face which had been recurrent for years. She seemed in remission neurologically. Med. recs. at Ex. 3, p. 53.

On May 7, 1995, Dr. Herskowitz saw petitioner who was doing better. She was less dizzy and no longer had difficulty walking after getting up. She felt her legs were stronger and she had fewer headaches. The MRI was unchanged since 1994. Dr. Eisner found no change in her visual exam from prior visits several years ago. Dr. Liebling did not see recurrent adenopathy. Neurologically, she was stable. She had minor bladder leaking several weeks prior,

but this cleared up. Dr. Herskowitz reassured her that her MS was stable. Med. recs. at Ex. 3, p. 62.

On September 22, 1995, she was having light flashes in her left eye. Med. recs. at Ex. 2, p. 10.

On September 26, 1995, Dr. Herskowitz wrote that petitioner had questionable optic neuritis in the left eye in the past and, three weeks previous, had a very transient five-minute episode of loss of vision or white-out in her right eye. She saw Dr. Eisner and no abnormalities were found. Neurologically, she was unchanged. She still had impaired vibratory and position sense in both feet distally to the knees. Med. recs. at Ex. 3, p. 54. Nerve conduction studies were normal, just as in June 1994. Med. recs. at Ex. 3, p. 99. Petitioner had a combination of significant physical and emotional problems. Med. recs. at Ex. 3, p. 55.

On October 17, 1995, Dr. Herskowitz noted that petitioner was still complaining of weakness in her legs and now of cramps in the left hamstring. Her neurologic examination was unchanged. Med. recs. at Ex. 3, p. 56.

On November 17, 1995, Dr. Herskowitz noted petitioner was still the same. She complained of headaches which had cleared and continued to complain of proximal leg weakness. She had diffuse leg cramps. Neurologically she was unchanged over the past year. Neither the cramping nor the joint pain was due to MS. Med. recs. at Ex. 3, p. 57.

On February 20, 1996, petitioner saw Dr. Liebling. She had been diagnosed with MS and also with a lupus-like crossover syndrome. He suggested to petitioner that her diseases may be interrelated in that she now had three immune diseases: (1) nephrotic syndrome with her original Hodgkin's disease; (2) MS; and (3) a lupus-like syndrome. Med. recs. at Ex. 6, p. 13.

On April 2, 1996, petitioner saw Dr. Howard L. Zwibel, a neurologist. Petitioner had her first major neurological symptoms in 1981 when she had numbness in her lower extremities. Dr. Herskowitz treated her with steroids. In 1983, petitioner had an episode of diplopia, again treated with steroids. In 1990, petitioner had an episode of visual loss in the left eye which was felt to represent optic neuritis. Her current complaints were weakness in her lower extremities and some degree of pain in her lower back and legs. She had a diagnosis of both MS and lupus. Her significant past history included Hodgkin's disease and a nephrotic syndrome. Her brain MRI of 1994 showed white matter disease consistent with a diagnosis of demyelinating disease. Med. recs. at Ex. 9, p. 12. Dr. Zwibel found petitioner's symptoms most compatible with the diagnosis of relapsing-remitting MS. Her titers suggested lupus. Med. recs. at Ex. 9, p. 13.

On August 2, 1996, petitioner saw Dr. Jeffery S. Ritter, a rheumatologist, complaining of pain in her left shoulder. In 1994, her ANA was 1:640, followed by ANAs of 1:16, 1:6, and 1:80. Med. recs. at Ex. 9, p. 48. Neurological examination revealed no focality. Med. recs. at Ex. 9, p. 49. Dr. Ritter diagnosed her with left shoulder tendinitis. Dr. Ritter did not believe petitioner had a systemic collagen vascular disease such as a lupus-like syndrome. While her ANA was positive once, it was negative on subsequent occasions. Her DNA antibodies had been up and down. A lot of her symptoms may have been related to fibromyalgia. *Id.*

On April 7, 1997, Dr. Herskowitz noted he had not seen petitioner for the past year. She complained that, for the past six months, when she rose from a sitting position, she had trouble walking. For the past several months, she had lightheadedness and some headaches with vague visual symptoms. She had retired on disability. The neurologic examination was basically unchanged from September 1995. Med. recs. at Ex. 3, p. 61.

On April 15, 1997, an MRI was done of petitioner's brain, showing bilateral multifocal lesions, but no worsening of her MS since the prior MRI of June 21, 1994. Med. recs. at Ex. 2, p. 16; Ex. 3, p. 101.

On April 18, 1997, petitioner saw Dr. Liebling. Her MS was a little bit progressive. She recently had frequent episodes of dizziness and light headedness intermittently. She had occasional stress incontinence. She told Dr. Liebling her rheumatologist finally felt that she did not have lupus. Med. recs. at Ex. 6, p. 14.

On April 18, 1997, Dr. Eisner wrote to Dr. Alan Herskowitz that he found no significant change in petitioner's eye examination from her visit on September 22, 1995. She had slight optic atrophy in the left eye due to old optic neuritis related to her MS. This had no relationship to her lightheadedness, dizzy spells, and headaches. Med. recs. at Ex. 2, p. 13.

On April 6, 1998, petitioner returned to Dr. Herskowitz. She had been stable until the prior several months. A lot of her old symptoms returned. She had brief scotomata in her left eye. Her lower extremities became progressively weaker. She again had difficulty rising and walking. Her neurologic examination was basically unchanged. She had a positive Lhermitte's sign. Med. recs. at Ex. 3, p. 64.

On October 14, 1998, petitioner saw Dr. Antonio F. Muina. She was recently diagnosed with MS and started taking beta interferon but was concerned it might affect her platelet count. She had multiple petechiae and purpura. Dr. Muina diagnosed thrombocytopenia, most likely secondary to beta interferon. Med. recs. at Ex. 6, p. 15.

On November 8, 1999, petitioner saw Dr. Bhupinder S. Mangat, a neurologist. In 1980, petitioner started having numbness in her feet without paralysis. In 1990, she received hepatitis

B vaccine. A few days later, she had optic neuritis. She had deteriorating vision in her right eye and was treated with steroids. In 1994, she had a brain MRI and MS was diagnosed for the first time. Med. recs. at Ex. 11, p. 19. Her main complaint was low back pain. She got spasms in her lower extremities and had deteriorating vision in her right eye. A large grayish spot came and went, lasting from 10 to 15 minutes without pain. She also had headaches, mostly at night. She gave a history of deteriorating memory and clumsiness with her hands. Her hands and feet were weak and she lost her balance. On examination, there was pallor of the optic discs, more on the left than on the right. Med. recs. at Ex. 11, p. 20. Her upper extremities were not weak. Romberg's sign was positive. Med. recs. at Ex. 11, p. 21.

On December 29, 1999, petitioner had an MRI of her brain. White matter changes and symmetrical ventricular dilatation were not significantly changed since her MRI of April 15, 1997. Med. recs. at Ex. 11, p. 18.

On January 25, 2000, petitioner saw Dr. Howard E. Gross, a cardiologist. She had mild to moderate aortic insufficiency. Med. recs. at Ex. 12, p. 1.

On August 10, 2000, petitioner saw Dr. Mangat. She had a history of memory deficit and loss of balance. In 1994, after an MRI of her brain, she had a diagnosis of MS for the first time. She complained of visual disturbance in her right eye. On examination, there was pallor of the optic discs, more on the left than on the right. Med. recs. at Ex. 11, p. 15.

On December 14, 2000, petitioner saw Dr. Mangat. She did not have any recent history of double vision, blurred vision, numbness in the face, difficulty swallowing or talking, numbness, weakness, or any paralysis of the arms and legs. She sometimes got extremely weak

and tired. Dr. Mangat found no deterioration in her demyelinating disorder. Med. recs. at Ex. 11, p. 13.

On December 18, 2000, petitioner saw Dr. Gross. Petitioner was asymptomatic. Med. recs. at Ex. 12, p. 4.

On August 2, 2001, petitioner complained to Dr. Mangat of slight blurred vision and transient face numbness. Med. recs. at Ex. 11, p. 10. She did not have numbness in the lower extremities. *Id.*

On October 5, 2001, petitioner saw Dr. Mangat. She had an antiphospholipid syndrome. She complained of weakness in the arms and legs, and extreme fatiguability. Med. recs. at Ex. 11, p. 8.

An upper GI series performed on April 2, 2002 showed large, spontaneous gastroesophageal reflux. Med. recs. at Ex. 13, p. 58.

A Lupus Anticoagulant Assay ordered by Dr. David F. Fernandez on April 6, 2002 proved negative. There was no evidence of lupus anticoagulant. Med. recs. at Ex. 13, p. 31.

On April 1, 2003, petitioner saw Dr. Mangat, complaining of extreme vertigo and extreme loss of balance. An MRI of her brain would be done to see if there were a worsening of her MS. Med. recs. at Ex. 11, p. 6.

On April 14, 2003, petitioner had an MRI done of her brain with and without contrast. Med. recs. at Ex. 11, p. 4. Dr. Paul A. Goldberg described areas of abnormal white matter signal predominantly periventricular and compatible with MS. There were no enhancing lesions and no evidence of a recent cerebrovascular accident. Med. recs. at Ex. 11, p. 5.

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 either causation or the purported significant aggravation of her MS, but also that the vaccine was a

substantial factor in bringing about the causation or purported significant aggravation of her MS. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

The undersigned doubts that petitioner will find an expert to provide a report that petitioner's neurological symptoms changed in degree or kind since their onset in 1981.

Petitioner is ORDERED TO SHOW CAUSE why this case should not be dismissed by July 31, 2006.

IT IS SO ORDERED.

_____ _____

DATE Laura D. Millman
Special Master