In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 02-1490V
June 14, 2007

CAROLYN REED,	*	
	*	
Petitioner,	*	
	*	
v.	*	Hepatitis B vaccination followed a few days later by symptoms never consistently diagnosed; no evidence of neurologic illness
	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

ORDER TO SHOW CAUSE[1]

Petitioner filed a petition dated November 1, 2002, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that hepatitis B vaccine administered on December 20, 2001 caused her an adverse reaction of neurological-demyelinating injury, specifically, multiple sclerosis (MS)-like symptoms.

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[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 has a history of chronic lower back pain that preceded her vaccinations by years. Petitioner had a lumbar MRI done 13 days before her third hepatitis B vaccination for low back pain and numbness in her left leg. Petitioner's first medical visit after her third vaccination was because of back pain due to a physical therapist who did a lot of manipulation over her sacral iliac region. Petitioner does not have a neurologic condition and diagnosis of her complaints is, as petitioner's counsel recognizes, problematic. See petitioner's Response to Order of February 8, 2007, filed on March 8, 2007 ("it would appear that timing is not so much the issue in this case as the diagnosis").

Petitioner is ORDERED TO SHOW CAUSE by **August 31, 2007** why this case should not be dismissed.

FACTS

Petitioner was born on October 7, 1949.

On June 25, 1993, petitioner went to Washington County Hospital because of a sore throat. Med. recs. at Ex. 14, p. 255. The diagnosis was pharyngitis. Med. recs. at Ex. 14, p. 258.

On April 30, 1994, petitioner went to Washington County Hospital because of pain in her ears, jaws, and sinus. Med. recs. at Ex. 14, p. 245. She was diagnosed with sinusitis. Med. recs. at Ex. 14, p. 248.

On December 23, 1994, petitioner had an MRI done of her spine at Washington County Hospital because of degenerative joint disease of the left posterior thigh, calf, and ankle causing pain. Med. recs. at Ex. 14, p. 242. Dr. I.K. Gunadi's impression was a large disc herniation at the level of L5-S1, extending from the midline toward the left. Med. recs. at Ex. 14, p. 244.

On March 25, 1999, petitioner had an MRI done of her lumbar spine because of low back pain. Med. recs. at Ex. 14, p. 233. She had a moderate-sized left posterior paracentral disc herniation at L5-S1. *Id.* On a form petitioner filled out for the MRI on March 24, 1999, petitioner stated she had a history of L5-S1 disc herniation in 1992. Med. recs. at Ex. 14, p. 239. She stated that she had low back pain with pain radiating into her legs, mostly the left leg entirely and to the ankle. The pain was worse when sitting. Med. recs. at Ex. 14, p. 241.

On July 16, 1999, petitioner took a cardiac stress test for evaluation of chest pain. Med. recs. at Ex. 14, p. 226. Dr. Scott M. Hamilton's impression was episodic chest pain of uncertain etiology. Petitioner described a one-year history of positional substernal chest pain, triggered by left lateral decubitus positioning and relieved by repositioning. Med. recs. at Ex. 14, p. 227. The pain was sharp in character. Med. recs. at Ex. 14, p. 226. The pain occasionally wakened her from sleep. *Id.* Petitioner had an abnormal baseline EKG. Med. recs. at Ex. 14, p. 229. She had a left axis deviation and nonspecific St-T abnormality. Med. recs. at Ex. 14, p. 228.

On September 8, 2000, petitioner had an MRI done of her lumbar spine. Med. recs. at Ex. 14, p. 219. She had leftward disc herniation at L5-S1. Similar findings were seen on a prior study dated March 24, 1999. *Id.* On September 8, 2000, petitioner filled out a form for the spinal MRI, stating she had had low back pain for 28 years after falling down the stairs in 1971 or 1972. The pain radiated into her left leg. The pain was worse when sitting or standing and changed the way she walked. Med. recs. at Ex. 14, p. 223.

On September 12, 2000, petitioner saw physician's assistant Kathy Walton-Vecchio. Med. recs. at Ex. 16, p. 24. A few weeks ago, she was cleaning her home and awoke the next day with excruciating exacerbation of her low back discomfort which caused pain down the

posterior left leg that was so intense, she could barely lift her leg. She was given Ultram and Relafen, but developed severe nausea and dizziness. She stopped the drugs. MRI revealed the same L5-S1 disc herniation. The assessment was low back pain with radiculopathy. She was very frightened of surgery. *Id.*

On October 9, 2000, petitioner had a neurosurgical evaluation with Dr. Richard V. Buonocore for low back pain with radiation down the left leg. Med. recs. at Ex. 16, p. 8. Petitioner stated her low back pain with occasional radiation down her left leg dated back 28 years. She had had intermittent, brief flare-ups. Most recently, in September 2000, she developed low back pain with severe radiation down her left leg into the posterior thigh and calf as well as the left heel associated with numbness and tingling in the toes. She said this pain was quite severe compared to previous symptoms. It interfered with her activities and she missed a few days of work. She had difficulty walking because of the pain. The pain went from her low back into her left buttock, left posterior thigh, calf, and heel associated with numbness and tingling in her toes. The pain increased when she sat for a long time or got into an awkward position. *Id.* She had anxiety at times but did not take medication. *Id.* On examination, petitioner did not have any neurological deficits or evidence of cauda equina syndrome. Med. recs. at Ex. 16, p. 9. The MRI revealed a disc herniation at L5-S1 compressing the S1 nerve root. This did not appear to be a large piece of disc though there was eccentric paracentral extending at L5-S1 on the left. *Id.*

On October 18, 2000, petitioner telephoned Dr. Buonocore, stating she had taken the full Medrol Dose Pack and had no relief of her low back and left leg pain. The pain was so severe, she could not sit. She wanted to proceed with surgery. Med. recs. at Ex. 16, p. 20.

On October 23, 2000, petitioner returned to Dr. Buonocore, complaining that, even though she was given anti-inflammatory agents and analgesic therapy, her pain increased and was so debilitating that she could not continue with her daily activities. It often woke her at night. Med. recs. at Ex. 16, p. 19. She could not get in a comfortable position. The pain went down the posterior lateral aspect of her leg and terminated in her foot associated with severe numbness. On physical examination, she did not have any significant weakness. She could do a deep knee bend and walk on her heels and toes. *Id.*

On October 31, 2000, petitioner had a left L5-S1 microdiscectomy for a herniated lumbar disc, left L5-S1. Med. recs. at Ex. 14, p. 180. Petitioner had a six- to eight-week history of progressive pain down her left leg in an S1 distribution. She was given aggressive medical therapy, steroids, anti-inflammatory agents, and analgesics, but said her symptoms had increased. She said the pain was so severe, she could not walk. *Id.*

On March 1, 2001, petitioner saw Dr. Buonocore, the neurosurgeon, after twisting to grab a book and experiencing significant low back strain and pain which radiated down her left leg. Dr. Buonocore thought she had some muscle strain which was improving on its own. Med. recs. at Ex. 16, p. 15.

Petitioner received her first hepatitis B vaccination on June 20, 2001. Med. recs. at Ex. 1, p. 1.

Petitioner received her second hepatitis B vaccination on July 20, 2001. *Id.*

On September 14, 2001, petitioner went to Total Rehab Care at Robinwood and saw physical therapist Mark R. Lewis. Med. recs. at Ex. 14, pp. 156-57. She was referred to the clinic for lower back pain. She had a discectomy in October 2000 secondary to herniations

causing pain, but currently had lower extremity pain and some residual pain in the lower back. She had decreased lumbar flexion with pain in the sacral region and in the contralateral hips, and pain and parasthesias in both legs. Petitioner had pain lifting, bending, and sitting. She had decreased ability to perform work-related tasks unhindered by pain. Med. recs. at Ex. 14, p. 156.

On September 17, 2001, petitioner went to rehab at Washington County Health System and said she felt more flexible and less stiff. Med. recs. at Ex. 14, p. 149. She complained of sharp pain along her left chest both anteriorly and posteriorly last night when sleeping on her left side and on her back. She had this a year ago and had her heart checked out. She was told that the pain was from her bone structure. *Id.*

On September 19, 2001, petitioner returned for rehab and continued to complain of soreness across the lower lumbar spine left to right. Her stiffness had decreased from doing exercises. She continued to experience lower leg pain in both legs and pain behind the left knee. She reported feeling sore after taking medication. *Id.*

On September 24, 2001, petitioner returned to rehab, reporting an increase in pain over the weekend. She decided to stop the strengthening exercises and just do stretching until she could see the physical therapist again. Med. recs. at Ex. 14, p. 150. Palpation revealed pain in the lower posterior superior iliac spine, left rotated sacrum, elevated anterior superior iliac spine. Petitioner was to continue with home exercise program. The assessment was that petitioner had confirmed pelvic instability and trunk weakness. *Id.*

On September 26, 2001, petitioner returned to rehab and rated her pain as two out of 10 with a complaint of tenderness along the right sacral iliac region. She also complained of discomfort in both heels of her feet. *Id.*

On October 2, 2001, petitioner returned to rehab, reporting that her pain was two out of 10 in the left sacral iliac region. Petitioner reported a pulling sensation when doing cat and camel exercises. She was assessed with trunk instability and weakness. Med. recs. at Ex. 14, p. 151.

On October 9, 2001, petitioner returned to rehab, reporting two out of 10 pain in the lower sacral iliac region. She stated, "I'm just falling apart I guess." *Id.* The assessment was that residual pain might be from degeneration. *Id.*

On December 7, 2001, petitioner had an MRI done of her lumbar spine because of low back pain and numbness in her left leg. Med. recs. at Ex. 14, p. 136. This was compared with a prior study done September 8, 2000. At the L1-2 level, there was minimal diffuse posterior disc bulge which seemed similar to that seen previously. *Id.* At the L2-3 level, there was slightly more prominent left foraminal focal disc protrusion demonstrated, causing mild left neural foraminal stenosis. Med. recs. at Ex. 14, pp. 136-37. At the L5-S1 level, there was interval laminectomy with removal of the previously-seen L5-S1 intervertebral disc herniation. Scar tissue was about the operative site, including the area of the left S1 nerve root. Med. recs. at Ex. 14, p. 137.

Petitioner received her third hepatitis B vaccination on December 20, 2001. Med. recs. at Ex. 1, p. 1.

On December 28, 2001, petitioner went to Washington County Hospital and saw Dr. J.S. Gomes, complaining of back pain. Med. recs. at Ex. 14, pp. 118, 120. Petitioner had a history of chronic back pain with surgery two years previously for discectomy. She went to physical therapy yesterday and, since that time, she had increasing numbness to the left leg as well as back

pain. She denied weakness, numbness, tingling to the upper extremities or to the right leg. She stated it worsened immediately after she had her physical therapy which involved a lot of manipulation over the sacral iliac region. She denied any saddle anesthesia, loss of control of her bladder or bowel or other complaints at that time. She took Skelaxin which gave her minimal relief. She felt as if she had jumping in her back. Med. recs. at Ex. 14, p. 118. Neurological examination was normal and there were no motor or sensory deficits. Med. recs. at Ex. 14, p. 119. Dr. Gomes diagnosed reticular back pain. Med. recs. at Ex. 14, p. 120.

On January 4, 2002, petitioner saw physician's assistant Sherry Berglund, complaining of back pain, some bladder pressure, and urinary frequency in the prior two days, but stated she was better that day. Med. recs. at Ex. 9, p. 23. She had no burning with urination. She had back surgery in October 2000. She had an MRI in November 2001 for persistent sciatica. The MRI showed a disc protrusion at L2-3, more prominent than on previous MRIs. Petitioner stated she had been going to physical therapy, but at the last treatment, the new therapist pressed on her lower back and caused nerve irritation. She went to the ER on December 28, 2001 and was given five days of Prednisone which helped the pain somewhat. She was also taking Skelaxin. She wanted to see a neurosurgeon. The diagnosis was persistent sciatica. *Id.*

On January 8, 2002, petitioner saw Dr. Michael G. Radley for a neurosurgical evaluation concerning her lower back pain, bilateral leg pain, and burning in her feet. Med. recs. at Ex. 16, p. 6. On December 23, 2001, petitioner had an abrupt onset of diffuse body ache and burning sensation throughout her body which then localized into her back. She did not have fever or chills. She had hepatitis B vaccine about two days before the onset of her symptoms. She had bilateral leg pain which she described as a burning sensation to the feet. Her primary care

physician put her on Prednisone and Vioxx which caused her to develop diarrhea and she stopped taking it. The Prednisone initially relieved her discomfort. After stopping the Prednisone, she had return of her symptoms. Currently, she said she had diffuse burning pain that started in her back and radiated down both legs. *Id.* Physical therapy exacerbated her symptoms with discomfort in the lower back. *Id.* Petitioner's physical examination was normal neurologically. Med. recs. at Ex. 16, p. 7. Dr. Radley diagnosed radiculitis vs. neuritis. *Id.*

On January 10, 2002, petitioner saw Dr. Louise R. Butler, stating that on December 23, 2001, three days after receiving her third hepatitis B vaccination, she had multiple joint pain throughout her body which was like burning pain. Med. recs. at Ex. 9, p. 22. She also had increased low back pain. An MRI showed slightly more bulging disc than before but her neurosurgeon said this was not causing her pain. She had abdominal cramping and diarrhea for quite some time. She thinks that all her symptoms are due to hepatitis B vaccine. Dr. Butler agreed. She took Lortab for pain and broke out in a rash. She took Benadryl for the rash and her joint pain and diarrhea improved. She was extremely nervous about the whole situation. She had some tenderness to palpation of the knees and elbows but no weakness or sensory/motor deficits. Dr. Butler diagnosed a vaccine reaction. *Id.*

On January 11, 2002, petitioner went to the Washington County Hospital where she saw Dr. Scott Wegner who diagnosed chronic low-back pain. Med. recs. at Ex. 14, pp. 106-07. Petitioner had a long history of back pain. She had lumbar discectomy in December 2000. Since December 2001, she had a recurrence of low-back pain and some burning pain in her lower legs. She saw her neurosurgeon and had an MRI. Petitioner reported that her symptoms significantly worsened since the MRI. The MRI did not show any significant pathology. Petitioner did not

have focal numbness or weakness. Med. recs. at Ex. 14, p. 106. Dr. Wegner prescribed Prednisone. Med. recs. at Ex. 14, p. 107.

On January 17, 2002, petitioner had an MRI of her lumbar spine which showed mild degenerative disc disease at L1-2 and L2-3, as well as postoperative left-sided discectomy changes at L5-S1. Med. recs. at Ex. 14, p. 94. There was a small amount of enhancing scar tissue in the left S1 nerve root. Med. recs. at Ex. 14, p. 95. In a form filled out for the Washington County Health System before the spinal MRI on January 17, 2002, petitioner wrote that she had had low back pain for years with pain radiating into both legs which was worse when she sat or stood and changed the way she walked. Med. recs. at Ex. 14, p. 100.

On January 21, 2002, petitioner saw Dr. Marc Loev, a pain specialist. Med. recs. at Ex. 2, p. 2. Petitioner complained of pain in her low back, legs, and arms. She complained of tingling and burning sensations diffusely throughout her body, most prominent in her lumbosacral axial spine with extension down the posterolateral portion of both legs in the L5 and S1 dermatomes. She noted similar sensations in all thoracic dermatomes, neck, and upper extremities. She complained of blurriness. She stated onset was several days following a hepatitis B vaccination. She had a L5-S1 microdiscectomy in October 2000. She had degenerative joint disease of her left shoulder, arm, and cervical spine. She denied any bladder or bowel changes. She lay down constantly during the day. She lost five pounds over the last few weeks. She denied fever. *Id.* Her physical examination was normal. Med. recs. at Ex. 2, p. 3.

On January 23, 2002, petitioner returned to Dr. Butler for follow-up of her low back pain. Starting the day before, she had urinary frequency. Med. recs. at Ex. 9, p. 24. She was extremely anxious. An MRI did not show any significant nerve impingement. *Id.*

On January 24, 2002, petitioner had a brain MRI with gadolinium done because of a burning sensation in all extremities. Med. recs. at Ex. 14, p. 86. She had two foci of increased T2 signal in the periventricular white matter which was likely due to age-related changes, although the possibility of MS could not be ruled out completely. *Id.*

On January 30, 2002, petitioner returned to Dr. Loev after having a brain MRI, which revealed two foci of increased T2 signal in the periventricular white matter. Med. recs. at Ex. 2, p. 1. Dr. Loev recommended petitioner see a neurologist at Johns Hopkins who specializes in MS. *Id.*

On February 1, 2002, petitioner saw Dr. Ira L. Fedder, an orthopedic surgeon, for significant back, buttock, and leg symptoms. Med. recs. at Ex. 13, p. 6. An MRI done on January 17, 2002 showed degenerative changes in the L5-S1 disc space. *Id.*

On February 20, 2002, petitioner had a nerve conduction study and electromyography because of a stinging and burning sensation at the posterior aspect of the leg to the heel. Med. recs. at Ex. 11, p. 3. Dr. Jamal F. Ali wrote that the NCS was normal and there was EMG evidence of a possible mild degree of chronic bilateral L5 radiculopathy. There was no EMG evidence of peripheral neuropathy or peroneal mononeuropathy. *Id.*

On February 23, 2002, petitioner went to the hospital and saw Dr. Scott Wegner for severe pain. Med. recs. at Ex. 14, p. 76. She had a long history of burning pain involving her neck, back, arms, trunk, and legs since December 2001. The onset was two to three days after

she received hepatitis B vaccine. She had extensive work-up from neurosurgery, neurology, and her primary care physician to try to ascertain the cause for the pain. *Id.* On examination, she did not have any obvious motor or sensory deficits. Med. recs. at Ex. 14, p. 77. Dr. Wegner diagnosed her with myofascial pain syndrome. *Id.*

On March 1, 2002, petitioner saw registered nurse Lisa Santor for a questionable reaction to hepatitis B vaccine for two months. Med. recs. at Ex. 14, p. 70. Petitioner had intermittent bumps on the roof of her mouth, fast heart beat, and a funny sensation over her entire body. *Id.*

On March 12, 2002, petitioner saw Dr. Michael G. Radley, the neurosurgeon, for follow-up. Med. recs. at Ex. 16, p. 11. He did not find evidence of an acute radiculopathy. Petitioner had good strength in her extremities. She ambulated without difficulty. *Id.*

On May 4, 2002, petitioner saw Dr. Kris Oursler of the University of Maryland Institute of Human Virology, for an evaluation of a reaction to hepatitis B vaccine. Med. recs. at Ex. 10, p. 4. Petitioner's examination was essentially unremarkable. Med. recs. at Ex. 10, p. 8. Dr. Oursler discussed at length with petitioner and her husband that a systemic, non-IgE-related reaction to the hepatitis B vaccine may be a possibility but it would be a diagnosis of exclusion. There were no focal neurologic findings. *Id.*

On May 28, 2002, petitioner saw Dr. Mitesh Kothari for a possible yeast infection. Med. recs. at Ex. 7, p. 9. She did not have a yeast infection. Dr. Kothari suspected mild atrophic vaginitis due to menopause. *Id.*

On June 13, 2002, petitioner saw Dr. Charles J. Supernavage, an audiologist, for tinnitus. Med. recs. at Ex. 3, p. 1. She developed tinnitus over the prior three weeks. She had left ear pain and occasional off balance sensation. The right ear had a great deal of wax as did the left ear.

She had an improvement of her hearing following removal of the wax. *Id.* She had a high frequency hearing loss in both ears which might explain the tinnitus. Med. recs. at Ex. 3, p. 2. Petitioner complained of a salty taste in her mouth for about five years. It seemed to be increasing lately. Her dentist did not find anything wrong. Her primary care physician did not find anything wrong. *Id.* Dr. Supernavage diagnosed acute pharyngitis, Eustachian tube dysfunction, wax removed, and sensorineural hearing loss. Med. recs. at Ex. 3, p. 3.

On June 17, 2002, petitioner saw Dr. Violeta Rus, a rheumatologist, at the University of Maryland. Med. recs. at Ex. 8, p. 2. Petitioner had the onset of burning over her entire body associated with generalized arthralgias without true joint swelling or morning stiffness three days after her last hepatitis B vaccination. She did not have any constitutional symptoms, shortness of breath, chest pain, or facial or leg swelling. Later in the month, she had tingling in the sacral area and was referred to physical therapy. Around New Year's, she went to the ER where she was diagnosed with nerve root irritation secondary to spinal manipulation. She was prescribed Prednisone which relieved 75% of her symptoms. She could not tolerate Vioxx or Celebrex. A second round of Prednisone had no effect. She had a brain MRI which revealed two lesions that were felt to be benign. EMG and nerve conduction studies were normal. She complained to Dr. Rus that she had restless legs and arm twitchings. She still had a stinging sensation over her lower occiput, pain in her shoulders, and left-sided neck pain radiating to her deltoids. She had stiffness in her elbows in the morning, back of her knees, and both feet. She had poor sleep habits and frequent sleep interruption. She was hypersensitive to noise. She had age-related hearing loss. *Id.* Her mother had a benign brain tumor by MRI. Med. recs. at Ex. 8, p. 4. Petitioner had a normal physical examination except for minimal tenderness over the

supraspinatus tendon bilaterally. There was a small well-healed vertical scar post-discectomy. Med. recs. at Ex. 8, p. 3. Petitioner did have 12 out of 18 tender points. Dr. Rus diagnosed petitioner with a history of paresthesias, negative physical examination, and multiple tender points. The most likely diagnosis was fibromyalgia syndrome. Her paresthesias had an unclear etiology. Dr. Rus prescribed Flexeril to improve petitioner's sleep. *Id.*

On July 9, 2002, petitioner saw Dr. Louise R. Butler for diffuse joint pain. Med. recs. at Ex. 9, p. 15. Dr. Butler was unsure if petitioner had fibromyalgia or continued mild lupoid[2] reaction to hepatitis B vaccine. Petitioner refused to take anti-depressants. *Id.*

On July 24, 2002, petitioner went to physical therapist Kay C. Reed, unsure of the fibromyalgia diagnosis. Med. recs. at Ex. 14, p. 50. Petitioner stated she had had difficulty sleeping for several years and experienced body aches and pain as well. However, her symptoms significantly increased in the prior year. She reported having a hepatitis B vaccination in June 2001, July 2001, and December 2001 with a severe increase in pain after the third injection. She complained of pain in her shoulders, hips, and knees which was burning. She had fatigue and non-restful sleep. *Id.* She went to bed from 9-10 p.m. and woke at 5:30 a.m. but woke 6-10 times a night. Med. recs. at Ex. 14, p. 51. She stated she walked one and one-half miles a day. Med. recs. at Ex. 14, p. 52.

On July 26, 2002, petitioner had an MRI of her brain done. In comparison with her brain MRI of January 24, 2002, she did not have any new white matter abnormalities. She had small

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[2] Lupoid "is pertaining to or resembling lupus." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1072.

areas of white matter signal abnormality in both frontal lobes which were non-specific in appearance. Med. recs. at Ex. 14, p. 64.

Also on July 26, 2002, petitioner had an MRI of her cervical spine done. *Id.* She had significant disc disease at C6-7 with disc narrowing more prominent ventrally with prominent ventral osteophyte formation. *Id.*

On August 6, 2002, petitioner saw Dr. Christopher T. Bever, Jr., a neurologist, at the University of Maryland School of Medicine, Maryland Center for MS. Med. recs. at Ex. 6, p. 3. His impression was that petitioner had generalized pain, but no MS on clinical presentation. Med. recs. at Ex. 6, p. 5.

On August 27, 2002, petitioner saw Dr. John A. Flynn and Dr. Rachel L. Derr at Johns Hopkins for evaluation of myalgias and an elevated rheumatoid factor. Med. recs. at Ex. 15, p. 6. Petitioner had onset of stinging pain throughout her body in December 2001, two days after her third hepatitis B vaccination. She tolerated the first two hepatitis B vaccinations well but, in retrospect, noted some radical pain and a week of severe headaches after the second vaccination. On December 23, 2001, the onset of stinging pain occurred while she was sleeping, awakening her. Even light touch caused significant pain and her clothes hurt her. Her skin felt as if it were on fire. She did not have associated joint swelling, redness, warmth, or pain. She did have an associated skin rash on her arms and the medial portion of her legs. *Id.* Together with the onset of her pain was constipation alternating with diarrhea. Petitioner's symptoms were quite severe in January and February 2002 and she stayed in bed unable to go to work. She responded to Prednisone at first. A brain MRI showed two areas of increased T2 signal intensity in the periventricular white matter, but two neurologists did not diagnose MS. A second brain MRI in

July 2002, six months after the first MRI, showed the white areas completely unchanged. She had nerve conduction studies done which were normal. *Id.* A nurse practitioner in rheumatology diagnosed fibromyalgia. Med. recs. at Ex. 15, p. 7. Petitioner returned to work on March 8, 2002, and had gradual improvement in symptoms. She stated she was 80% improved. On a daily basis, she had mild stinging pain which worsened when she was tired. She had normal bowel movements. She denied fever, chills, night sweats, changes in weight, headaches, visual disturbances, oral lesions, difficulty swallowing, shortness of breath, chest pain, abdominal pain, joint swelling, joint stiffness, numbness, tingling, or dizziness. She had a low back surgery, L5-S1 discectomy in October 2000. Her mother had arthritis, osteoporosis, hypertension, and stroke. Her physical examination was normal. On January 10, 2002, petitioner had a rheumatoid factor of 8.6. On April 23, 2002, it was 92.5. On June 7, 2002, it was 42.8. On July 16, 2002, it was 57.4. ANA was nonreactive on two measurements. The doctors' assessment was that petitioner did not have rheumatoid arthritis. *Id.* In addition, there was no evidence of any active autoimmune disease. Med. recs. at Ex. 15, p. 8. It was unclear what caused the onset of her stinging pain in late December, but she was markedly improved. *Id.*

On January 28, 2003, petitioner had a repeat brain MRI. MEd recs. at Ex. 14, p. 22. She had minimal non-specific periventricular white matter signal abnormality in the left frontal lobe. She also had microvascular ischemic changes. There were no new abnormalities. *Id.*

On March 20, 2003, petitioner went to Dr. Kothari for her annual physical examination. Med. recs. at Ex. 7, pp. 7-8. Her examination was normal. *Id.* at 8.

On May 2, 2003, petitioner saw Dr. Paul C. Waldman, a dermatologist, for areas of erythematous, eczematous patches involving several fingers and the forearm region. Med. recs. at Ex. 4, p. 17. Dr. Waldman diagnosed psoriasis or possibly dermatitis. *Id.*

On May 5, 2003, petitioner returned to Dr. Supernavage, with continuing tinnitus. Med. recs. at Ex. 3, p. 3. Her right and left ears had a great deal of wax. *Id.* Dr. Supernavage diagnosed wax removal and sensorineural hearing loss. Med. recs. at Ex. 3, p. 4.

On June 3, 2003, petitioner saw Dr. Flynn again. Med. recs. at Ex. 15, p. 4. Symptomatically, she improved significantly. A neurologist at the University of Maryland evaluated her for possible MS and found that she had no firm evidence of MS. She described self-limited intermittent myalgias and arthralgias. She was on a regular walking program. Her physical examination was normal. Dr. Flynn could not diagnose rheumatoid arthritis. *Id.* He concluded she had no clinical evidence to suggest an autoimmune disease. Med. recs. at Ex. 15, p. 5.

On July 21, 2003, petitioner had a bilateral lower extremity venous ultrasound because of left leg pain. Dr. Daniel O. Donkor wrote there was no evidence of deep vein thrombosis in the lower extremities. Med. recs. at Ex. 9, p. 6.

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, 956 F.2d 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 whatever she had, but also that the vaccine was a substantial factor in bringing about whatever she had. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

In the instant action, petitioner has had pain in her back and leg for decades. She has not been diagnosed with a neurologic condition post-vaccination. She has never been diagnosed with MS and her symptoms are not MS-like. She has one diagnosis of fibromyalgia and also myofascial pain syndrome. The one constant is that all her physical examinations are normal. Except for a rough physical therapy session on December 27, 2001 which exacerbated the

chronic pain in her low back, she has never been diagnosed consistently with any particular condition. The holdings in the Omnibus proceeding concerning hepatitis B vaccine and demyelinating illnesses such as MS do not apply to this case.

Petitioner is ORDERED TO SHOW CAUSE why this case should not be dismissed by **August 31, 2007.**

IT IS SO ORDERED.

June 14, 2007
DATE

s/Laura D. Millman
Laura D. Millman
Special Master