In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. [redacted]V
July 31, 2008
To be Published

JANE DOE/22,	*	
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Petitioner,	*	
	*	
v.	*	Entitlement; hepatitis B vaccine followed by heel pain; next hepatitis B vaccine followed by arm pain; upper respiratory infection and small fiber neuropathy/GBS variant
	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

Clifford J. Shoemaker, Vienna, VA, for petitioner.
Rebecca I. Trinrud, Washington, DC, for respondent.

MILLMAN, Special Master

RULING ON ENTITLEMENT[1]

Petitioner filed a petition on May 21, 1999, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that she received hepatitis B vaccine in January 1995,

[1] 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. Because of the sensitive nature of some of petitioner's medical history, the undersigned assumes petitioner would want her name redacted and has done so sua sponte.

followed by pain in her heels within a week, and received hepatitis B vaccine on February 25, 1995, followed by pain in her arms within 24 hours. Petition, ¶ 2 (this is the second paragraph 2). Over the next two months, she had fatigue and heel pain and, a few weeks after an upper respiratory infection, had symptoms diagnosed as small fiber neuropathy.

According to petitioner's affidavit dated April 24, 2002, she received her first hepatitis B vaccination on January 28, 1995, which was a Saturday. P. Ex. 11, p. 1. The next day, she woke to severe pain in both her heels. After one week, the symptoms disappeared. *Id.* On the day after her second vaccination in February 1995, she had pain in her arms from her shoulders to her hands, which lasted 48 hours. P. Ex. 11, p. 2. She states that, throughout March and April 1995, she had several episodes which lasted 48 hours and then disappeared. *Id.* In June 1995, petitioner started a new job and her heel pain returned, spreading to her toes and ankles. *Id.*

On May 21, 1999, this case was initially assigned to former special master E. LaVon French.

On August 3, 1999, the chief special master reassigned the case to himself.

On April 5, 2001, the chief special master reassigned the case to the undersigned.

On December 5, 2002, the chief special master reassigned the case to himself.

On May 7, 2003, the chief special master reassigned the case to former special master Margaret M. Sweeney.

From October 13-15, 2004, former special master Margaret M. Sweeney held an Omnibus proceeding concerning whether hepatitis B vaccine can cause demyelinating diseases, specifically transverse myelitis (TM), multiple sclerosis (MS), Guillain-Barré syndrome (GBS), and chronic inflammatory demyelinating polyneuropathy (CIDP). The instant action was one of

the 65 cases in the Omnibus proceeding which focused on four paradigm cases. The results in those paradigm Omnibus cases apply to all the cases.

On January 11, 2006, the chief special master reassigned this case and all the Omnibus cases to the undersigned. The undersigned held in the four paradigm cases of the Omnibus proceeding that hepatitis B vaccine could cause TM, MS, GBS, and CIDP and did so in all the paradigm cases.[2]

On April 25, 2008, the undersigned held a hearing in this case. Testifying for petitioner were petitioner and Dr. Carlo Tornatore. Testifying for respondent was Dr. Subramaniam Sriram.

FACTS

Before Hepatitis B Vaccination

Petitioner was born on November 25, 1961.

On September 29, 1982, petitioner saw Dr. Robert G. Feldman, a neurologist, on referral from her neurologist Dr. Herbert Bernstein for a second opinion. Med. recs. at Ex. 29, p. 2. Petitioner had been unsteady, heavy-headed, nauseated, and "drugged" since beginning Tegretol, which was reasonable because the drug is very potent. She began with 200 mg. three times daily. This was discontinued since the prior evening. Before that, she had been on Dilantin 300 mg. daily until September 3rd or 5th. *Id.* This was started in August when she was diagnosed with headaches. An EEG was interpreted in August as abnormal. No definite diagnosis of epilepsy,

[2] Stevens v. Secretary of HHS, No. 99-594V, 2006 WL 659525 (Fed. Cl. Spec. Mstr. Feb. 24, 2006) (TM); Gilbert v. Secretary of HHS, No. 04-455V, 2006 WL 1006612 (Fed. Cl. Spec. Mstr. Mar. 30, 2006) (CIDP); Werderitsh v. Secretary of HHS, No. 99-310V, 2006 WL 1672884 (Fed. Cl. Spec. Mstr. May 26, 2002) (MS); Peugh v. Secretary of HHS, No. 99-638V, 2007 WL 1531666 (Fed. Cl. Spec. Mstr. May 8, 2007) (GBS and death).

seizure equivalent, or migraine was ever made. Review of the reports of August 24, 1982 and the description of the EEG were compatible with a drowsy and sleeping record of a person of petitioner's age. Dr. Feldman did not consider the EEG abnormal. An EEG done on April 23, 1976 was also normal. This EEG was also done because of the diagnosis of headache associated with some other systemic illness. Petitioner had not had headaches regularly until the summer. During the summer, she began to have a dull ache almost daily. It was not pounding or associated with nausea, vomiting, or flashing lights. She did not have any other neurological symptoms except for distractibility, poor concentration, and light-headedness. *Id.* She felt she was short of breath. She described some tingling over the right temporomandibular area and over the temporalis muscle. The tenderness was under the scalp on the right side of her head more than on the left, but it occurred bilaterally. A CT scan done at Cardinal Cushing Hospital in early September was normal, but Dr. Feldman wanted to see the pictures. Petitioner's past history included periodic abdominal pain . There was a family history of Mediterranean fever.[3] *Id.*

Hypoglycemia was diagnosed with a blood sugar as low as 38. Med. recs. at Ex. 29, pp. 2-3. Symptoms of cold and clammy agitation common during the summer did not recur while petitioner was in school. Med. recs. at Ex. 29, p. 3. The headaches occurred mostly in the evening around 7:00 p.m. about one and one-half to two hours after she ate supper. The dull ache persisted. *Id.*

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[3] Mediterranean fever or brucellosis is "a generalized infection caused by species of *Brucella*. transmitted by contact with the natural animal reservoirs, including cattle, sheep, goats, swine, deer, and rabbits, or their infected products or tissue. It involves primarily the reticuloendothelialsystem and is characterized by fever, sweating, weakness, malaise, and weight loss." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 256.

Petitioner's bite was a little bit off to the side when she opened her mouth. There was some crepitus at the temporomandibular joint bilaterally, but more laxity and mobility on the right as compared to the left. After opening her jaw and putting pressure in the joints, she reproduced the discomfort she had when she had a headache. *Id.*

On January 24, 1991, petitioner went to the Cambridge Hospital with panic attacks. She had an increase in acute anxiety. She had the same attacks three years previously. She had an increase in palpitations, stomach pain, diffuse concentration, and an increase in dread. Med. recs. at Ex. 21, p. 76.

On March 8, 1994, petitioner went to the Cambridge Hospital because she had thoughts of killing herself. Med. recs. at Ex. 21, p. 54. She was referred by Dr. Barnes. She reported feeling suicidal for one month, making plans to overdose on heroin with an IV overdose. She reported having heroin at home and a needle to use. She denied ever having hurt herself in the past. She had been "getting ready for this" for a month, cleaning out her closets and cleaning up her computer files. *Id.*

Petitioner was not in treatment at present. She discontinued medications and therapy in December 1993, reportedly at the urging of her husband. She had seen a therapist from May to December 1993 named Virginia Youngren at MacLean. She was on Prozac, Depakote, Trilator, Augmentin, and Xanax. She was on Depakote for a positive EEG which she reported disagreeing with because of no history of seizures. She felt she was overmedicated and the medicines did not help. She spoke with Dr. Barnes about getting a new therapist. She was last hospitalized in December 1993, precipitated by the news that her partner had a terminal illness. The diagnosis was to rule out major depression. *Id.*

Petitioner reported family problems, but would not elaborate. Her mother had a history of depression and her mother's father committed suicide. Med. recs. at Ex. 21, p. 55. Petitioner was employed as a per diem psychiatric nurse at a hospital. She had been married for two years to a gay man. She was a lesbian who had not been seeing a female partner since October. The hospital notes describe petitioner as a 32-year-old lesbian who was casually dressed with adequate hygiene who was guarded and initially slow to engage. Her mood was depressed and her affect constricted. She had planned to commit suicide by overdosing on heroin but denied having a specific time or date to do it. She denied psychotic symptoms. She had audiovisual hallucinations and paranoid ideation. She had flight of ideas and looseness of associations. *Id.* Her insight and judgment were poor. She was hopeless, stating, "I don't think I can be helped." The doctor's opinion was that she was commitable. The plan was section 12 to Waltham Westan for admission, treatment, and medication. Dr. Barnes was aware of this and would be in contact. Petitioner was not happy about the hospital admission and starting rocking and shaking when she found out. *Id.*

On March 15, 1994, petitioner saw Dr. Monika M. Eisenbud, a psychiatrist, for depression. Med. recs. at Ex. 23, p. 10. Petitioner had been hospitalized several times for depression. *Id.*

On March 21, 1994, petitioner saw Dr. Eisenbud again. Med. recs. at Ex. 23, p. 14. She had some depression as an adolescent. Med. recs. at Ex. 23, p. 15. She had difficulties with her therapist and was sent to a hospital for one week. Med. recs. at Ex. 23, p. 16. Petitioner filled out a questionnaire for Dr. Eisenbud on March 21, 1994. Med. recs. at Ex. 23, p. 118. She stated

she had a chronic medical problem of back injury. Med. recs. at Ex. 23, p. 119. She had a psychiatric hospitalization in March 1994 for depression. *Id.*

On March 28, 1994, petitioner saw Dr. Eisenbud again. She looked depressed but was able to go to work. She felt down and her chest hurt as if it were hard to breathe. Med. recs. at Ex. 23, p. 11. On March 28, 1994, Dr. Eisenbud filled out a psychiatric/substance abuse outpatient treatment authorization request. Med. recs. at Ex. 23, p. 123. Petitioner had major depression which was recurrent, severe, and in remission. *Id.* She had been severely depressed, acutely suicidal with a plan with multiple psychiatric hospitalizations during the prior year. She developed repressive transference relationships with past therapies. She had some dissociative episodes, including physically destructive episodes, in therapists' waiting rooms. *Id.* Petitioner had several years of psychotherapy, particularly in the prior two years, some of it intensive. *Id.* Her present functioning was much improved. She was able to work and planning to resume studies. *Id.* Dr. Eisenbud hoped to keep petitioner that way, but there might be recurrent decompensation. *Id.* Petitioner had a mild case of post-traumatic stress disorder following a relationship that in effect was victimizing. Med. recs. at Ex. 23, p. 124. The target symptoms to be addressed were that she remained steeped in recollection and had emotion cathecting[4] in that situation. *Id.*

On April 6, 1994, petitioner saw Dr. Eisenbud again. Increasing her dose of Zoloft helped. Med. recs. at Ex. 23, p. 18.

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[4] Cathexis is "in psychiatry, conscious or unconscious investment of psychic energy in a person, idea, or any other object." Dorland's Illustrated Medical Dictionary, 38th ed. (2003) at 310.

On April 19, 1994, petitioner saw Dr. Eisenbud again. She felt less depressed and mentally better. Med. recs. at Ex. 23, p. 13.

On May 2, 1994, petitioner saw Dr. Eisenbud again. She wanted to know if the prescriptions were making her sick. Past therapy did not serve her well. She was diagnosed with a dissociative disorder.[5] Med. recs. at Ex. 23, p. 21. She wanted to visit monthly. *Id.*

On May 14, 1994, Dr. Eisenbud wrote a letter to Dr. Barnes stating petitioner was continuing to do well. With petitioner's recent turbulent history, she might experience changing needs. Med. recs. at Ex. 23, p. 22.

On May 31, 1994, petitioner saw Dr. Eisenbud. She was doing well. She was still socially awkward in lesbian circles and "came out" April 28th. She was on Xanax. Med. recs. at Ex. 23, p. 23.

On July 5, 1994, petitioner saw Dr. Eisenbud. She was stressed out. Dr. Eisenbud increased her Zoloft. Med. recs. at Ex. 23, p. 24. Petitioner saw Dr. Eisenbud on September 20, 1994, September 27, 1994, October 11, 1994, October 19, 1994, October 25, 1994 (discussing the issue of anxiety), and December 27, 1994. Med. recs. at Ex. 23, pp. 25-30.

After Hepatitis B Vaccination

On Wednesday, January 25, 1995, petitioner began working as a licensed practical nurse for Health Resources in its Woburn, Massachusetts, office. (Woburn is 11 miles north of Boston.) P. Ex. 51, p. 1.

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[5] Dissociative disorders are "mental disorders characterized by sudden, temporary alterations in identity, memory, or consciousness, segregating normally integrated memories or parts of the personality from the dominant identity of the individual." Dorland's Illustrated Medical Dictionary, 38th ed. (2003) at 548.

Also on Wednesday, January 25, 1995, the human resources personnel of Health Resources in Boston gave petitioner a physical examination, testing her for TB exposure, hepatitis B surface antibody, and immunity to rubella, as well as examining her blood, urine, blood pressure, and pulse. Med. recs. at Ex. 24, p. 1.

On Friday, January 27, 1995, the report of the results of these tests came back from SmithKline Beecham Clinical Laboratories to Health Resources. Med. recs. at Ex. 24, p. 2. Petitioner had a high level of antibody to rubella, suggesting either previous infection or vaccination with rubella virus. However, petitioner had no detectable antibody to hepatitis B surface antigen, meaning she needed to be vaccinated. *Id.*

On January 27, 1995, according to a nurse's letter, petitioner received her first hepatitis B vaccination. Med. recs. at Ex. 24, p. 3. There is no record of her February 1995 vaccination although it was standard protocol to administer the second vaccination one month after the first. *Id.*

Deborah T. Talbot, RN, vice-president of Occupational Medicine at Health Resources in Woburn, sent a letter dated August 28, 1998 to petitioner. Med. recs. at Ex. 24, p. 3. Nurse Talbot stated that she had been looking for petitioner's specific hepatitis B vaccination forms, as she mentioned in an earlier conversation with petitioner. These vaccinations forms had been pulled and provided to petitioner some time previously. Nurse Talbot confirmed that Health Resources had documentation indicating that petitioner received her first hepatitis B vaccination on January 27, 1995. Jeanne Cotter, the nurse who delivered most of Health Resources' employee vaccinations, kept a list of vaccinated employees in her own files. Nurse Talbot stated that, although she could not locate petitioner's vaccination form, she had every reason to believe

that petitioner received her second hepatitis B vaccination in February 1995. That was part of their standard protocol to provide a second hepatitis B vaccination one month after the first vaccination. *Id.* Nurse Talbot, in a follow-up letter dated August 31, 1998, sent a letter to petitioner with the lot numbers of the two lots of hepatitis B vaccine that were administered from Oct. 13, 1994 to Apr. 27, 1995. Med. recs. at Ex. 24, p. 4.)

On June 28, 1995, five months after receiving her first hepatitis B vaccination and four months after receiving her second hepatitis B vaccination, petitioner saw Dr. Hilary Worthen at Cambridge Family Health. Med. recs. at Ex. 3, p. 13. She came in urgently that evening because of foot pain. She started a new job two and one-half weeks previously and had been having increasing pain in both feet. The pain was not bad in the morning, but as she stood all day, her feet became increasingly sore, until she was in agony at the end of the day. The pain started at the heel pad and extended along the lateral margin under the fourth and fifth metatarsals and then across the ball of the foot. When the pain was really bad, it seemed to develop into numbness and extend to her shins. She had an episode of this four months ago (February 1995), but she changed her shoes and it seemed to resolve. Otherwise, she never had a problem like this. Med. recs. at Ex. 2, p. 5.

On examination, petitioner had marked tenderness under the insertion of the plantar fascia and along the lateral aspect of the pad of the foot and into the metatarsal heads, particularly the left fourth metatarsal head which seemed to have dropped slightly. The x-rays looked unremarkable although the alignment might be off. The doctor was unsure of the problem but petitioner could have had some plantar fasciitis and there might be a neuroma developing. She needed orthotics, some nonsteroidals, and attention to the mechanics of her feet. The doctor

doubted petitioner had a vascular problem. *Id.* Dr. Worthen would try to get her an urgent appointment with a podiatrist on the next day. Med. recs. at Ex. 3, p. 13.

From June 29 to July 18, 1995, petitioner was at Mount Auburn Hospital. Dr. Barnes diagnosed short fiber polyneuropathy with neuropathic pain, probable GBS variant. Med. recs. at Ex 2, p. 138. About four weeks prior to admission, petitioner had a viral illness from which she recovered completely. Two days prior to admission, she developed a burning pain in the sole of one foot. Over the next two days, the pain increased to cover her entire foot, accompanied by a loss of sensation and numbness to her knees. She had no motor weakness and her reflexes were intact. She denied any prior episodes. *Id.*

Her past medical history included a herniated disc with back surgery in the 1980s, severe depression, chronic hospitalizations (with the last hospitalization in 1993), and migraine headaches. *Id.* On examination, she had normal motor strength and tone but sensory examination revealed decreased sensation to pin and light touch in a stocking distribution up to her ankles bilaterally. She had some dysesthesias[6] in her calves. She had normal reflexes. CSF showed a protein of 65. *Id.* Nerve conduction studies of her lower extremities and somatosensory evoked potentials were normal. An MRI of her cervical spine through lumbosacral spine was also negative. Rheumatoid factor was negative. Med. recs. at Ex. 2, p. 137. Over the next two weeks, petitioner had a gradual progression of her symptoms to include a loss of pinprick and light touch over her entire body, sparing only the inner aspect of her upper arms and upper thighs, and including her face. She developed severe, burning neuropathic pain

[6] Dysesthesia is "distortion of any sense, especially of that of touch ...an unpleasant abnormal sensation produced by normal stimuli." Dorland's Illustrated Medical Dictionary, 38th ed. (2003) at 574.

in both legs, right greater than left, extending on the right to her right lower quadrant and buttocks. Her reflexes remained brisk. She did not respond to a five-day course of Methylprednisolone IV. She also did not respond to a five-day course of IV immunoglobulin. She was transferred to the neurology unit of St. Elizabeth's Hospital. *Id.*

On July 1, 1995, petitioner had nerve conduction studies which were normal in the lower extremities. These findings excluded a pan-sensory polyneuropathy but not a small fiber nerve involvement. Med. recs. at Ex. 2, p. 134.

On July 18, 1995, petitioner was transferred to St. Elizabeth's Medical Center. Med. recs. at Ex. 10, p. 1. She was discharged two days later with a diagnosis of acute small fiber polyneuropathy and intractable pain. *Id.* A neurological fellow's note for Dr. Allan Ropper was that petitioner was previously healthy when three weeks previously, she developed bilateral burning and painful pins and needles on the bottom of both feet that spread up to the ankles over five days. Med. recs. at Ex. 10, p. 5. She had similar symptoms in the feet one month ago that resolved on its own. *Id.*

Another history and physical was taken on July 18, 1995. Petitioner had a three-week history of bilateral decreased sensation and burning pain in both lower legs. She was in her usual state of good health until June 27, 1995 when she developed burning pain in the soles of her feet. Over the next few days, the area of pain and decreased sensation advanced to the level of her knees. She had difficulty walking due to the pain, but denied any leg weakness or dizziness. Med. recs. at Ex. 10, p. 7. She also denied any similar episodes in the past. While hospitalized at Mount Auburn, her pain and decreased sensation advanced to the groin level and, on occasion, also involved both arms. *Id.*

On July 18, 1995, a nursing progress note states that petitioner was transferred from Mount Auburn Hospital with a chief complaint of bilateral foot pain and difficulty walking. She had no known past medical history. She was very weepy on admission. She ambulated independently from the stretcher to bed. She complained of burning pain in both feet. She was able to lift her legs off the bed. Strength was 4-/5 in the lower extremities and 5/5 in the upper extremities. Med. recs. at Ex. 10, p. 11.

A resident agreed with the nurse's note of two-week history of progressive paresthesias with burning, tingling, and numbness in the feet. *Id.*

On July 19, 1995, Dr. Ropper wrote that, on careful examination, there was a disturbing degree of inconsistency. Petitioner reported sensation was altered in her entire legs, buttocks, and perhaps above on the right side of her abdomen. This was in contrast to July 18, 1995, when petitioner felt pinprick without difficulty in her feet and posterior calves on some occasions, but was analgesic[7] on her anterior lower legs without clear dermatome[8] borders. Med. recs. at Ex. 10. p. 12. On pinprick of her legs, buttocks and low back, she jumped and winced, responding that pinprick was painful beyond normal. On the left lower back up to T8-T10, coolness was not felt well but pinprick was okay. On the anterior trunk (lower abdomen and groin), there were no sensory changes. Vibration and position sense were normal in the toes and feet. She could tell coolness from warmth in her legs. Her abdominal superficial and leg deep tendon reflexes were

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[7] Analgesic means "not sensitive to pain." Dorland's Illustrated Medical Dictionary, 38th ed. (2003) at 71.

[8] Dermatome means "the area of skin supplied with afferent nerve fibers by a single posterior spinal root; called also *dermatomic area*." Dorland's Illustrated Medical Dictionary, 38th ed. (2003) at 498.

normal. Sweating was normal. Dr. Ropper wrote, "We cannot easily attribute this to a small fiber neuropathy in view of buttock and truncal symptoms and unusual exam. A myelopathy[9] is possible but odd syndrome for demyelination." *Id.* Pain was still quite severe and she could not walk. She had had a depression but preferred not to have her psychiatrist involved. She had been recently divorced. *Id.*

On July 19, 1995, petitioner was tested for visual evoked responses, and tibial and median somatosensory evoked responses, all of which were normal. Med. recs. at Ex. 2, pp. 131-32.

On July 19, 1995, petitioner complained of nausea, but was able to eat a full lunch. Med. recs. at Ex. 10, p. 13.

On July 20, 1995, petitioner had an EMG which Drs. Drasko Simovich and Michael Hayes interpreted as normal, showing no electrophysiologic evidence of polyneuropathy,[10] radiculopathy,[11] or plexopathy.[12] Sympathetic skin response was present (normal) in all four extremities. Med. recs. at Ex. 2, p. 129; Ex. 10, p. 38.

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[9] Myelopathy is "any of various functional disturbances or pathological changes in the spinal cord, often referring to nonspecific lesions in contrast to the inflammatory lesions of myelitis." Dorland's Illustrated Medical Dictionary, 38th ed. (2003) at 1211.

[10] Polyneuropathy is "neuropathy of several peripheral nerves simultaneously." Dorland's Illustrated Medical Dictionary, 38th ed. (2003) at 1482.

[11] Radiculopathy is "disease of the nerve roots." Dorland's Illustrated Medical Dictionary, 38th ed. (2003) at 1562.

[12] Plexopathy is "any disorder of a plexus, especially of nerves." A plexus is "a network of lymphatic vessels, nerves, or veins." Dorland's Illustrated Medical Dictionary, 38th ed. (2003) at 1453.

On July 20, 1995, petitioner had an MRI of her thoracic spine which showed disc herniation at T3-T4, T5-T6, and T6-T7. Med. recs. at Ex. 10, pp. 47-48.

On July 20, 1995, at 2:00 a.m., petitioner complained that the bed was flipping and a woman was trying to strangle her. Med. recs. at Ex. 10, p. 16. She was reassured and fell asleep for two and one-half hours when she woke again and hallucinated more about a woman strangling her. *Id.*

From July 25 to August 3, 1995, petitioner was at Mount Auburn Hospital for a possible relapse of an acute sensory neuropathy. Med. recs. at Ex. 2, p. 126. In late June 1995, she developed pain and paresthesias in her heels and legs which progressed to severe paresthesias of her lower legs, hands, and arms, and eventually involved decreased pinprick sensation over her entire body. She had no motor involvement and her reflexes were preserved. She had a CSF protein of 65. An MRI of her entire spinal cord was negative. She had negative evoked sensory potentials and nerve conduction studies and electromyographic studies. A five-day course of IVIG did not help. On July 18, 1995, she was transferred to St. Elizabeth Hospital, Dr. Allen Ropper's service, for further evaluation and possible plasmapheresis.[13] A repeat CSF showed protein of 44. All central neurological studies were negative and her symptoms markedly improved. *Id.*

On physical examination, her motor strength was normal, her reflexes were intact, her sensory examination, including pinprick, light touch, and proprioception were within normal limits. *Id.* She had a fluctuating neurological examination with variable hypoesthesia in her legs

[13] Plasmapharesis is "the removal of plasma from withdrawn blood, with retransfusion of the formed elements into the donor." Dorland's Illustrated Medical Dictionary, 38th ed. (2003) as 1446.

up to her knees or thighs and sometimes in her arms to her shoulders, sparing her face. Med. recs. at Ex. 2, p. 125. A repeat CSF showed a protein of 38. Rheumatologic screening, including ANA, was negative. *Id.*

From August 3 to 16, 1995, petitioner was at Youville Hospital and Rehabilitation Center. She had initially been admitted to Mount Auburn Hospital in June 1995 with pain and paresthesias of the lower extremities, hands, and her entire body. Lumbar puncture, nerve conduction studies, EMGs, evoked sensory potentials, and MRI were all negative. Med. recs. at Ex. 2, p. 117. She was diagnosed with acute sensory polyneuropathy, variant of GBS. She was transferred to St. Elizabeth's Medical Center on July 18, 1995 and discharged two days later. She went back to Mount Auburn Hospital on July 25, 1995 with opiate withdrawal and hypoadrenal syndrome. Med. recs. at Ex. 2, p. 117.

Petitioner's past history included depression. She was on medication for it until 1993. She had had psychologic follow-up in the past. She had migraine headaches several years ago. She had low back pain secondary to disc disease at L4-L5 in 1984. *Id.* On examination, she had no focal neurologic deficit. She was divorced in March 1995. Med. recs. at Ex. 2, p. 116.

On September 8, 1995, petitioner saw Dr. Henrietta N. Barnes at Cambridge Family Health for follow-up for acute sensory polyneuropathy. Med. recs. at Ex. 2, p. 7. Petitioner could not walk around the block with exhaustion and continued to have some pain in her feet, and occasional tingling and numbness of her legs and occasionally her arms. Some days, she said she felt quite well whereas, on other days, she had more sensory problems. Occasionally, she had nausea and malaise. *Id.* Her examination revealed no motor findings. She had slight decrease in pinprick in her feet, but otherwise pinprick was intact. Her reflexes were 2+ and

symmetrical. Dr. Barnes' impression was that she was doing very well and gradually recuperating from sensory polyneuropathy. *Id.*

On October 5, 1995, Dr. Allan H. Ropper, Chief of the Department of Neurology at St. Elizabeth's Medical Center, wrote to Dr. Robin Barnes that he had seen petitioner again for her persistent pain. On examination, her reflexes were all quite brisk but not pathologic. Her sensory examination was "rather curious in that she reports the pin prick as dull all over the body, including the distal extremities. She easily distinguishes between sharp and dull and between several degrees of thermal difference on two sides of a tuning fork." Med. recs. at Ex. 39, p. 3. Joint position sense was quite normal. *Id.* To Dr. Ropper, there was "a premium on determining the genuineness of her symptoms and their relationship to a small fiber sensory neuropathy." Med. recs. at Ex. 39, p. 2. He was inclined to take petitioner's complaints at face value and acknowledge that conventional EMG tests and the like are insensitive to small fiber dysfunction. She might have perineuritis, an inflammatory disorder of the small sensory nerves in the skin. *Id.*

On October 13, 1995, petitioner saw Dr. Barnes with significant increase in her neuropathic pain in her legs up to her thighs over the past week. Med. recs. at Ex. 2, p. 10. She had such burning discomfort that she was barely able to walk around her apartment, even with crutches. She also noted some pain in her hands. She denied localized weakness. *Id.* She had a mild sore throat over the last several days. On examination, she looked depressed and in moderate discomfort. Her feet and legs were uncomfortable to touch. She had decreased pinprick over the entire leg as well as her arms, back, and chest. *Id.*

From October 19 to October 21, 1995, petitioner was in Mount Auburn Hospital for severe neuropathic pain, according to Dr. Barnes. Med. recs. at Ex. 33. p. 268. Dr. Wasserman

said there was no additional neurologic diagnosis to explain petitioner's symptoms. On examination, petitioner had dysesthesias and decreased pin sensation in her feet, legs, and lower arms, sparing her inner upper arms, face, and anterior trunk. *Id.*

On January 24, 1996, petitioner saw Dr. Margaret A. Caudill for a behavioral medicine pain program consultation at Deaconess Hospital. Med. recs. at Ex. 22, p. 8. She stated that she had a six-week episode of a viral illness. She was checked for mononucleosis and other problems by her employer, an occupational health group, and nothing showed up. She then switched jobs and received two hepatitis B vaccinations when, one morning, she woke with burning in her feet. After about five to six days, she could hardly walk because of the pain. A podiatrist examined her and found nothing wrong. Over days to weeks, her pain ascended her legs and eventually developed into burning, throbbing, and aching increasing in her upper and lower extremities (primarily the latter), and her trunk, ending at the neck. *Id.* She felt she had respiratory compromise, but this was not documented by pulmonary function testing. She was tachycardic, short of breath, and hardly able to sit up. *Id.* She separated from her husband in September 1994 and divorced in March 1995. Med. recs. at Ex. 22, p. 9. She was hospitalized in 1993 for reactive depression. *Id.*

On January 30, 1996, petitioner had a brain MRI which was normal, without evidence of demyelinating disease. Med. recs. at Ex. 2, p. 102.

On January 30, 1996, petitioner had an MRI of her cervical spine which showed no evidence of cervical spinal cord demyelinating lesions. Med. recs. at Ex. 2, p. 103.

On May 21, 1996, petitioner saw Dr. Paul B. Lesser, a gastroenterologist, for persistent nausea. Med. recs. at Ex. 28, p. 144. Dr. Lesser diagnosed her nausea as related to her narcotics. *Id.*

On August 28, 1996, petitioner saw Dr. Andrea J. Wagner, Medical Director of Physical Medicine and Rehabilitation at Somerville Hospital. Her problems began June 1995 with pain in her feet, especially in her heels. Med. recs. at Ex. 2, p. 145. On examination her voluntary motor strength was 5/5 in upper and lower extremities. Med. recs. at Ex. 2, p. 144. Deep tendon reflexes were +2 and symmetrical. Sensation to pinprick was decreased distally in upper and lower extremities. Proprioception was intact in both lower extremities. There was no muscle atrophy. Cerebellar testing heel to shin was intact bilaterally. Straight leg raising was asymptomatic. Light palpation of the skin on the plantar surface of the feet increased petitioner's pain. Dr. Wagner diagnosed a chronic pain problem and recommended pain management with tricyclic anti-depressant as well as a psychiatric consultation. *Id.*

On September 25, 1996, petitioner saw Dr. Francis X.J. Bohdiewicz for a physical medicine and rehabilitation evaluation. Med. recs. at Ex. 2, p. 154. She was currently on Social Security Disability. Med. recs. at Ex. 2, p. 153. On examination, she had functional active range of motion throughout all major joints. Light touch sensation was essentially absent over the lateral aspect of the lower extremity including the feet, with sparing of light touch sensation along the inner aspects of the lower extremities. She had normal tone. Strength in the upper extremities was generally 4-/5 throughout, and in the lower extremities, generally 4 to 4+/5 throughout without any focal or lateralizing weakness. *Id.* Deep tendon reflexes were 2+ and equal bilaterally throughout. Cerebellar testing revealed intact finger to nose bilaterally. *Id.*

Dr. Bohdiewicz's impression was chronic pain with ascending sensory neuropathy, including absent or severely impaired light touch sensation over the lateral aspects of bilateral lower extremities and over the entire surface of both feet. Med. recs. at Ex. 2, p. 152. She was appropriate for an electric/motorized mobility device. Bilateral ankle foot orthoses could help her ambulate. *Id.*

On October 16, 1996, petitioner saw Dr. Janice Wiesman. Med. recs. at Ex. 29, p. 13. On examination, petitioner's deep tendon reflexes were 2/4 and symmetrical. Motor examination in the lower extremities was normal. Sensory examination to cold, vibration, and joint position sense in the lower extremities was normal. Left median and peroneal motor nerve conduction studies with F response were normal. Left median, ulnar, and superficial peroneal sensory responses were normal. Concentric needle EMG of the left upper and lower extremities was normal. Motor unit potentials were of normal morphology and recruited normally. Dr. Weisman did not note any abnormal spontaneous activity. Her impression was that petitioner had a normal study. There was no evidence of a muscle, nerve, plexus, or root lesion. *Id.*

On October 30, 1996, petitioner saw Dr. James A.D. Otis. Med. recs. at Ex. 2, p. 161. Petitioner was in her usual state of health until approximately the beginning of March 1995 when she developed a viral illness. She recovered completely but, about three weeks later, she developed a burning pain on the sole of one foot. Over the next few days, the pain increased to cover the entire foot and was accompanied by a loss of sensation and numbness to both knees. There was no motor weakness. *Id.*

Petitioner said that she had burning pain affecting both lower extremities and both hands which was considerably worse at the bottom of her feet. She characterized it as continuous 10/10

range pain, increased with walking and standing, but, interestingly, not with contact with clothes or water. Med. recs. at Ex. 2, p. 160. On examination, she had motor strength of 5/5 in the upper extremities and, when pain was accounted for, 5/5 in the lower extremities. Med. recs. at Ex. 2, p. 159. Sensory examination showed decrease to vibratory sensation below the knees bilaterally and in the hands bilaterally. Reflexes were 1+ in the upper extremities and 2+ in the lower extremities. EMG was normal, suggesting this was perhaps a small-fiber neuropathy. *Id.*

On April 24, 1997, petitioner saw Peter A. Mosbach, Ph.D., a clinical psychologist. Med. recs. at Ex. 2, p. 203. Petitioner's mother has a history of fibromyalgia. *Id.* Petitioner's responses to MMPI-2 suggested that she would experience an increase in her perceived pain when faced with stressful life events. Med. recs. at Ex. 2, p. 202. Her responses also suggested that she had a moderate level of depression. *Id.* She was seeing a psychiatrist weekly. Med. recs. at Ex. 2, p. 201.

On January 13, 1998, Dr. Barnes filled out a payment voucher form for the Massachusetts Rehabilitation Commission. Med. recs. at Ex. 2, p. 238. She first examined petitioner in January 1991. Med. recs. at Ex. 2, p. 237. The date of petitioner's first sign of illness was in June 1995. *Id.*

On April 9, 1998, Dr. Nathaniel P. Katz of the Pain Management Center of Harvard Medical School wrote to Dr. Barnes. Med. recs. at Ex. 2, p. 250. Petitioner's symptoms began rather suddenly in June 1995 with pain and paresthesias that began in her feet and ascended over approximately two weeks into her groin. After about one month, the pain was in her arms as well. The pain was quite severe. Examination showed diffuse loss of pinprick and temperature sensation with preservation of strength and reflexes. All her electrophysiologic studies were

negative, including nerve conduction studies and evoked responses. *Id.* Quantitative sensory testing was also negative. *Id.*

Dr. Katz's impression was that petitioner had a small fiber, painful, peripheral polyneuropathy. Med. recs. at Ex. 2, p. 249. The diagnostic tests primarily assess large fiber function. Dr. Katz's impression was that there was some amplification by psychological factors, but not a lot. *Id.*

On April 8, 1999, one month before petitioner filed her petition, Dr. Henrietta N. Barnes wrote a letter to an attorney about petitioner. P. Ex. 52, p. 1. Dr. Barnes stated that petitioner had been her patient since 1991. On June 28, 1995, Dr. Hilary Worthen of Dr. Barnes' office saw petitioner for severe pain and numbness on the soles of her feet for about one week. Petitioner had started a new job two and one-half weeks previously. Over the next week, the pain and paresthesias increased, involving her legs, and then her arms and trunk. She was admitted to Mt. Auburn Hospital in July 1995. She had loss of temperature and vibration sensation, but retained her motor function and reflexes. She had a tentative diagnosis of Guillain-Barré syndrome (GBS) variant and she was treated with corticosteroids and intravenous immunoglobulins without significant improvement. *Id.* Dr. Allan Ropper subsequently saw petitioner and in light of the negative results of her nerve conduction studies, median somatosensory evoked responses, visually evoked responses, and tibial non-essential evoked responses, he thought her clinical setting was diagnostic of a small fiber neuropathy. She developed cardiac dysautonomia,[14] with palpitations and dizziness which responded to beta-

[14] Dysautonomia is "malfunction of the autonomic nervous system." Dorland's Illustrated Medical Dictionary, 38th ed. (2003) at 573.

blockers, and she developed severe esophageal reflux, both thought due to her neuropathy. *Id.* She was hospitalized several times for pain control and continues to have severe pain in her feet. She developed vasomotor instability probably due to her neuropathy. *Id.* Petitioner gave a history of receiving hepatitis B vaccine in January 1995 following which she had pain in her heels for one week. After the second hepatitis B vaccination on February 28, 1995, she developed pain in both arms for 24 hours. Over the next two months, she had several episodes of fatigue and heel pain. P. Ex. 52, p. 2. Dr. Barnes states, "Given that no other cause for her neuropathy has been found despite extensive investigation, it is more likely than not that the vaccination caused her symptoms of neuropathic pain and paresthesias." *Id.*

On February 25, 2003, Dr. Paul L. Romain, a rheumatologist, wrote that petitioner had new onset of swelling and pain in the small joints in her hands for several months in the context of a small fiber neuropathy. P. Ex. 53, p. 1. The nature and clinical course of her neuropathy suggested a variant of GBS. P. Ex. 53, p. 2. Dr. Romain thought petitioner had early nodular inflammatory osteoarthritis developing Bouchard's nodes.[15] P. Ex. 53, p. 3.

Other Submitted Material

Petitioner filed a number of abstracts of medical articles as Ex. 54. The first is "Acute pandysautonomia and acute autonomic and sensory neuropathy" by F. Okada, 64 *Hokkaido Igaku Zasshi* 1:4-9 (1989). The disorder is characterized by severe sympathetic and parasympathetic impairment with relative or complete preservation of somatic motor and sensory functions. *Id.*

[15] Bouchard's nodes are "cartilaginous and bony enlargements of the proximal interphalangeal joints of the fingers in degenerative joint disease." Dorland's Illustrated Medical Dictionary, 38th ed. (2003) at 1268.

The second abstract is "Autonomic neuropathies" by P.A. Low, 7 *Curr Opin Neurol* 5:402-06 (1994). The author states there is a spectrum of acute neuropathies. At one end is acute panautonomic neuropathy or pandysautonomia (characterized by severe widespread sympathetic and parasympathetic failure) and, at the other end of the spectrum, is GBS. *Id.*

The third abstract is "Invited review: autonomic dysfunction in peripheral nerve disease" by J.G. McLeod, 15 *Muscle Nerve* 1:3-13 (1992). The author lists a small number of conditions, including GBS and familiar dysautonomia, in which autonomic dysfunction is of clinical importance. Autonomic disturbances were most likely to occur when there was acute demyelination or damage to small myelinated and unmyelinated fibers. *Id.*

TESTIMONY

Petitioner testified first. Tr. at 3. She stated she was in very good health as a child. Tr. at 4. When she was 20 or 21, she sought psychiatric help for depression. Tr. at 5. On Wednesday, January 25, 1995, she started work at Health Resources. Tr. at 8. Her employer asked her to report to the Boston office instead of the Woburn office where she was supposed to work and be trained. *Id.* She did report to the Boston office on January 25, 1995 and received her hepatitis B vaccination at the end of that day. Tr. at 8-9.

The two experts, Dr. Carlo Tornatore and Dr. Subramianiam Sriram, had a colloquy about the meaning of the testing of petitioner's blood on January 25, 1995 to see if she had hepatitis B surface antigen. Dr. Tornatore took the position that because the employer had tested petitioner for tuberculosis on January 25, 1995, the employer also administered the hepatitis B vaccination, whereas Dr. Sriram took the position that the employer merely tested petitioner on January 25, 1995 to see if she had antibody to hepatitis B rather than to administer the vaccination the same

day as the test to see if she needed the vaccination. Tr. at 12-14. When the undersigned asked Dr. Tornatore why Health Resources would have administered the hepatitis B vaccine to petitioner on the day they tested her (January 25, 1995) to see if she had antibodies to hepatitis B surface antigen instead of waiting two days for the results of the test to come out and then vaccinating her on January 27, 1995 when the Health Resources nurse said petitioner had been vaccinated, Dr. Tornatore responded: "I don't disagree with your logic and that would be the reasonable sequence to do things in, but apparently this is the way it played out I guess." Tr. at 16.

Dr. Sriram stated that the records do not show that petitioner received hepatitis B vaccine on January 25, 1995. Tr. at 18. The undersigned noted that Health Resources tested not only for TB and hepatitis B surface antigen on January 25, 1995, but also for antibody to rubella and discovered in the results on January 27, 1995 that she did have antibody to rubella and did not need rubella vaccination. Tr. at 18-19. Dr. Tornatore agreed with that interpretation. Tr. at 19. In addition, nurse Talbot wrote a letter to petitioner that she had documentation that indicated petitioner received her first hepatitis B vaccination on January 27, 1995 and that nurse Jean Cotter kept a list of vaccinated employees. Tr. at 19-20. Nurse Talbot opined also that petitioner would have received a second vaccination in February. Tr. at 20.

Petitioner stated she received hepatitis B vaccine in the Boston office. Tr. at 22. She told nurse Jean Cotter on Friday, January 27, 1995 that she had already received the vaccination. Tr. at 23. Petitioner stayed at Health Resources for four months and then moved on to General Medical West. Tr. at 25. She is not sure where her vaccination documentation is. Tr. at 24.

Petitioner testified that the day before she was to report to work at Health Services in Woburn, she received a phone call from her immediate supervisor, Maxine Wiley, to report to the Boston office instead where she trained with a nurse named Linda. At the end of the day, January 25, 1995, Linda administered the hepatitis B vaccination to petitioner. Tr. at 25-26. She did not return to Boston that week but went to Woburn on Thursday and Friday. Tr. at 26. Petitioner told nurse Jean Cotter on Friday, January 27, 1995, that she had already received hepatitis B vaccine. Tr. at 26.

On Saturday, January 28, 1995, petitioner woke up with pain in her heels. *Id.* Petitioner described the pain as stabbing. Tr. at 27. She attributed the pain to her being at a new job and on her feet. She went with her mother to a shoe store and bought a pair of Easy Spirit shoes. *Id.* The heel pain stayed the same during the week so she returned the shoes on Friday, February 3, 1995, to the store. Tr. at 28. Petitioner bought a different pair of shoes and went back to work on Monday and did not have any more pain. The pain had resolved on the weekend. Tr. at 29.

Petitioner testified she received the second vaccination on February 27, 1995 in the Boston office by the same nurse Linda. Petitioner remembers the day because it was her mother's birthday. *Id.* Within a couple of days of vaccination, she had pain from the top of her shoulder to the side of her hand bilaterally. Tr. at 30. The pain lasted 48 hours. *Id.* The pain was sharp but not so bad that she could not go to work. Tr. at 30-31. The pain in her heels in January was a stabbing pain on the bottom center of her heels the size of a silver dollar. Tr. at 32-33. When she took her shoes off, her heels felt worse when she stood but better when she sat. Tr. at 33-34.

Returning to her arm pain, after it was gone, she had similar episodes that lasted about 48 hours with pain from she shoulder to the outside portion of her hand at least two or three times in March and April. Tr. at 36. She did not tell a physician about this. *Id.*

In May, petitioner developed a viral illness with a sore throat and more than the usual fatigue and she asked a physician in her office if he would swab her throat to check for streptococcus and take a blood test to check for mononucleosis. Tr. at 37. The symptoms lasted two to four weeks. *Id.* She did not have strep or mono. Tr. at 38. She had a runny nose but no cough. *Id.* She did not have a fever. Tr. at 39. After this, she noticed the pain return to both arms only it was more of a burning and tingling sensation. Tr. at 40. She had two episodes that resolved after about 48 hours. *Id.* Petitioner switched to a new job on June 10, 1995. Tr. at 60.

On June 22nd, she started having heel pain again. Tr. at 40. On June 28, 1995, petitioner saw Dr. Hillary Worthen to get a referral. Tr. at 44. She told him about the heel pain which he noted occurred four months before, which would be February but it was actually January. Tr. at 46.

On June 29, 1005, petitioner woke and was unable to walk. Tr. at 47. The full bottoms of her feet were painful. She called the doctor's office and her doctor referred her to a podiatrist, Dr. Alper. *Id.* She saw Dr. Alper who opined that her problem was mostly neurological. *Id.* She was sent to Cambridge Hospital and saw Dr. Glick, a neurologist, who found her normal on examination. *Id.* However, he felt there was some underlying neurological problem and wanted her to be admitted. *Id.* Her insurance allowed her to be admitted only to Mt. Auburn hospital. *Id.* Her primary care physician, Dr. Barnes saw her in the Mt. Auburn emergency room and she was admitted for further evaluation and pain management. Tr. at 48. Her pain ascended to the

outer aspects of her thighs into the pelvic area and both her arms down to her hands. Tr. at 61. She had paresthesia which made her very uncomfortable as if things were crawling under her skin. Tr. at 62. She felt as if her feet were constantly burning and tingling, as if someone were stabbing her or put a vice around each toe and squeezed her toes really tight which standing up worsened. She felt as if she were walking on bone and in extreme pain. *Id.* Her feet were worse than her arms. *Id.* The working diagnosis was Guillain-Barré variant. Tr. at 63.

Petitioner was put on IV Solu-Medrol, which did not help, and a five-day course of IVIG, which also did not help. Tr. at 64. She was transferred to St. Elizabeth's Hospital for plasmapharesis. *Id.* She left the hospital after a few days to live with her parents, but she had palpitations and excruciation pain and went to Falmouth Hospital. Tr. at 66. She then returned to Mt. Auburn Hospital. *Id.* This was mid-July or the beginning of August. *Id.* Tests of her severe palpitations determined she had cardiac dysautonomia. *Id.* She had bowel and bladder problems starting at the first hospital admission. Tr. at 67.

Petitioner was transferred to Youville Rehabilitation Hospital. Tr. at 68. Over the years, she has had a waxing and waning course. Tr. at 70. A relapse usually starts with heel pain in the middle of her heel and severe burning pain in the whole bottom of her foot ascending to her shins. Tr. at 71. She had a severe relapse at Thanksgiving 2006. Tr. at 72. She was readmitted to Cambridge Hospital for pain management and went on a course of steroids. *Id.* She went to Spalding Rehab Hospital in 2007. Tr. at 73. She is on Social Security disability and rated 100% disabled. Tr. at 75.

On cross-examination, petitioner was asked about the accuracy of her 2002 affidavit in which she relates onset of severe pain in both heels of her feet to have occurred the day after she

received her first hepatitis B vaccination. Tr. at 76. That affidavit was based on her memory of the events at that time. Tr. at 77. Her testimony is that this affidavit is wrong. Tr. at 78. She is not sure when she realized the affidavit is wrong. *Id.* Petitioner has no written records to show she received her vaccination on January 25, 1995. Tr. at 79. She believes that nurse Jean Cotter's statement in a letter that she had documentation indicating petitioner received her first hepatitis B vaccination on January 27, 1995 is a mistake. Tr. at 80-81.

The undersigned asked petitioner about her April 24, 2002 affidavit in which she stated that the onset of the pain in her heels was one day after she received hepatitis B vaccination. Tr. at 82. However, petitioner's counsel interjected that it was his fault that petitioner had put that in her affidavit because she remembered that the onset of her pain was Saturday, January 28, 1995 and he was relying on nurse Cotter's statement in the letter that petitioner received her first hepatitis B vaccination on January 27, 1995. Tr. at 83. He stated that petitioner's recollection when petitioner filed her petition was that she had the onset of her heel pain within one week of her vaccination and, in her affidavit, that the heel pain began on January 28, 1995. *Id.* Petitioner's affidavit states that her pain began on January 29th because she thought the vaccination was on January 28th. Tr. at 88. Petitioner could not answer why she put in the affidavit that her heel pain began on January 29th when her counsel just said, by way of explanation of why she said it was a one-day onset after the vaccination that petitioner was adamant her pain began on Saturday, January 28th. Tr. at 88-89.

Petitioner was not sure when she had the viral illness. Tr. at 90. She omitted from the affidavit that she had arm pain return in June 1995. Tr. at 93. Petitioner has been taking a number of painkillers and they affect her memory. Tr. at 94.

Petitioner's arm pain in March and April 1995 was not severe enough for her to miss work. Tr. at 97. Her heel pain in January 1995 did not feel better when she changed her shoes. Tr. at 98. It went away on its own. *Id.* The arm pain also went away on its own. Tr. at 99. None of these episodes was severe enough for her to seek medical attention. *Id.*

On redirect, petitioner said she could not have gone to the shoe store on Sunday, January 29, 1995, because it was closed. She was at her parents' home that day, celebrating her brother's birthday. Tr. at 100. Therefore, her heel pain began on Saturday, January 28, 1995, and it was on that day that she went with her mother to the shoe store. Tr. at 101. She had told Dr. Worthen about prior heel pain. Tr. at 102.

Dr. Tornatore testified next for petitioner. Tr. at 103. He is an associate professor of neurology at Georgetown medical school and runs the MS clinic and the associated autoimmune disorders clinic. Tr. at 104. His opinion is that petitioner has a perineuritis or a small fiber sensory neuropathy that appears to be inflammatory and was due to the vaccinations. Tr. at 105. Following her first hepatitis B vaccination, petitioner had bilateral heel pain lasting for a week. He would accept timing of onset of one or three days. He relied on an epidemiological study by Dr. Schoenberger (Ex. 44) which showed reports of Guillain-Barre syndrome following swine flu vaccine of 12 people on the first day. Tr. at 106-07. There were another 16 people reported from one to three days post-vaccination. Tr. at 107.

Petitioner's heel pain would be consistent with a sensory neuropathy and the fact that it got better is consistent with the nature of autoimmune disorders. *Id.* The immune system modulates itself. Tr. at 108. That is why people receive multiple vaccinations because the initial antibody titer or even the cell-mediated portion of immunity fades away. *Id.*

The undersigned asked Dr. Tornatore if, as a result of the first hepatitis B vaccine, petitioner had heel pain, why did a different part of her body (her arms) react to the second hepatitis B vaccine? Tr. at 109. Dr. Tornatore responded that MS patients do not always have the same symptoms. *Id.* There are sensory nerves in the arms, legs, and trunk. Tr. at 100. When petitioner had her viral syndrome in May, she had symptoms in her arms and eventually the legs, a replication of her earlier symptoms in each area. *Id.* An infection triggers the immune system leading to symptoms called pseudorelapses. *Id.* In the body's attempt to fight the virus, there is a diffuse activation of the immune system, including some of those cells already primed against antigens on the sensory nerves. Tr. at 110-11. Dr. Tornatore has many MS patients who, when they get a cold, their old symptoms recur and they may have new symptoms as well. Tr. at 111. Half of Guillain-Barré syndrome patients have a prior infection, respiratory or otherwise, that triggered the illness because the immune system was reacting against that particular virus. *Id.*

Dr. Tornatore was not concerned with a one-day onset of symptoms after the first hepatitis B vaccination even though, during the Omnibus proceeding on hepatitis B vaccine and demyelinating illnesses, Dr. Vera Byers testified that a one-day onset would be problematic unless the vaccination were the second or third and not the first one. Tr. at 112. In other autoimmune disorders, individuals have T-cells that are already responsive to myelin-basic proteins without having the clinical disease. These T-cells are primed to attack areas of the body. *Id.* As we age, there is a culling out of white cells or T-cells that are autoreactive. But occasionally, some people still have groups of them left that were not removed as part of the normal pruning mechanism. Thus, they can react very quickly to a vaccination. Tr. at 113. This is very rare. *Id.*

Dr. Tornatore stated that petitioner's second hepatitis B vaccination was a positive rechallenge because she had symptoms in her arms followed in June with symptoms in her arms and feet replicating what occurred to her in January (feet) and February (arms). Tr. at 114. In June, Dr. Alan Ropper diagnosed petitioner with perineuritis. *Id.* Petitioner had the same symptoms following two flu vaccinations and a flu-like illness. If it were not for her previous vaccinations, Dr. Tornatore believes she would not have had perineuritis or sensory neuropathy after her viral illness. *Id.* The viral infection triggered the illness to go to the next step. Tr. at 115. The viral illness was a substantial contributing factor to petitioner's illness. *Id.* Petitioner's flaccid bladder is typical of people with autonomic or peripheral nerve problems. Tr. at 117.

The undersigned asked petitioner about her initial heel pain and she replied it was more like stabbing than burning. Tr. at 118. Dr. Tornatore did not think it significant whether the pain was stabbing or burning. Tr. at 119. That indicates a problem in the fibers. *Id.* Inflammatory diseases are capricious with symptoms in various parts of the body. Tr. at 121. Dr. Alan Ropper proposed an inflammatory component and called it perineuritis. *Id.* "Perineuritis" means inflammation around the nerve. Tr. at 122. Some sensory nerves are myelinated, some are not, and some are very weakly myelinated. *Id.* If an EMG is normal, we are more likely dealing with less myelinated fibers. Tr. at 123.

Dr. Tornatore's opinion is that petitioner's first and second hepatitis B vaccinations as well as the viral illness in May 1995 were substantial factors in her causing her small fiber sensory polyneuropathy. Tr. at 127. If she had not received hepatitis B vaccine, Dr. Tornatore does not think she would have had a subsequent neuropathy. *Id.* Petitioner's blood tests showed she was producing immunoglobulins out of proportion to other proteins, indicating her immune

systems was overactive on July 20, 1995. Tr. at 129-30. Petitioner's protein in her cerebrospinal fluid was modestly elevated at 64 on July 1, 1995. Tr. at 131. Petitioner had not only a sensory neuropathy, but a peripheral autonomic neuropathy, which included cardiac, gastric, and bladder problems. Tr. at 132, 135-36.

In answer to respondent's Dr. Sriram's objection in his report that a progressive disorder would not have an abatement of symptoms in 48 hours, Dr. Tornatore stated that the immune system in an autoimmune problem can turn itself off. Tr. at 137. His MS patients frequently have symptoms that spontaneously resolve. *Id.* One cannot lump all sensory neuropathies together. Some types of sensory neuropathies that are not inflammatory will have progressive symptoms that do not abate. But petitioner has inflammation of her sensory nerves and a different course. Tr. at 137-38. The same nerves that cause sharp pain in the heels also cause burning pain there. Tr. at 140.

On cross-examination, Dr. Tornatore stated that the pathogenesis of petitioner's sensory neuropathy and of Guillain-Barré syndrome is identical: inflammation and demyelination of the nerves and subsequent clinical symptoms. Tr. at 145. The onset of her demyelinating neuropathy was January 28, 1995 when she had heel pain. Tr. at 146. Petitioner must have had some priming in her immune system in order to have a one-day onset. Tr. at 149. The symptoms she had in June in her arms and feet which were diagnosed as perineuritis, she also had in January and February. *Id.* There are animal models where peripheral nerve dysfunction, although not inflammatory, occurs within one day of an immune challenge. Tr. at 151.

Dr. Tornatore stated that petitioner's heel pain in January 1995 would not necessarily mean her nerves were damaged. They could just have been irritated. Tr. at 152. A nerve that is

inflamed is not necessarily demyelinated or injured. *Id.* Petitioner's heel pain went away in January, meaning that the nerves were not sufficiently damaged to cause lingering symptoms. *Id.* Her heel pain in January was her only complaint, not numbness, loss of sensation, or tingling. Tr. at 153. The pain was confined to her feet. *Id.* Petitioner had sensory symptoms in her arms in February and June, and petitioner then testified that her symptom in February was pain but not tingling or numbness. Tr. at 154. In May, her arms were painful, numb, and tingling. Tr. at 154-55. Dr. Tornatore considers a one-day onset after the first hepatitis B vaccination biologically plausible because petitioner had something going on in her body that primed her for a fast, almost anamnestic, response. Tr. at 156. The second hepatitis B vaccination was a rechallenge. Tr. at 157. She was already primed to a particular antigen and one would expect a response within 24 hours. *Id.* Only after the second hepatitis B vaccination aftermath could one recognize the significance of the first one. Tr. at 160.

The virus petitioner had in May triggered her illness in June. *Id.* and 161-62. Dr. Tornatore agreed that 50 percent of Guillain-Barré syndrome cases are triggered by a viral illness. Tr. at 163. The timing between petitioner's viral illness in May and her symptoms in June is appropriate for a reaction. *Id.* He believes that the etiology of her June symptoms is the hepatitis B vaccine because of the similarity of her symptoms to her prior symptoms in January and February. *Id.* Petitioner's blood work on July 20, 1995 showed an elevation of her immunoglobulin (IgG) levels which means she had more antibodies circulating than one would expect. Tr. at 165. Some inflammatory component was going on. Tr. at 166. The elevation of protein in her spinal fluid also indicates abnormality. *Id.* Recurring symptoms are not unusual for inflammatory diseases. Tr. at 171. Petitioner's course is waxing and waning. *Id.* Petitioner

has what Dr. Alan Ropper described as perineuritis–inflammation of the sensory nerves which had an onset of a pattern in January and February and recurred in June. Tr. at 172.

The undersigned asked Dr. Tornatore why, if onset after the first two hepatitis B vaccinations of pain in the heels (either one or three days after the first vaccination) or in the arms (one day after the second vaccination), the onset of petitioner's recurring symptoms in June occurred two weeks after her viral infection. Tr. at 175. He explained that the antigen in the vaccine is totally different than the antigen in the viral infection, taking the clones are longer time to multiply. He calls this a pseudoexacerbation. *Id.* He sees this in MS patients and stroke patients. Tr. at 176. He calls it "pseudo" because the original problem is not causing the symptoms. *Id.*

Dr. Subramaniam Sriram testified for respondent. Tr. at 179. He is a professor of medicine and chair of the Department of Neuroimmunology at Vanderbilt Medical Center, and practices in the department of neurology at the same center. Tr. at 180, 181. He is board-certified in internal medicine and neurology. Tr. at 180-81. Dr. Sriram stated that we do not know the final diagnosis for petitioner's illness. Tr. at 183. Something happened to her in June 1995 that led to the development of sensory symptomatology that failed to have a clear neuroanatomical and neuropathological description. *Id.* The best diagnosis Dr. Sriram can give is that petitioner has some form of sensory neuropathy. *Id.* We do not know if petitioner has demyelination because there was no nerve biopsy done. Tr. at 184. All of her testing was normal. Tr. at 185. However, someone with a small fiber neuropathy may have nerves affected that are either unmyelinated or poorly myelinated. *Id.* People with a small fiber neuropathy characteristically have the kind of symptoms petitioner described as very painful even though

their nerve conduction tests are normal. *Id.* It is unknown if what petitioner had was inflammatory because of the absence of a biopsy and the failure of anti-inflammatory therapy such as steroids and IVIG (intravenous immunoglobulin) to work. Tr. at 185-86. But then Dr. Sriram described it as a very recalcitrant inflammatory response not amenable to therapy. Tr. at 186. Dr. Sriram felt the best diagnosis for petitioner's condition was a sensory polyneuropathy. Tr. at 189. Petitioner had some wild virus infection which caused her peripheral nerve disorder. Tr. at 192. Small fiber neuropathies can wax and wane. Tr. at 194.

Dr. Sriram said that if petitioner's heel pain began one day after her first hepatitis B vaccination, it was too quick to be causally related. Tr. at 195. After vaccination in the deltoid, the lymph vessels pick up the vaccine antigen. Tr. at 195-96. The antigen has to find T-cells that recognize these antigens and proliferate and exit the lymph node into circulation. Then they have to find their target in the peripheral nerves. It takes time for all that to happen. Tr. at 196. It takes a day for T-cells to divide. *Id.* It takes another day or so to amplify the immune response to manifest a disease process. The T-cells have to educate the B-cells to make immunoglobulin. They have to go through their maturation process to get into circulation and target the peripheral nerves. This takes a fairly lengthy time. *Id.*

Dr. Sriram said he has worked on an experimental model for multiple sclerosis called experimental allergic encephalitis (EAE) in animals and it takes five days for the animals to become paralyzed after injection. Tr. at 197. That is why he thinks the time frame has to be even longer in humans who are immunized. Even 72 hours would not be long enough. *Id.* Whatever process we postulate, whether T lymphocytes going to peripheral nerve and damaging

myelin or antibody being deposited and complement being fixed, these processes are time-dependent and do not happen in a matter of hours. Tr. at 198-99.

Dr. Sriram did not agree that someone could come immunologically primed to a first hepatitis B vaccination. Tr. at 200. Petitioner's description of her painful heels after the first vaccination is highly unlikely for a nerve damage process and more suggestive of a mechanical process. Tr. at 201. He is not familiar with any disease that begins in January, goes away after two weeks, recurs for 48 hours in February, and goes away until a viral infection in June when it recurs in more than the peripheral nerves. Tr. at 202-03. Petitioner's pain in her arms in February could not have been significant since she continued to work right through it. Tr. at 203.

Petitioner had a lot of fluctuation in her symptoms as reflected in Dr. Ropper's records which puzzled Dr. Ropper, i.e., numbness in the trunk and buttocks but normal sensation in the feet, which was very inconsistent with a prior examination and with a diagnosis of sensory neuropathy. Tr. at 204. We do not have a good explanation for this fluctuation in symptomatology. *Id.*

Two things are puzzling here, according to Dr. Sriram. Tr. at 205. First is that although petitioner complained of discomfort and pain, objective evidence was lacking. Secondly, her neurological examination fluctuated which was difficult to fit with a diagnosis of progressive neurological disease. *Id.* How could petitioner have such an amount of disorder of her peripheral nerves when her examinations were normal and she had normal reflexes and normal nerve conduction. Tr. at 207. Petitioner's elevated IgG (immunoglobulin) in July 1995 does not mean that she had an inflammatory response of the nerve. It could be a clinical infection. Tr. at 209-10.

If petitioner has a small fiber neuropathy, her autonomic functions would be affected, including the sweat glands and she should not have the ability to sweat. But she has normal sweating. Tr. at 210. The undersigned asked Dr. Sriram if Dr. Ropper was one of the stars in neurology and he agreed he was. Dr. Ropper has written a large neurology textbook. Tr. at 211. His specialty is Guillain-Barré syndrome. *Id.*

Before May 1995, petitioner does not look like someone with a demyelinating neuropathy. Tr. at 212. What happened to her in June is distinct from what happened to her in January, February, March and April. *Id.* A viral illness can cause a demyelinating condition. *Id.* But we do not know if petitioner has a demyelinating condition. Tr. at 213. A time frame of two to three weeks makes more sense than one day. Tr. at 213-14. Regarding the Schoenberger article (Ex. 44) on the occurrence of GBS among swine flu vaccinees, Dr. Sriram said that the data indicating occurrence of onset of weakness or numbness 24 hours after vaccination does not indicate the vaccine caused the GBS one day after vaccination. Tr. at 214-15. This was just a survey. Tr. at 215.

Dr. Sriram admitted on cross-examination that petitioner has a sensory variant of GBS. Tr. at 218. He admitted that in small fiber sensory neuropathy, reflexes often are normal. Tr. at 221. He also admitted that in small fiber sensory neuropathy, EMGs and nerve conduction studies can be normal. Tr. at 222. Dr. Sriram agreed that petitioner has small fiber sensory neuropathy even without any objective evidence. *Id.* Some autoimmune inflammatory conditions do not respond to steroid treatment, for instance, GBS. Tr. at 223. Petitioner then testified that sweating too much has been a problem for her for years and her doctor thinks it is part of her autonomic neuropathy. Tr. at 224, 225. Dr. Tornatore then stated that too much or

too little sweating can be part of a problem with the autonomic nervous system. Tr. at 225. Dr. Sriram said that most small fiber neuropathies are associated with too little sweating. Tr. at 225-26. Small fiber neuropathy where the cause is unrelated to diabetes, alcoholism, cancer, or heavy metals is a very rare condition. Tr. at 228.

Dr. Sriram reiterated that when an isolated sensory symptom such as heel pain begins very suddenly without progression and suddenly resolves, he has a problem calling it an immune process. Tr. at 230. A three-day onset would be cutting it close, but better than a one-day onset. Tr. at 230-31.

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[.]"

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).

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 . . . ." The Federal Circuit in Capizzano emphasized that the special masters should consider seriously the opinions of petitioners' treating doctors. In Capizzano, four treating doctors were of the opinion that hepatitis B vaccine caused petitioner's rheumatoid arthritis. 440 F.3d at 1326.

Close calls are to be resolved in favor of petitioners. Capizzano, 1440 F.3d at 1327; Althen, 418 F.3d at 1280. *See generally*, Knudsen v. Secretary of HHS, 35 F.3d 543, 551 (Fed. Cir. 1994).

The Federal Circuit stated in Althen, 418 F.3d at 1280, that "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body."

Petitioner herein must show not only that but for the vaccine, she would not have had small fiber neuropathy or a GBS variant, but also that the vaccine was a substantial factor in bringing about her small fiber neuropathy or GBS variant. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999) (where vaccination is a substantial factor together with a non-vaccine substantial factor in causing illness, petitioner prevails).

In one of the four paradigm Omnibus cases, Gilbert v. Secretary of HHS, No. 04-455V, 2006 WL 1006612 (Fed. Cl. Spec. Mstr. March 30, 2006), the undersigned ruled that hepatitis B vaccine can cause GBS and CIDP, and did so in that case.

In the Omnibus proceeding, respondent's neurological expert Dr. Roland Martin testified that the appropriate onset interval, if a vaccination were to cause an acute demyelinating reaction, would be a few days to three to four weeks. Omnibus tr. at 219; Stevens v. Secretary of HHS, No. 99-594V, 2006 WL 659525, at *15 (Fed. Cl. Spec. Mstr. Feb. 24, 2006) (petitioner had same TM symptoms after each of two hepatitis B vaccinations; positive rechallenge; ruled for petitioner)

Also as part of the Omnibus proceeding, petitioners' expert immunologist Dr. Vera Byers, when asked whether an onset of demyelinating disease of one day after hepatitis B vaccination was consistent with causality, testified:

> [Someone could have onset of] demyelinating symptoms beginning as early as one day. But that can only occur in my opinion in cases where people have had a very strong boost fairly shortly before. So in other words and I think it's probably got to be B-cell mediated because it's difficult to think that the T-cells could be activated, throw all the cytokines out, pull in all the inflammatory cells, and start demyelination within one day. But I think that if you have preformed antibodies that have been built up to a fairly high concentration because you've had repeated recent boosters that you could produce antigenic body complexes which then could produce some neurologic symptoms. But I agree, one day is difficult.

Omnibus tr. at pp. 102-03; Augustynski v. Secretary of HHS, No. 99-611V, 2007 WL 3033614, at *3 (Fed. Cl. Spec. Mstr. Sept. 28, 2007) (symptoms of eventually diagnosed MS one day after second hepatitis B vaccination; ruled for petitioner based on prior immune priming from first hepatitis B vaccination).

Dr. Roland Martin, respondent's expert, had a similar reply when asked if there were a "very big inflammatory reaction you would be able to see the onset [of] demyelination earl[ier] [thatn] the time that you indicated?" Dr. Martin said:

> The onset of demyelination you would probably see if there's a preexisting condition. Then you might see it. So somebody who has already the disease has an open blood brain barrier and then receives a broad immune stimulus, then you could make the case that there could be some activation.

Omnibus tr. at 220-21.

In the instant action, petitioner testified that she had stabbing heel pain within 24 hours of her first hepatitis B vaccination, which disappeared after one week, and shoulder and arm pain within 24 hours of her second hepatitis B vaccination, which disappeared after 48 hours. She also testified that, over the next four months, she had intermittent episodes of pain in the same areas. Petitioner had a viral illness within three weeks of the onset of her burning feet which brought her to Mount Auburn Hospital in June 1995. .

The undersigned notes that Dr. Allan Ropper, an expert in GBS, found in examining petitioner on July 18 and 19, 1995 that she had inconsistency in her symptoms that made diagnosing a small fiber neuropathy difficult, and her presentation was odd for a demyelinating disease. However, in subsequent writings, he was willing to take petitioner's assertions of pain at face value and he diagnosed her with a small fiber neuropathy and later perineuritis (inflammation of many small sensory nerves). Dr. Ropper has a sterling reputation as a neurologist specializing in GBS.

This case has a number of difficulties. Perhaps the easiest way to begin a discussion is to note what both parties accept–that petitioner's viral illness in May led to her neurologic symptoms in June about three weeks later. Where their agreement diverges is that petitioner's expert Dr. Tornatore considers the viral illness to be the final immunologic trigger for petitioner's small fiber neuropathy or GBS variant and a substantial factor in causing her illness

together with the substantial factors of her two prior hepatitis B vaccinations whereas respondent's expert Dr. Sriram considers the viral illness to be the sole cause of her illness.

A difficulty in the case is diagnosing what petitioner has. What started out as a diagnosis of plantar fasciitis to explain petitioner's heel pain eventually became a diagnosis by treating doctors of a GBS variant (since she retained her reflexes and had normal nerve conduction studies and EMGs whereas, in typical GBS, a patient loses her reflexes and has abnormal nerve conduction studies and EMGS) to Dr. Ropper's diagnosis of perineuritis. The fact that her symptoms waxed and waned and she reported inconsistent symptoms when petitioner saw Dr. Ropper makes diagnosis even more difficult. The undersigned, however, has great respect for Dr. Ropper and is impressed that he saw petitioner and made a diagnosis of perineuritis, giving petitioner the benefit of the doubt. The Federal Circuit in Capizzano urges the special masters to give petitioners the benefit of the doubt in close cases, and to pay close attention to the opinions of treating physicians. It is also useful to remember that Dr. Barnes, another treating physician, opined that petitioner's vaccinations caused her neurologic problem.

The next difficult aspect of the case is onset of petitioner's initial symptoms–the stabbing pain in her heels. In her petition, filed in 1999, petitioner states onset was within a week of her first hepatitis B vaccination. In her affidavit, filed in 2002, she states it occurred one day after vaccination and that the vaccination was on January 28, 1995 (a Saturday). In her testimony, in 2008, petitioner stated that the vaccination was on January 25, 1995 (a Wednesday) and the onset of her heel pain was on January 28th. The documentation, such as it is, states the date of vaccination was January 27, 1995 (a Friday) with testing for hepatitis B surface antigen on Wednesday, January 25th. It makes no sense, of course, for petitioner's employer to test her to

see if she had hepatitis B surface antigen so as to determine if she needed vaccination, and then to give her the vaccination two days before the results came out. The undersigned does not understand how petitioner's memory is better in 2008 when she testified without the aid of any documentation than it was in 1999 when she filed her petition. Since there is no clear way out of this morass, the undersigned adopts petitioner's counsel's suggestion to take petitioner's earliest recorded memory (her petition) as correct, i.e., that her heel pain began within a week of her first hepatitis B vaccination, whenever it was.

This obviates discussing how petitioner could have a transient neurologic episode within one day of immune challenge. However, the undersigned notes Dr. Tornatore's testimony, though speculative, that she could have had a prior exposure to some virus before vaccination which primed her immune system, which echoes the Omnibus testimony of Drs. Byers and Martin that prior immunologic priming shortens onset time. The undersigned also notes the undersigned's decision in Herkert v. Secretary of HHS, No. 97-518V, 2000 WL 141263 (Fed. Cl. Spec. Mstr. Jan. 19, 2000), in which a child contracted transverse myelitis (TM) within one day of acellular DPT vaccination while he was harboring cytomegalovirus. The undersigned held that both the vaccination and the virus were substantial factors causing his TM.

In the instant action, Dr. Tornatore posited a biologically plausible medical theory relating hepatitis B vaccination in January to petitioner's heel pain and, in February, to shoulder and arm pain one day post-vaccination. The process of waxing and waning makes sense in light of the subsequent history of petitioner's illness where foot and arm pain, numbness, and burning were hallmarks. Petitioner's viral illness in May was the last immunologic challenge to petitioner, resulting in her hospitalization in June. There is a logical sequence of cause and effect

between the vaccinations and her symptoms, and the viral illness and the recurrence of her symptoms. Once petitioner had become sensitized to the antigens in her first hepatitis B vaccination, her one-day onset of shoulder and arm pain after the second hepatitis B vaccination is consistent with the Omnibus testimony of Drs. Byers and Martin that prior priming can speed up immunologic response. That it took three weeks after her viral illness for her symptoms to manifest badly enough to be hospitalized in June is explained by the difference in the antigen. Thus, the time of onset of all of her symptoms is medically appropriate.

Petitioner has proven a prima facie case of causation in fact.

CONCLUSION

Petitioner is entitled to reasonable compensation. The undersigned hopes that the parties may reach an amicable settlement, and will convene a telephonic status conference soon too discuss damages.

IT IS SO ORDERED.

July 31, 2008
DATE

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