In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 07-304V
January 28, 2008

SHERYL GABRIELLE,	*	
	*	
Petitioner,	*	
	*	
v.	*	Order to Show Cause why
	*	case should not be dismissed;
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	no proof of GBS and/or CIDP
	*	
	*	
Respondent.	*	

ORDER TO SHOW CAUSE[1]

On May 15, 2007, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10 et seq, alleging that an influenza vaccination she received on October 19, 1998 caused her to develop Guillain-Barré syndrome (GBS) and/or chronic inflammatory demyelinating polyneuropathy (CIDP).

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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.

Medical records that petitioner filed show that petitioner received pneumonia vaccine on September 19, 1998. The two-year window for filing a petition for pneumonia vaccine expired on December 18, 2001. 66 Fed. Reg. 21866. Therefore, if any of petitioner's alleged condition is due to pneumonia vaccine, petitioner is time-barred from receiving compensation for said condition.

The medical records show that petitioner has and had neither GBS nor CIDP. Petitioner is ORDERED TO SHOW CAUSE by **March 28, 2008** why this case should not be dismissed.

FACTS

Petitioner was born on February 6, 1958.

On December 13, 1993, petitioner saw Dr. Mandel, the neurologist, after she had a motor vehicle accident on September 2, 1993. Med. recs. at Ex. 8, p. 561. She complained of pain in the right side of her neck, tingling in both hands, waking with her hands falling asleep, aching in her neck, and pain going down both arms with a feeling of weakness and numbness in her arms. *Id.* She said she always wore tinted glasses but felt as if she could not see. She had blurring vision and saw an eye doctor but he said she did not have any abnormalities. *Id.* She could not see clearly when she attempted to read. She had difficulty sleeping. She had another motor vehicle accident in 1991, but also a number of other accidents in 1980, 1986, 1989, and 1990. *Id.* In 1991, she had an EMG and was informed she had a right ulnar neuropathy. She smoked one pack of cigarettes daily. *Id.*

Dr. Mandel commented that petitioner's complaints did not follow an ulnar distribution. Med. recs. at Ex. 8, p. 562. She had only mild evidence of ulnar conduction slowing across the right elbow. Her complaints involved primarily the thumb, index and middle fingers, suggesting

a carpal-tunnel type of illness. *Id.* Dr. Mandel thought petitioner had brachial plexus neuritis. Med. recs. at Ex. 8, p. 563. He recommended she have a brain MRI regarding her headaches and blurring of vision. *Id.*

On December 15, 1993, Dr. Mandel wrote a letter of referral to Dr. Edward Gerner because of petitioner's complaints of vision blurring, neck pain, and headaches. Med. recs. at Ex. 8, p. 564. Dr. Mandel wondered if petitioner had abnormalities of sympathetic dysfunction. *Id.*

On April 5, 1994, petitioner had a brain MRI done. Med. recs. at Ex. 8, p. 630. Petitioner had bilateral nonspecific foci of increased signal in the white matter, the largest in the periatrial corona radiata on the right, most likely vascular as seen in migraine headaches or vasculitis.[2] Demyelination was a less likely possible diagnosis. *Id.*

On May 17, 1994, petitioner saw Dr. Mandel, the neurologist. Med. recs. at Ex. 8, p. 559. She described continued problems in her neck, right arm, and occasional tingling in the right arm and hand. She said her neck had become severe with aching involving her neck and shoulders. At times, her right arm felt numb. She was still receiving physical therapy. A brain MRI showed nonspecific white matter changes that can be seen with migraine. Less likely was demyelinating plaques. *Id.*

On May 28, 1997, petitioner saw Dr. Jay Szathmary, an osteopath. Med. recs. at Ex. 2, p. 3. Petitioner had had a motor vehicle accident on May 16, 1997 and complained of pain in her mid and lower back, in her neck, and in her right shoulder. *Id.* Dr. Szathmary diagnosed

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[2] Vasculitis is "inflammation of a blood or lymph vessel...." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 2009.

petitioner with a permanent orthopedic disability. She had difficulty tolerating prolonged sitting, standing, lifting, and bending along with difficulty lifting with her right shoulder girdle. Med. recs. at Ex. 2, p. 14.

On June 2, 1997, petitioner saw Holly Thayer, a physical therapist, for her initial P-T evaluation. Med. recs. at Ex. 2, p. 48. She had been in a motor vehicle accident on May 16, 1997 and, since then, had pain from her neck to her buttocks. She also had numbness and tingling in both hands. *Id.*

On June 19, 1997, petitioner went for physical therapy, complaining of pain from her neck to her buttocks. Med. recs. at Ex. 2, p. 29.

On September 9, 1998, petitioner saw Dr. Szathmary and received pneumonia vaccine. Med. recs. at Ex. 2, p. 15.

On September 21, 1998, petitioner saw Dr. Szathmary, complaining of congestion and ear pain with fever. Med. recs. at Ex. 2, p. 16.

On October 19, 1998, petitioner saw Dr. Szathmary and received flu vaccine. *Id.*

On November 2, 1998, petitioner saw Dr. Szathmary, complaining that her right hand was swollen. Med. recs. at Ex. 2, p. 17.

On November 5, 1998, petitioner saw Dr. Thomas E. Cataldo, a colorectal surgeon. Med. recs. at Ex. 2, p. 64. Petitioner had seen him and Dr. Mark J. Pello routinely for perianal complaints. On that day, petitioner complained to Dr. Cataldo of severe pain in her right fifth digit whose onset was about one week. *Id.* It was a burning sensation but did not radiate proximally on her hand and she had no other complaints. With Dr. Cataldo questioning her, petitioner said some of her complaints related to changes in temperature. There might be some

aspect of worsening with smoking cigarettes. Petitioner denied any fever, chills, or any constitutional symptoms. In the past, there had been some swelling of the finger. *Id.*

On physical examination, on the distal aspect of all petitioner's fingers, there was significant damage to the cuticles of varied amounts. There were artificial nails, some of which had been removed, and there was significant venous congestion at the very tips of her fingers and around the paranychial region on all the fingers of her right hand. To Dr. Cataldo, it seemed most significant on the fourth digit of her right hand, and the fifth digit was very similar to the fourth digit. There was significant venous congestion with early re-capillary refill. Otherwise, her fingers were warm without evidence of vascular compromise. Dr. Cataldo's impression was that petitioner most likely had some type of vascular disorder, possibly Raynaud's disease. She might also have some type of reaction to the glue involved in her finger nails. *Id.* He instructed petitioner to keep her hands warm and to "discontinue smoking as this has a strong effect on the small blood vessels and capillaries of her fingers." *Id.*

On April 19, 1999, petitioner saw Dr. Robert C. Calvo, a hematologist/oncologist, for an infectious/inflammatory reaction in both her hands. Med. recs. at Ex. 2, p. 34. Petitioner was a hairdresser and a bartender who smoked one pack of cigarettes daily. She claimed she was well until she received Pneumovax and influenza vaccine in October/November 1998. She then developed some problems in one digit of her right hand which subsequently involved burning discomfort in both hands. *Id.* Petitioner had been treated by February 20, 1999 with Cipro three times, Floxin twice, and Lamisil for six weeks. *Id.* She had seen numerous doctors, including dermatologists, infectious disease experts. *Id.*

On physical examination, petitioner had purplish discoloration of the toes of her right foot and erythematous changes of the distal digits of both hands. Med. recs. at Ex. 2, p. 35. Dr. Calvo's initial impression was an erythromyalgia of the Raynaud's[3] type which probably reflected some degree of vasculitis in petitioner who had COPD (chronic obstructive pulmonary disease). *Id.* Dr. Calvo insisted that petitioner stop smoking. He ordered a chest x-ray. He prescribed low-dose aspirin. "Until she stops smoking, the situation is unlikely to improve and will not be remedied with any further antibiotic treatment." *Id.*

On May 12, 1999, petitioner saw Dr. Todd M. Lipschultz, an orthopedic surgeon. Med. recs. at Ex. 2, p. 37. Petitioner stated she had not worked since January 1st. She complained of a redness and swelling of the digits of her hands with particular attention around the eponychium folds. Petitioner stated this condition occurred shortly after she switched beauty salons where she had her nails done. She used to have sculptured nails but then went to this new salon. After they placed sculptured nails on her, she developed significant redness and swelling. *Id.* She had the new nails removed but had persistent problems since then. She thought she developed an infection. Petitioner told Dr. Lipschultz she had seen multiple physicians for this, including a dermatologist and an infectious disease doctor. She had been on multiple medications. She thought the dermatologist thought she had a fungal infection. She had used topical medicine as well as an oral anti-fungal. She was then on Cipro. *Id.*

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[3] Raynaud's is an "intermittent bilateral ischemia of the fingers, toes, and sometimes ears and nose, with severe pallor and often paresthesias and pain, usually brought on by cold or emotional stimuli and relieved by heat...." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1420.

On physical examination, petitioner had good wrist and digital range of motion. Med. recs. at Ex. 2, p. 38. She was neurologically intact. Her sensation was normal. There was no joint instability. She had slight redness around the perionychial folds of all her digits which was slightly tender. She did not have fluid extravasation. There was no significant grooving or other discoloration of the nails with pressure. Dr. Lipschultz concluded that, clinically, she seemed to have a generalized inflammation of all the eponychi/perionychial folds of her digits, which could have been a reaction to a topical product she used in the past. *Id.*

On June 11,1999, petitioner saw Dr. Mandel, the neurologist. She said she had been in a motor vehicle accident on May 18, 1999, and reported problems in her neck and shoulders dating to this accident. Med. recs. at Ex. 8, p. 557. She described the pain as shooting, stabbing, cramping, gnawing, hot-burning, aching, heavy, tender, moderate throbbing, sharp, hot-burning, tiring-exhausting, punishing, cruel, mild gnawing, splitting, sickening, fearful, and distressing. She rated her pain as 6-7 out of 10. She smoked one pack of cigarettes daily. On examination, she appeared to have limited movement in her neck. She did not have focal motor weakness in her upper or lower extremities. She had significant hyperreflexia in the knee jerks and ankle jerks. Her toes were downgoing. *Id.*

On June 20, 1999, petitioner had an MRI done of her cervical spine. Med. recs. at Ex. 8, p. 599. She had degenerative changes with disc space narrowing at C3-C4 through C5-C6. Med. recs. at Ex. 8, p. 600. She had ventral osteophyte formation and uncovertebral hypertrophic change at multiple levels at C3-C4 through C5-C6. The most prominent changes were at C3-C4. At this level, there was flattening of the ventral surface of the spinal cord. *Id.*

On July 20, 1999, petitioner saw Dr. Mandel, the neurologist. Med. recs. at Ex. 8, p. 556. She complained of problems in her neck and shoulders, but not in her arms. She described aching which she said was sharp, gnawing, heavy, tender, splitting, exhausting, shooting, stabbing, cramping, aching, and distressing. She was taking physical therapy and on SOMA. On examination, her neck area was tender with paraspinal muscle spasm. Her gait was normal without footdrop. She could turn without difficulty. Her motor strength was normal in the upper and lower extremities. She did not have atrophy. Her reflexes were 2+ and symmetrical. Her toes were downgoing. Sensation was normal to pin and touch. *Id.*

On July 22, 1999, petitioner's blood was drawn. Med. recs. at Ex. 5, p. 330. Her ANA was negative. *Id.*

On September 29, 1999, petitioner had a biopsy of the skin of her right upper back and of her right fifth finger. Her skin showed that the superficial dermis had an increased number of dilated venules, but no inflammation. Med. recs. at Ex. 2, p. 46.

On November 1, 1999, petitioner saw Dr. Mandel, the neurologist. Med. recs. at Ex. 8, p. 554. She said she had problems with her left elbow and severe pain in her neck which was horrible, excruciating, the worst possible, severe shooting, stabbing, sharp, heavy, tender, splitting, tiring-exhausting, sickening, fearful, punishing-cruel, moderately throbbing, hot-burning, and aching. She said it was frequent and any touch of the elbow made it worse. The pain was constant. *Id.*

On November 2, 1999, petitioner had an MRI done on her left elbow which was negative except for patient motion on a portion of the examination. Med. recs. at Ex. 8, p. 587.

On December 14, 1999, petitioner saw Dr. Mandel, the neurologist. Med. recs. at Ex. 8, p. 552. Petitioner complained of problems in her neck and upper extremities, with tingling and numbness paresthesias in her hands. She said her symptoms were unchanged with continued stabbing, shooting, sharp, cramping, aching, hot-burning, heavy, and tender symptoms. She said her fingers were falling asleep. Her left elbow hurt. Her fifth, and to a lesser degree, fourth finger of each hand was numb. On physical examination, she had no focal motor weakness. Her gait was normal. She did not have footdrop. She could turn without difficulty. Her motor strength was normal in the upper and lower extremities. She did not have atrophy. Reflexes were 2+ and symmetrical. Toes were downgoing. Sensation was normal to pin and touch. *Id.* Dr. Mandel diagnosed petitioner with minimal right thoracic outlet syndrome and left cubital tunnel syndrome. He thought the left elbow complaint had an orthopedic origin. Med. recs. at Ex. 8, p. 553.

On March 13, 2000, petitioner's urine was collected for analysis and she was found to have 3355.9 mg of protein (normal range is 30-150). Med. recs. at Ex. 7, p. 531. IgM was 419 mg (normal range is 48-271). Med. recs. at Ex. 7, p. 533. Petitioner was also positive for Epstein-Barr Virus (EBV) at 5.66 (normal is 0.00–0.90). Med. recs. at Ex. 7, p. 532.

On April 4, 2000, petitioner saw Dr. Mandel, the neurologist. Med. recs. at Ex. 8, p. 551. She said she rarely had neck problems and occasionally had problems between her shoulder blades. Weights relieved her pain. She had occasional stabbing, sharp, tender, and tiring-exhausting symptoms. She said bench weights eased her pain which she rated as 6 out of 10. She said that at times it could be horrible. Her cervical spine MRI showed some degenerative changes. On examination, there was no evidence of paraspinal muscle spasm. Her gait was

normal without footdrop. She could turn without difficulty. Her motor strength was normal in the upper and lower extremities. She did not have atrophy. Her reflexes were 2+ and symmetrical. Her toes were downgoing. Sensation was normal to pin and touch. She did not have tremor. Dr. Mandel's impression was that petitioner had a normal neurological examination. He wrote, "She has more subjective complaints that objective findings at this point." *Id.* He dictated his notes before petitioner and told her she did not need a neurologic follow-up or treatment. *Id.*

On May 1, 2000, petitioner's urine was collected for analysis and she was found to have 1416 mg of protein (normal range is 28-141) and IgG (Kappa) monoclonal protein. Med. recs. at Ex. 7, p. 529.

On November 20, 2000, petitioner's urine was collected for analysis and she was found to have 1776 mg of protein (normal range is 28-141). Med. recs. at Ex. 7, p. 528.

On December 7, 2000, petitioner saw Dr. Mandel, the neurologist. Med. recs. at Ex. 8, p. 549. Petitioner reported having problems in her right shoulder, right side of her neck, right arm, low back, left leg, and left hip. She had aching and difficulty walking with the left leg. She said the left hip pain was horrible. She described throbbing, shooting, stabbing, sharp, cramping, gnawing, hot-burning, aching, heavy, tender, splitting, tiring-exhausting, sickening, fearful, punishing-cruel. Lying down relieved some of her discomfort. *Id.* On examination, petitioner had tenderness in the low back and the right clavicular region. Dr. Mandel performed an EMG and nerve conduction studies on both lower extremities. Petitioner had normal sural sensory nerve action potentials, including latency, amplitude, and conduction velocity. Petitioner's peroneal motor responses were normal. *Id.* This included peroneal F wave responses. Med.

recs. at Ex. 8, p. 550. Petitioner had normal absolute latencies on bilateral H reflexes with no abnormality comparing the right and left legs. Petitioner had normal posterior tibial motor and sensory responses, including amplitude, latency, conduction velocity, and F waves. Needle EMG showed slight fibrillations, positive waves, and polyphasic units in a left L-5 distribution, including the lumbar paraspinal muscles. Dr. Mandel's impression was that petitioner had a mild left L-5 radiculopathy. *Id.*

On January 11, 2001, petitioner saw her doctor and stated that when she shook her foot, the pain was gone. Her flu symptoms were gone. Her rashes were fading and her fatigue was gone after four to five months of sleeping excessively. Med. recs. at Ex. 3, p. 159.

On March 9, 2001, petitioner saw Dr. Joel Steinberg, a vascular specialist. Med. recs. at Ex. 7, p. 468. He diagnosed her with erythromelalgia.[4] *Id.*

In a subsequent letter dated March 12, 2001, Dr. Steinberg, who is vice-president of the Guillain-Barré Syndrome Foundation International, states that petitioner told him she was healthy until October 30, 1998 when she received a pneumonia vaccine, followed about a week later by a flu vaccine, and then four days afterward became quite sick with fever, lung congestion and dyspnea. Med. recs. at Ex. 7, p. 525.

(Dr. Steinberg did not have petitioner's prior medical records when he noted petitioner's oral history on March 9, 2001. If he had had her prior records, he would have seen that she had been complaining about pains, numbness, tingling, and blurry vision since 1993, and had a 1994 brain MRI showing multiple sites of increased frequency in her white matter. Dr. Steinberg

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[4] Erythromelalgia is "a disease affecting the feet and sometimes the hands, marked by paroxysmal, bilateral vasodilation with burning pain, increased skin temperature, and redness." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 641.

would also have learned from the medical records that petitioner received Pneumovax on September 9, 1998, not October 30, 1998 as she told Dr. Steinberg on March 9, 2001. Dr. Steinberg would also have learned from the medical records that petitioner had congestion, ear pain, and fever on September 21, 1998, which was before she received flu vaccine, and not four days after she received flu vaccine as she told Dr. Steinberg on March 9, 2001. Dr. Steinberg would also have learned from the medical records that petitioner received flu vaccine on October 19, 1998, not around November 7, 1998 which is the scenario she gave Dr. Steinberg on March 9, 2001. There is nothing in the medical records showing she had congestion, fever, and dyspnea four days after she received flu vaccine. Dr. Steinberg did not know petitioner had told Dr. Cataldo on November 5, 1998 that she had severe pain in her right fifth finger whose onset was about a week earlier and she had no other complaint. Dr. Cataldo diagnosed her with Raynaud's syndrome. Dr. Steinberg did not know that petitioner had told Dr. Calvo on April 19, 1999 that she had problems with both her fingers and toes and that Dr. Calvo attributed her problem to Raynaud's brought on by her smoking which he advised her to stop. Dr. Steinberg did not know that petitioner had told Dr Lipschultz on May 12, 1999 that the problem in her hands began when she switched beauty salons and had false nails put on. Dr. Lipschultz attributed her general finger inflammation to a topical product.)

Continuing his March 12, 2001 letter, Dr. Steinberg recounts petitioner's history to him on March 9, 2001 that she had fever, lung congestion, and dyspnea from four days after the flu vaccine until mid-January 1999. The medical records do not support this history, but Dr. Steinberg did not have access to the medical records. Dr. Steinberg diagnosed her erythematous painful extremities as typical of erythermalgia, sometimes called erythromelalgia. It is a

temperature-induced vascular syndrome about which relatively little is known. *Id.* Because her symptoms began after vaccinations, he invoked an autoimmune process, triggered by one or both of the vaccines. *Id.* He then goes on to analogize swine flu vaccine causing GBS in 1976, and that GBS is an autoimmune disease. Med. recs. at Ex. 7, p. 526. In GBS, myelin is the target of the dysimmune process whereas in erythermalgia, a presumptive autoimmune process appears to have affected petitioner's distal skin vasculature. Her elevated IgM levels support there being an autoimmune process. *Id.* He states that erythermalgia might reflect an underlying myeloproliferative disorder, and petitioner had a monoclonal protein. He analogizes this scenario to demyelinating peripheral neuropathies which are sometimes associated with a monoclonal gammopathy of unclear etiology. He recommended that petitioner undergo a two-week course of two aspirins a day. If that did not work, Dr. Steinberg thought pharmacologic sympathetic blockage with Phenoxybenzamine would be a consideration. Since erythermalgia was exacerbated by warmth, he suggest petitioner wear light clothing and avoid warmth. *Id.* Dr. Steinberg noted that petitioner had left L-5 radiculopathy picked up on EMG which could explain why her left foot was not diffusely warm as he would expect from pure erythermalgia, and why some parts of her foot were actually cool. He would consider nerve blocks if her symptoms were greater. Dr. Steinberg noted that petitioner had substantial proteinuria which she related to Sporanox,[5] but he reflected that the proteinuria level had not normalized off Sporanox. *Id.* He suggested a kidney evaluation and petitioner told him she had been advised to get a

[5] Sporanox is a "trademark for preparations of itraconazole." Itraconazole is a "triazole antifungal, which inhibits the synthesis of ergosterol and so disrupts the fungal cell membrane; used in a variety of infections, administered orally." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1744, 960.

kidney biopsy to rule out amyloidosis. Dr. Steinberg thought an autoimmune process causing erythermalgia might also be acting on the glomerular level to cause a protein leak. *Id.* Dr. Steinberg further analogized to GBS and CIDP and suggested that high dose intravenous immunoglobulins vs. plasma exchange vs. immunosuppressive drugs such as Cyclophosphamide might work for petitioner. Med. recs. at Ex. 7, p. 527.

On April 27, 2001, petitioner saw Dr. Mandel, the neurologist. Med. recs. at Ex. 8, p. 548. She told him that she saw Dr. Joel Steinberg who said she perhaps had GBS. She described a great deal of pain with aching, numbness, pins and needles, and paresthesia. Heat made it worse and cold made it better. It sometimes lasted for weeks at a time. On physical examination, she had limited movement in her neck and low back. She had slight hyperreflexia at the knee and slight reduced ankle jerks. She had some reddening in the lower extremities. *Id.*

On June 25, 1991, petitioner saw Dr. Ramon Mañon-Espaillat, a neurologist who practices with Dr. Mandel. She told him that she had a year of painful paresthesias starting in the hands and now affecting her feet since December 2000. Med. recs. at Ex. 8, p. 546. She saw multiple doctors without a definite diagnosis except for a possible monoclonal gammopathy. She said all her symptoms started soon after she had two vaccines in 1998. (She did not tell Dr. Mañon-Espaillat that her two vaccinations were in early September 1998 and mid-October 1998. Onset in December 2000 would mean that there was a gap of two months between the flu vaccination and the onset of her symptoms. She also did not tell him that she had symptoms of pain, numbness, tingling, and blurry vision since 1993 and an abnormal brain MRI in 1994.) Petitioner told Dr. Mañon-Espaillat that her history was negative for other systemic illness. On examination, she had normal mental status and no motor deficits. She had a distal drop in pin

prick sensation in the lower extremities and hands. She had tender feet and hyperemic hands and feet. There was edema in the feet. Reflexes were present symmetrically and she had downgoing toes. *Id.* Dr. Mañon-Espaillat diagnosed petitioner with a sensory polyneuropathy. Med. recs. at Ex. 8, p. 547.

From July 9-27, 2001, petitioner was in Thomas Jefferson University Hospital. Med. recs. at Ex. 6, p. 401. She was given a trial of plasmaphoresis for peripheral neuropathy. Med. recs. at Ex. 6, p. 402. She told one consultant on July 20, 2001 that her right foot had been swollen since childhood. Med. recs. at Ex. 6, p. 406.

On July 11, 2001, petitioner had a single lev pressure index done. She had severe arterial disease (ischemia range) in the left lower extremity. There was no detectable signal in the left digits. Med. recs. at Ex. 6, p. 449. She had a history of peripheral vasculopathy. *Id.*

On July 12, 2001, petitioner had an MRI done of her brain which showed multiple nonspecific white matter intensities. One possible diagnosis was microvascular disease. Another was vasculitis. Similar findings have been described in patients with migraine headaches. Another possibility was demyelinating disease. A brain MRI in 1994 also showed multiple nonspecific white matter hyperintensities. Med. recs. at Ex. 6, p. 447. On the same date, an MRI was done of petitioner's cervical spine, showing cervical spondylosis and degenerative disc disease, worst at C3-C4 where there was retrolisthesis, disc herniation, and cord impingement. *Id.*

On July 16, 2001, an MRA (magnetic resonance angiography) of petitioner's lower extremity and abdomen showed left proximal superficial femoral artery (SFA) stenosis, about 50-

60%. Med. recs. at Ex. 6, p. 442. There was occlusion of the distal left SFA with reconstitution of the popliteal artery below the knee joint. *Id.*

On July 18, 2001, petitioner underwent a biopsy of the right kidney. Med. recs. at Ex. 8, p. 607. There was no hydronephrosis. *Id.*

The July 18, 2001 pathology report on the kidney showed adult minimal change disease,[6] mesangial hypercellularity variant. Med. recs at Ex. 6, p. 423.

On July 23, 2001, petitioner had a study of the bone of her right foot which resulted in a diagnosis of cellulitis without evidence of osteomyelitis. Med. recs. at Ex. 6, p. 441. However, the presence of significant peripheral vascular disease might have caused a false negative examination. *Id.*

On September 5, 2001, petitioner saw Dr. Steinberg, the vascular specialist. Med. recs. at Ex. 7, p. 487. When he saw petitioner in March 2001, he diagnosed her with erythermalgia and left L-5 radiculopathies. On April 13, 2001, he saw her again and she had findings of cyanotic left foot changes supportive of Raynaud's syndrome. Petitioner's history suggested a frequent hand-washing syndrome, but she denied it was an issue. Petitioner was to see Dr. Steinberg a week later to address further her vasospastic dysfunctional syndromes, but she did not return until September 5, 2001 to see him. She said she had received plasma exchange treatments for CIDP at Jefferson Hospital. She also indicated problems with pus at the left hallux and scabs. She used six to eight Percocet daily for pain. She said she had developed left more than right foot drop. Hallux pain limited walking. *Id.* Physical examination revealed a crusty dorsum and

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[6] Minimal chain disease is "subtle alterations in kidney function demonstrable by clinical albuminuria and the presence of lipid droplets in cells of the proximal tubules...." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 538.

scabs with a cool tip at the left hallux. Pedal pulses were not palpable. The palms of the hands showed bright erythema and warmth. Dr. Steinberg stated that clinically the left hallux supported the presence of ischemic cellulitis from severe Raynaud's syndrome. Blue toe syndrome from embolization was another possibility but less likely because only one toe was involved. She continued on Coumadin for protein S[7] deficiency-related clots. *Id.*

On September 11, 2001, petitioner saw Dr. Mandel, the neurologist. Med. recs. at Ex. 8, p. 544. Her left large toe was worse and the pain so severe she was taking Percocet. She described increased improvement in her hands and feet other than the toe. On examination, she had normal reflexes with downgoing toes. Her left large toe looked possibly infected. Position and vibratory sense were normal. *Id.*

From September 12-25, 2001, petitioner was at Thomas Jefferson University Hospital. Med. recs. at Ex. 6, p. 362. She had left big toe cellulitis, a history of deep venous thrombosis, peripheral vascular disease, minimal chain disease, HIT (heparin-induced thrombocytopenia), and questionable protein S deficiency. Her chief complaint was left big toe pain. *Id.* Petitioner had been taking nine to ten Percocets daily. Her left forearm became numb when she increased the dose of Percocet. *Id.* Petitioner was a 42-pack per year smoker who initially stated she had quit smoking in August 2001, but who smoked throughout her hospital stay. *Id.*

On September 14, 2001 and November 5, 2001, Dr. Steinberg wrote an affidavit saying that petitioner's symptoms were triggered by one or perhaps both of the vaccines she received in late October or early November 1998. Med. recs. at Ex. 7, pp. 482, 485. These affidavits are

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[7] Protein S is "a vitamin K-dependent plasma protein that inhibits blood clotting by serving as a cofactor for activated protein C." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1525.

identical except for the date of the notary republic. He does not state what his diagnosis is.

On January 2, 2002, petitioner saw Dr. Mandel, the neurologist. Med. recs. at Ex. 8, p. 543. She had a nonfocal examination. Her gait was normal without footdrop. She could turn without difficulty. Motor strength was normal in the upper and lower extremities. She did not have atrophy. Her reflexes were 2+ and symmetrical. Her toes were downgoing. Her sensation was normal to pin and touch. She did not have tremor or dysmetria. The toes on her left foot had a bluish discoloration. *Id.*

On February 1, 2002, petitioner had a CT scan done of her head. Med. recs. at Ex. 8, p. 565. There were mild periventricular white matter changes unchanged from her prior MRI likely representing chronic small vessel ischemic disease. *Id.*

From February 1-4, 2002, petitioner was in Thomas Jefferson University Hospital. Med. recs. at Ex. 6, p. 346. Petitioner had a history of protein S deficiency, DVT,[8] polycythemia,[9] proteinuria,[10] and sensory neuropathy. She came to the emergency room complaining of left-hand clumsiness and bifrontal headache. She had difficulty opening a bottle and blurry vision associated with flu-like symptoms and sinusitis. She complained of congestion and eye tearing.

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[8] Deep venous thrombosis (DVT) is "thrombosis of one or more of the deep veins of the lower limb, characterized by swelling, warmth, and erythema, frequently a precursor of a pulmonary embolism." A thrombus is "a stationary blood clot along the wall of a blood vessel, frequently causing vascular obstruction." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1907.

[9] Polycythemia is "an increase in the total red cell mass of the blood...." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1479.

[10] Proteinuria is "excessive serum proteins in the urine, such as in renal disease, after strenuous exercise, and with dehydration." Dorland's Illustrated Medical Dictionary. 30th ed. (2003) at 1526.

She reported severe nausea for a few days and abdominal pain. She complained of numbness in her left fourth and fifth digits. *Id.* On physical examination, she had decreased to pinprick left fourth and fifth digits. Her reflexes were 3+ bilaterally with downgoing toes. *Id.* Her brain MRI showed multiple acute infarctions in the cortex and deep white matter with several additional bilateral hyperintensities representing chronic ischemic changes, less likely demyelination. *Id.*

On February 4, 2002, petitioner had an MRI of her brain which showed several additional bilateral hyperintensities that probably also represented chronic ischemic change, less likely demyelinating disease. Med. recs. at Ex. 6, p. 359.

On February 13, 2002, petitioner saw Dr. Mañon-Espaillat, the neurologist. Med. recs. at Ex. 8, p. 542. She had multiple lesions on her brain MRI suggestive of ischemic disease, and polycythemia probably secondary to chronic smoking. On physical examination, she had normal mental status, no weakness or coordination problems, brisk and symmetrical reflexes, and bilateral downgoing toes. Dr. Mañon-Espaillat recommended that petitioner stop smoking which she stated she did three weeks ago, start Plavix because she cannot tolerate aspirin, and proceed with intermittent phlebotomy. *Id.*

On May 2, 2002, petitioner had serum protein electrophoresis which showed that she had decreased albumin. Med. recs. at Ex. 5, p. 341.

On June 21, 2002, petitioner saw Dr. Mandel, the neurologist, complaining of terrible pain at times involving her neck, back, and upper and lower extremities. Med. recs. at Ex. 8, p. 541. She described aching discomfort of her arms and legs and, occasionally, her hands. On examination, she had limited movement in her neck and back. Her gait was normal without footdrop. She could turn without difficulty. Motor strength was normal in the upper and lower

extremities. She did not have atrophy. Her reflexes were 2+ and symmetrical. Her toes were downgoing. Her sensation was normal to pin and touch. She did not have tremor or dysmetria. *Id.*

On December 23, 2002, petitioner had peripheral blood drawn which was interpreted as showing white blood cell disease. Med. recs. at Ex. 4, p. 229.

On August 22, 2002, petitioner saw Dr. Steinberg, the vascular specialist. His initial assessment in March 2001 was erythromeralgia, painful erythematous changes of the limbs, of uncertain etiology. She also had findings of left L-5 radiculopathy, Sporanox-related hyperproteinuria, and dry leg skin. Med. recs. at Ex. 7, p. 478. Petitioner told him she had been at Jefferson Hospital in January 2002 where they suspected transient cerebral ischemic attack. She was told she had thick blood for which regular phlebotomies were instituted. She stated her kidneys were healed and she was off Coumadin in spite of a history of protein S deficiency. Her primary complaint was left foot pain with inability to walk. She was concerned about infection. The bottom and heel of the foot had been hurting for four days without prior injury. The left calf cramped with a two-block walk when she had to stop. In the past, she could walk over a half-mile. *Id.* On physical examination, petitioner had swelling of the feet without pulses, moderate palmar erythema, good right but lack of left common femoral pulse, and lack of more distal pulses. Arterial doppler analysis showed findings of mild right and advanced left lower limb arterial obstruction. Dr. Steinberg's impression was acute left iliofemoral artery obstruction. "Although the left limb is not in imminent danger of loss, I am concerned about the potential for this in the not so distant future." *Id.* He noted detection of a faint IgG Kappa monoclonal

immunoglobulin. In November 2000, petitioner had substantial proteinuria at 1776 mg per 24 hour. Petitioner implied the proteinuria related to Sporanox. *Id.*

On December 10, 2003, petitioner saw Dr. Mandel, the neurologist. Med. recs. at Ex. 8, p. 538. She complained of some paresthesias and numbness. On physical examination, she had limited movement in her neck and low back. Her gait was normal. She did not have foot drop. She could turn without difficulty. Motor strength was normal in the upper and lower extremities. She did not have muscle atrophy. Her reflexes were 2+ and symmetrical. Her toes were downgoing. Her sensation was normal to pin and touch. She did not have tremor or dysmetria. *Id.*

On February 12, 2004, petitioner had a brainstem auditory evoked potentials EEG done which showed no abnormalities in the white matter pathways and was normal. Med. recs. at Ex. 7, p. 511.

Also on February 12, 2004, petitioner had visual evoked potentials EEG done which showed dysfunction of the white matter pathways anterior to the optic chiasm in her right eye. Med. recs. at Ex. 7, p. 509.

Also on February 12, 2004, petitioner had median nerve somatosensory evoked potentials EEG done which showed no abnormalities in the white matter pathways and was normal. Med. recs. at Ex. 7, p.

On February 23, 2004, petitioner saw Dr. Steinberg, the vascular specialist. Med. recs. at Ex. 7, p. 506. He states:

> She had been seen in the past with innumerable symptoms, beginning in February 2001, when she had a clinical picture supportive of erythromelalgia, a syndrome affecting the distal

> limbs, typified by hot and painful skin changes, and likely reflective of neurovascular dysfunction. A seriologic workup had shown an IgG Kappo Monoclonal Protein, with a negative bone survey, likely representative of a gammopathy of undetermined clinical significance. And in August, 2002, she presented with findings supportive of acute left iliofemoral artery obstruction, which retrospectively likely reflected spasm rather than fixed obstructive disease.
>
> At a visit a year later, in September 2003, she related undergoing phlebotomies every six weeks for polycythemia. She complained of ongoing migraine headaches. CAT scan of the sinuses was negative.
>
> At the patients' most recent visit on February 23, 2004, she related exacerbations of the feet and hand symptoms, presumably with pain and swelling, typical of vasospasm, as with Raynaud's syndrome, likely within the same family of neurovascular disorders, as erythromelalgia. She related diffuse morning stiffness, continued half pack per day smoking, senses of blinding light after headaches, with right eye stabbing pains. She related diffuse cephalgia.
>
> Exam highlights demonstrated bright erythematous changes of the palmar hands with mild hyper hydrosis, and similar erythematous changes of the distal toes, with pedal edema.

Id.

Dr. Steinberg's diagnosis was that petitioner had acrovasospasm, likely Raynaud's. He recommended petitioner stop smoking. He told her that Raynaud's typically responds to peripheral vasodilator therapy such as calcium channel blockers, but petitioner chose not to take them. Dr. Steinberg also diagnosed migraine syndrome as well as osteoarthritis due to her morning stiffness. *Id.* Her dysfunctional white matter anterior to the right eye optic chiasm and brain MRI showing some white matter changes suggested ischemia vs. demyelination. Med. recs. at Ex. 7, p. 507.

On March 11, 2004, petitioner had an MRI done of her brain and cervical spine. Med. recs. at Ex. 5, p. 234. There was one new lesion in the left suprainsular cortex of her brain which was dumbbell-shaped and measured 10 mm along its long axis and 7 mm along its base. *Id.* The cervical sign did not show anything suggestive of demyelinating plaque formation within the spinal cord. Med. recs. at Ex. 5, p. 235. She had a mild central stenosis secondary to a diffuse disc extrusion at C3-C4 prolapsing into the midline aspect of the adjacent lateral recess of C4. *Id.*

On May 28, 2004, petitioner had x-rays done of her cervical spine because of neck pain. They showed mild degenerative changes, worse in the mid-cervical region. Med. recs. at Ex. 7, p. 515.

On June 2, 2004, petitioner saw Dr. Steinberg, the vascular specialist. Med. recs. at Ex. 7, p. 494. She had a background of Raynaud's syndrome. She told him of migraine headaches with what sounded like scintillating scotomas. She related morning stiffness, strongly suggestive of arthritis. She had electrodiagnostic evidence of abnormal visual evoked potentials, due to pathology anterior to the optic chiasm. She had development of phlebotomies for polycythemia of migraine headaches and vision changes. She smoked half a pack a day. Her left foot became cyanotic in cold weather. On physical examination, she had erythema and warmth of her palms and toes. A May 28, 2004 x-ray of her cervical spine showed tiny osteophytes and narrowing of intervertebral disc spaces, supportive of arthritis and degenerative disc disease. *Id.* Dr. Steinberg concluded that petitioner's preeminent vascular challenge was Raynaud's syndrome. Her sed rate was only 1 and her ANA was negative. She had an elevated phosphatidylserine IgM antibody at 45, above a normal of 25, but the clinical significance was unclear. Petitioner

seemed to have another type of headache that might relate to scapular muscle tension from underlying cervical arthritis. She related headaches, migraines, with apparent scotomas. There was no hard evidence to support a diagnosis of multiple sclerosis. *Id.*

DISCUSSION

To satisfy her burden of proving causation in fact, petitioner must prove by preponderant evidence "(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 1317, 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...."

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).

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 influenza vaccine, she would not have had GBS and/or CIDP, but also that the vaccine was a substantial factor in bringing about her GBS and/or CIDP. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

Petitioner has not provided any evidence from a neurologist that she has GBS and/or CIDP. Petitioner is ORDERED TO SHOW CAUSE by **March 28, 2008** why this case should not be dismissed.

IT IS SO ORDERED.

_____ _____

DATE Laura D. Millman
Special Master