OFFICE OF SPECIAL MASTERS
No. 05-420V
September 5, 2006

KELLY BOLEY,	*	
	*	
Petitioner,	*	
	*	
v.	*	Hepatitis B vaccines;
	*	headaches, dizziness, and
SECRETARY OF THE DEPARTMENT OF	*	lightheadedness occurred two
HEALTH AND HUMAN SERVICES,	*	years before vaccinations; no
	*	objective findings; causation?
Respondent.	*	Dr. Andrew Campbell not credible

ORDER TO SHOW CAUSE[1]

Petitioner filed a petition dated March 30, 2005, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., and an amended petition dated June 6, 2005, alleging that hepatitis B vaccine administered to her on June 12, 2002 caused her to suffer a demyelinating polyneuropathy. Petitioner does not have a neurological condition and has no

[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.

objective illness other than mitral prolapse. Her dizziness, lightheadedness, and headaches occurred two years before she received her 2002 hepatitis B vaccination.

Petitioner is ORDERED TO SHOW CAUSE by **October 13, 2006** why this case should not be dismissed.

FACTS

Petitioner was born on June 11, 1973.

On May 9, 2000, petitioner complained of dizziness. Med. recs. at Ex. 2, p. 7.

On December 12, 2000, petitioner went to University of Colorado Hospital Emergency Department, complaining of feeling dizzy and feeling faint for several days which had become worse that day. Med. recs. at Ex. 3, p. 194. She felt lethargic. Med. recs. at Ex. 3, p. 195.

On December 13, 2000, petitioner went to University of Colorado Hospital, where she told Dr. Kennon J. Heard, instructor/fellow in emergency medicine, that, for several days, she had been having dizzy spells. She felt as if she were going to faint but did not. They lasted about 10-15 minutes and resolved when she lay down. They were not associated with tachycardia, shortness of breath, or chest pain. She said she felt somewhat nauseated with them. The last episode was earlier that day. On neurological examination, her cranial nerves were intact, and she had normal gait, balance, and strength. She was neurologically stable. Med. recs. at Ex. 3, p. 190. Dr. Heard's impression was mild lightheadedness. She was possibly mildly dehydrated. Med. recs. at Ex. 3, p. 191.

On December 20, 2000, petitioner went to the University of Colorado Hospital, where she told nurse practitioner Keith A. Meier that she had had four to five episodes of lightheadedness over the last couple of weeks, off and on, lasting perhaps five minutes. The most severe episode

was the day before when she was in the shower. She felt as if she could not catch her breath, her heart beat fast, and she got all shaky and nervous inside. She lay down and it resolved. Then she had a bit of a headache which went away with Tylenol. She stated that, most of the time, she had a shaky feeling inside. She felt groggy after each episode, which cleared after half an hour to an hour, depending on the severity of the attack. She told FNP Meier that these attacks seemed like panic attacks to her and she was concerned about them. Med. recs. at Ex. 3, p. 96. On neurological examination, the Romberg test was negative and her cranial nerves were normal. FNP Meier diagnosed panic attacks and prescribed Tylenol for headaches. Med. recs. at Ex. 3, p. 97.

On December 21, 2000, petitioner complained to her doctor about headaches and dizziness. She was 14 weeks pregnant and the doctor queried whether she had anxiety. Med. recs. at Ex. 1, p. 3. In a separate record of the same day, she was noted to have had a couple of attacks which sounded like panic attacks. One was in the shower and she was dizzy, had some palpitations and shortness of breath, and felt the room closing in on her. The doctor discussed this at length with petitioner and suggested biofeedback, exercise, and deep breathing. She was to return in two weeks and start some serotonin reuptake inhibitor if this did not improve. Med. recs. at Ex. 1, p. 9.

At 17 and ½ weeks gestation, there was fetal demise. Med. recs. at Ex. 2, p. 6.

On May 13, 2002, petitioner received her first hepatitis B vaccination. Ex. 5, p. 87.

On Wednesday, June 12, 2002, petitioner received her second hepatitis B vaccination. Ex. 5, p. 88.

On Wednesday, June 19, 2002, petitioner saw Dr. Phillip Rosenblum, complaining of a two- to three-day history of extreme fatigue and malaise. She felt feverish but was not running a fever. The onset of her symptoms was Saturday, June 15, 2002 (three days after her second hepatitis B vaccination). She had her second hepatitis B vaccination last week and also was bit by a bug last week, which crusted but healed now. Med. recs. at Ex. 5, p. 86. She complained of sort of a sore throat, but it was negative on examination. She had chills and sweats and was very tired. The doctor diagnosed a viral syndrome and questioned if it were related to hepatitis B vaccine because the symptoms started shortly after the injection and seemed to be worsening a little bit each day. *Id.*

On June 20, 2002, petitioner called her doctor telling him that her symptoms were worse. Her head pounded and she was more tired. The back of her neck hurt. Med. recs. at Ex. 5, p. 65.

On June 21, 2002, petitioner went to HealthOne North Suburban Medical Center Emergency Department, complaining of headache, dizziness, and lethargy. Med. recs. at Ex. 9, p. 9. She was in good health until about a week ago when she developed symptoms of headache, dizziness, and lethargy the day after her second hepatitis B vaccination. The first vaccination made her feel tired. She had some very slight nausea but no vomiting or diarrhea. She ate and drank okay but complained of slight neck discomfort. The headache was mild. She denied blurred or double vision, numbness, tingling, weakness, cough, chest pain, or abdominal pain. She had no fever. She has not had any fever throughout the week. Her vital signs were normal. *Id.* She did not appear to be profoundly lethargic. She had complete range of motion of her neck. Her neurologic examination was normal. Her HEENT examination was completely

normal. She had a possible adverse reaction to hepatitis vaccine or a possible viral illness. Med. recs. at Ex. 9, p. 10. She was not acutely ill and was sent home in good condition. *Id.*

On June 24, 2002, petitioner had blood drawn which showed a low fasting glucose of 53 (normal range being 65-109). Med. recs. at Ex. 5, p. 13.

On July 29, 2002, petitioner saw her doctor, complaining that she still was having dizzy spells and extreme fatigue. She said she was stressed because she started going to dental hygienist school. Med. recs. at Ex. 5, p. 85.

On August 12, 2002, petitioner saw her doctor, complaining of dizzy spells and fatigue. She was lightheaded with occasional vertiginous episodes. The doctor wondered if this were due to anxiety since she noted her anxiety increased when she started school. Med. recs. at Ex. 5, p. 84.

On August 16, 2002, petitioner saw Dr. Dennis V. Barcz, an otolaryngologist, complaining of two months of dizziness. She described occasional spinning but more of a constant groggy lightheaded feeling associated with general fatigue. There was some nausea but no vomiting. She denied ear problems. She dated the symptoms to a hepatitis B vaccination. On examination, her ears were normal. Neuro-otologic testing was normal. Dr. Barcz put her on Meclizine in case she had an inflammatory labyrinthitis. Med. recs. at Ex. 5, p. 61. Labyrinthitis can be associated with viral infections. He was not sure if the vaccination caused this. *Id.*

On August 19, 2002, petitioner had a brain MRI which was normal. Med. recs. at Ex. 6, p. 7.

On October 8, 2002, petitioner saw her doctor, saying she was told in dental hygiene school that her thyroid felt big. She saw Dr. Barcz for dizziness and had a brain MRI which was

negative. She still felt dizzy and almost passed out in class. Her left arm was shaking. Med. recs. at Ex. 5, p. 83.

On October 30, 2002, petitioner saw Dr. Hua Judy Chen, a neurologist, for dizziness, shaking, and numbness. She said she had been healthy until June 2002 when she received hepatitis B vaccine. She had a two-week illness including body fatigue, chills, dizziness, and pain behind her eyes. She stayed in bed for that period of time. After two weeks, the mild fatigue and episodic dizziness continued. The dizziness could occur a few times a day or every day for a few days. Sometimes, it was as if the room were spinning. A brain MRI in August was normal. She also had been having episodic shaking inside her body. Her eyes felt as if they were jerking but she never had double vision. Occasionally, she saw tremor in her hands during the shaking. For the past few days, she had numbness in the right 4th and 5th fingers at night which lasted a few hours. She did not have neck or arm pain. She told Dr. Chen she had not been on any medications. Her examination was normal except for subtle decreased pinprick in the right hypothenar area. Med. recs. at Ex. 5, p. 59. Dr. Chen's impression was transient neurological symptoms after viral or virus immunization. She had a possible right ulnar nerve mononeuropathy across the elbow. Med. recs. at Ex. 5, p. 60.

On November 2, 2002, petitioner went to the Emergency Department of HealthOne North Suburban Medical Center, complaining of hand and foot numbness. Med. recs. at Ex. 9, p. 34. She said she developed some hand numbness, leg and foot numbness, then face numbness and carpopedal spasms lasting 10 minutes about a half-hour before. She had no chest pain or shortness of breath. She had some tingling at the tips of her fingers. She had no leg swelling or

pain. She felt she might pass out when this happened, but felt better. Complete review of systems was negative. *Id.* The impression was hyperventilation. Med. recs. at Ex. 9, p. 35.

On November 7, 2002, petitioner had a thyroid ultrasound because she claimed an enlarged thyroid. Med. recs. at Ex. 9, p. 41. No mass was identified and there was no significant enlargement of the gland. *Id.*

On November 10, 2002, petitioner went to HealthOne North Suburban Medical Center Emergency Department, complaining of substernal uncomfortable aching pain. She stated her arms began to ache the day before. She was on Klonopin until the prior week for anxiety. Med. recs. at Ex. 9, p. 45. She had the pain when she stopped the Klonopin abruptly. She had an anxiety disorder. Med. recs. at Ex. 9, p. 55. Her EKG was normal. Med. recs. at Ex. 9, p. 56. Her pain could be musculoskeletal or a reaction to stopping the Klonopin abruptly or it could be anxiety-related. Med. recs. at Ex. 9, p. 57.

On November 10, 2002, petitioner had a chest x-ray because of chest pain. The x-ray was negative. Med. recs. at Ex. 9, p. 59.

On November 11, 2002, petitioner saw Dr. Rosenblum as a follow-up to an ER visit for chest pain. Her tests were normal, but it felt like indigestion. She was still having panic attacks on and off. She had two that day. Med. recs. at Ex. 5, p. 81.

On November 12, 2002, petitioner phoned her doctor. She received a prescription for Zoloft. She had recently taken Klonopin. She felt nauseated and trembly. She had panic attacks, with her heart beating fast, and wanted to know if this was normal. The answer was yes; this was a classic panic attack. Med. recs. at Ex. 5, p. 80. She phoned again that day and said her panic attacks were worse on Zoloft. The nausea was better, but she just could not calm herself. She

complained of chest pain, muscle twitching, and loss of appetite. She went to the ER and they said it was due to anxiety. Med. recs. at Ex. 5, p. 73.

On November 14, 2002, petitioner went to HealthOne North Suburban Medical Center Emergency Department for anxiety. She had shortness of breath, left-sided chest pain, and dizziness. Med. recs. at Ex. 9, p. 63. She had been on Zoloft since Monday. *Id.* She was having repeated anxiety attacks which had been occurring over the prior several weeks. Med. recs. at Ex. 9, p. 68. She had some emotional distress at leaving her 6-year-old child for the first time since she had gone back to school. She also had dizzy spells. *Id.* Dr. Joseph B. Friedman concluded she had an identified anxiety disorder. Med. recs. at Ex. 9, pp. 69-70.

On November 16, 2002, petitioner saw Dr. Rosenblum, complaining of a reaction to medicine including difficulty swallowing, muscle spasms, trembling inside, which was getting worse. Med. recs. at Ex. 5, p. 79. She was diagnosed with panic attacks. *Id.*

On November 20, 2002, petitioner telephoned her doctor and said she saw the nurse practitioner on Saturday, November 16th, for Zoloft and was told to discontinue it and switch to Effexor which made her extremely tired and dizzy. She could not even drive. Med. recs. at Ex. 5, p. 76.

On November 26, 2002, petitioner saw Dr. Chen, the neurologist, again. Her examination was normal. His impression was "unexplained neurological symptoms" likely related to viral or virus immunization. Med. recs. at Ex. 5, p. 58.

On December 4, 2002, petitioner saw her doctor, questioning him about her anxiety medications. She had chest aches for three days. She had fatigue and lightheadedness. Med. recs. at Ex. 5, p. 77.

On December 6, 2002, petitioner saw her doctor for a follow up for chest discomfort and pain. The report of her symptoms was crossing over multiple systems. Med. recs. at Ex. 5, p. 74.

On December 6, 2002, petitioner had blood drawn which showed a negative antinuclear antibody (ANA) and a negative rheumatoid factor. Med. recs. at Ex. 5, p. 6.

On December 10, 2002, petitioner had an echocardiogram which showed a mild degree of anterior mitral leaflet prolapse with a minor degree of leaflet thickening, but without mitral regurgitation, according to Dr. Peter P. Steele. Med. recs. at Ex. 5, pp. 51-52.

On December 16, 2002, petitioner saw Dr. Chen. She had finished her semester and her shaking episodes disappeared. She had one week of eye pain with intermittently seeing black spots and blurring. Sometimes she was nauseated. She had an ophthalmological test which was normal. Dr. Chen's impression was "Unexplained dizzy and shaking symptoms possibly related to anxiety." Med. recs. at Ex. 5, p. 57. Her current eye pain, visual disturbance, and nausea might be migraine. *Id.*

Also on December 16, 2002, petitioner had a visual field test which was basically normal, according to Dr. Matthew C. Sanderson. Med. recs. at Ex. 10. p. 2.

On January 6, 2003, petitioner saw Dr. Jill R. Breen, another neurologist, for chronic dizziness. Med. recs. at Ex. 5, p. 53. She gave a history of receiving hepatitis B vaccine on June 13, 2002 (it was June 12, 2002). On the day following the vaccination, she was groggy and dizzy. She did not have fever. She improved incompletely over the next two weeks. Ever since then, she continued to have grogginess, lightheadedness, photophobia, pain when she focused her eyes, and a dull ache behind her eyes. There was no throbbing or unilaterality. She initially had some nausea when she was lightheaded but no vomiting. A couple of times, the room looked

hazy and dim. This lasted 20 to 30 minutes and was associated with an increase in pain. Her symptoms waxed and waned during the day and over the course of several days. She felt better if she slept, but there was no improvement since six months previously. *Id.* Dr. Chen evaluated her and diagnosed possible migraines without headache as well as possible nerve damage from the vaccination. Her primary care physician found no cause. ENT evaluation was negative as was ophthalmologic evaluation. The patient said she was very active, used a treadmill at school walked frequently during the day, denied arthralgias and myalgias, but occasionally her right leg felt heavy from the knee down, lasting from 15-20 minutes. She had no neck or back pain. She slept through the night, about nine hours per night, and fell asleep right away. Some mornings, she felt fatigue, but, at other times, she felt well-rested. *Id.*

Petitioner had occasional muscle twitch in random areas. One leg might twitch briefly and stop. Then the twitch would move to another area. Med. recs. at Ex. 5, p. 54. She had no cramping or ongoing fasciculation activity. She has tried Pamelor, Effexor, and Zoloft, all of which increased her anxiety. She also tried Clonazepam which made her dysfunctional. *Id.* Her thyroid test was within normal limits. Med. recs. at Ex. 5, p. 55. Her neurological examination was normal. *Id.* All her tests were normal. Dr. Breen stated, "I do not find any evidence of primary neurologic disease. I do not find any evidence for multiple sclerosis, CNS vasculitis, etc." *Id.* Dr. Breen thought petitioner's symptoms would be most consistent with a chronic fatigue syndrome which could be due to virus, nondefined immune-mediated abnormality, depression, and anxiety. Med. recs. at Ex. 5, p. 56. Dr. Breen recommended no further neurologic evaluation, but medication to treat CFS. She discussed Paxil because Zoloft caused her to be anxious. *Id.*

On January 24, 2003, petitioner saw Dr. Steele, the cardiologist. She had had reasonably consistent mitral prolapse symptoms, a non-predictable effort-induced chest pain, and dyspnea. These created a perception of arrhythmia. The issue was the sympathetic nervous system dysfunction rather than the cardiac response. Med. recs. at Ex. 5, p. 50.

On January 30, 2003, petitioner saw Dr. Rosenblum. She had mitral valve prolapse and had been getting dizzy. She complained of episodic dizziness and lightheadedness, not associated with palpitations or chest pain which she got occasionally. She complained of anxiety. Med. recs. at Ex. 5, p. 72.

On February 2, 2003, petitioner saw Dr. Rosenblum, complaining of a rapid heart beat for four days. She had worse chest pain and shortness of breath. It got worse after drinking hot chocolate the day before. The doctor diagnosed mitral valve prolapse, palpitations, and anxiety. Med. recs. at ex. 5, p. 71.

On February 7, 2003, petitioner saw Dr. Steele, the cardiologist, complaining of a continuation of a kind of vertigo. He did not think it was related to prolapse. He spoke to her about the potential for Xanax for inner dizziness. Med. recs. at Ex. 8, p. 2.

On March 15, 2003, petitioner saw Dr. Michael A. Volz, a specialist in allergy, asthma, and immunological disorders, complaining of dizziness and fatigue, a history of mitral valve prolapse, and minimal cervical lymphadenopathy. Med. recs. at Ex. 5, p. 20. Dr. Volz found the origin of her dizziness and fatigue uncertain. There had been no objective findings, but interestingly the onset occurred within 24 hours of her second hepatitis B vaccination. [This is unlike the initial history she gave Dr. Rosenblum that onset was three days after vaccination.] She had previously received two hepatitis B vaccinations ten years earlier without incident. The

complex of symptoms came and went, and had not changed in frequency or severity over the prior several months. The minimal cervical lymphadenopathy suggested some persistent upper respiratory tract inflammation. *Id.*

Petitioner's history to Dr. Volz was that, within 24 hours of receiving her second hepatitis B vaccination on June 13, 2002 (it was June 12th), her symptoms began and were most severe during the first few weeks. Since that time, they waxed and waned without changing patterns in terms of severity, frequency, disruption, or length of time. Initially, the symptoms were severe enough to keep her in bed for several days to two weeks. She may have gone up to several days to two or more weeks without any symptoms. She had been told this was a virus-like reaction, but she had not experienced any fevers. She sometimes had a floaty feeling when she was lightheaded. "So far she has visited her primary doctor, one otolaryngologist, one cardiologist, one ophthalmologist, and two neurologists with **no abnormal objective findings** [emphasis added]." *Id.* Petitioner had received two hepatitis B vaccinations in 1992 with no reactions at that time. Med. recs. at Ex. 5, p. 21.

On examination, objective findings showed rhinitis and non-tender anterior cervical lymphadenopathy. They could have been totally unrelated to her chief complaints. Dr. Volz found notable the absence of other palpable lymph node groups and objective or subjective fever. The onset of her symptoms within 24 hours of hepatitis B vaccination could have been coincidental, but maybe it stimulated an enhanced hypersensitive immunologic reaction. Med. recs. at Ex. 5, p. 22.

On March 15, 2003, petitioner had an ANA test which was 1:40, whereas negative is below 1:40. Med. recs. at Ex. 14, p. 251.

On May 28, 2003, petitioner saw Dr. Breen, the neurologist, for chronic dizziness. Med. recs. at Ex. 11, p. 5. She described a sense of being off balance. The dizziness was worse on awakening but better by noon. At night, she had no dizziness. Occasionally, she had pain behind both eyes. Her ophthalmologist told her she was normal and did not have optic neuritis. Photosensitivity could last one to two days. This was not associated with her dizziness. She had no nausea, vomiting, headache, or blurred or double vision associated with light sensitivity or eye pain. She slept well and woke feeling rested. Muscle twitching occurred during a one- to two-week period when she sat in chairs or lay in bed. *Id.* Her examination was normal. Med. recs. at Ex. 11, p. 6.

On June 2, 2003, petitioner had an electronystagmography (ENG) test for balance. Clinical audiologist Karen Schroer found that caloric testing with air irrigation produced a 25% left unilateral weakness with no significant directional preponderance. Her ocular-motor testing, static positional tests, and positioning tests were normal. From these findings, audiologist Schroer concluded the results of the ENG were abnormal, suggesting a peripheral pathology. Med. recs. at Ex. 14, p. 115.

On June 4, 2003, petitioner had an EEG which was normal. Med. recs. at Ex. 7, p. 3.

On July 7, 2003, petitioner saw her ophthalmologist, complaining of sharp shooting pain in her right eye for two days and headache. The doctor stated the eye pain was of an unknown nature. Med. recs. at Ex. 10, p. 1.

On August 1, 2003, petitioner saw Dr. Andrew W. Campbell. Med. recs. at Ex. 14, p. 18. The day after her second hepatitis B vaccination in 2002, she was lightheaded, dizzy, and had headaches and severe fatigue. *Id.* She told him her ENG on June 13, 2003 was abnormal,

suggesting a peripheral pathology. Med. recs. at Ex. 14, p. 19. She told Dr. Campbell she had an elevated ANA in March 2003. Med. recs. at Ex. 14, p. 20.

On August 12, 2003, petitioner had a somatosensory evoked potential (SEP) of her posterior tibial nerve which was normal, according to Dr. Patricia J. Burcar. Med. recs. at Ex. 5, p. 1.

Also on August 12, 2003, petitioner had auditory evoked responses which were normal. Med. recs. at Ex. 13, p. 5.

Also on August 12, 2003, petitioner had visual evoked responses which were normal. Med. recs. at Ex. 13, p. 6.

Also on August 12, 2003, petitioner had a somatosensory evoked potential of her median nerves which was normal. Med. recs. at Ex. 13, p. 7.

On August 29, 2003, a nerve conduction study (NCS) was performed to determine if petitioner had demyelination. Med. recs. at Ex. 11, p. 8. On examination, she had normal strength, sensation, and reflexes. The NCS showed slowing of the peroneal nerve impulses across the fibular head, which most commonly resulted from focal compression of the nerve. Petitioner was asymptomatic and without neurological signs from this slowing. The remainder of the study including H-reflexes were normal in both lower extremities. There was no evidence for a demyelinating process. *Id.*

On September 9, 2003, petitioner had an EMG. Dr. James A. Crosby stated there was a slight latency delay across the right median motor nerve distally which might signify carpal tunnel syndrome. Otherwise, the EMG of the right upper and lower extremities was normal. Med. recs. at Ex. 7, pp. 1-2.

On September 12, 2003, Dr. Campbell wrote a "To Whom It May Concern" letter stating that petitioner had been diagnosed with a demyelinating polyneuropathy with immune suppression (presumably, Dr. Campbell, who is not a neurologist or an immunologist, made this diagnosis). Med. recs. at Ex. 12, p. 4. He states she had an abnormal neurological examination with hyporeflexia in all four extremities. He also states she had an abnormal nerve conduction study and an abnormal brainstem auditory evoked response potential. *Id.*

On November 9, 2003, Dr. James A. Crosby wrote to Dr. Campbell about petitioner's EMG results. Because the right side was almost completely normal, the left side was not tested. Med. recs. at Ex. 14, p. 41. Although petitioner might have a mild carpal tunnel syndrome, her EMG of her right upper and lower extremities was normal. Med. recs. at Ex. 14, p. 42.

Astonishingly, Dr. Campbell attempted to obtain IVIG treatment for petitioner. Med. recs. at Ex. 14, p. 85.

On what looks like October 24, 2003, someone taking notes for Dr. Campbell or Dr. Campbell himself writes that he called Park Infusion and spoke with Jerry who stated that neither petitioner's personal care physician or neurologist wanted to write an order for petitioner to receive IVIG treatment. Med. recs. at Ex. 17, p. 275. Petitioner was infused any way. Med. recs. at Ex. 274. Petitioner got lightheaded and chills. *Id.*

On December 8, 2003, petitioner complained of an increase in fatigue, dizziness, and weakness. Med. recs. at Ex. 17, p. 270. She felt she was going to faint three times over the prior week. She had an increase in memory problems. She complained of dysequilibrium. She had vision problems and headaches behind her eyes. She felt groggy in her head. *Id.*

On May 7, 2004, petitioner saw Dr. Steele, the cardiologist, because of dizziness. Med. recs. at Ex. 18, p. 1. It was quite typically inner ear. It was orthostatic, but also occurred if she moved her head. Dr. Steele was pretty sure it was inner ear dizziness. *Id.*

On November 19, 2004, petitioner took another nerve conduction study. Dr. Everton A. Edmonson found her to be normal although there may have been some technical artifact because there was a discrepancy between the left and right H-reflexes but also a significant difference in the amplitudes. Dr. Edmondson tested petitioner's bilateral upper and lower extremity nerve conductions involving median, ulnar, common peroneal, superficial peroneal, and tibial nerves. Med. recs. at Ex. 17, p. 150.

Also on November 19, 2004, petitioner took an NTI Postural Sway (Balance) Test, which she passed. Med. recs. at Ex. 17, p. 148. On the same date, she took an NTI Reaction Time Test, which she passed. Med. recs. at Ex. 17, p. 147.

On November 30, 2004, petitioner took another EEG which was normal. Dr. Richard Foa compared this EEG with the one on August 12, 2003 that was also normal. The conduction in her auditory nerve in its peripheral course apparently improved since the prior test. Med. recs. at Ex. 17, p. 142.

On December 2, 2004, petitioner took another brain MRI, which was normal and unchanged compared to the brain MRI of August 19, 2002. Med. recs. at Ex. 17, p. 140.

However, these normal tests did not dissuade Dr. Campbell from diagnosing petitioner with chronic demyelinating polyneuropathy, immune suppression, chronic lymphocytic thyroiditis, and chronic fatigue syndrome in record of a telephone conference dated January 6, 2005. Med. recs. at Ex. 17, p. 129. Dr. Campbell felt that petitioner's new elevated antibody

levels to a number of neuronal tissues were a result of her painting with a number of different paints in her home. Med. recs. at Ex. 17, p. 128.

On May 26, 2005, petitioner phoned Dr. Campbell to report severe episodes of muscle jerking, most noticeable at rest, more headaches behind her eyes, and fatigue. Med. recs. at Ex. 17, p. 9.

On June 17, 2005, petitioner saw Dr. Campbell. Med. recs. at Ex. 17, p. 5. On examination, her cervical and submandibular lymph nodes were enlarged. *Id.* He found deep tendon reflexes either absent or diminished in the arms. Med. recs. at Ex. 17, p. 6. He diagnosed petitioner with feeling tired or poorly, dizziness, numbness, adenopathy, mitral valve disorder, adverse effect of vaccines, Hashimoto's thyroiditis, headache syndromes, movement disorder, demyelinating disorders, inflammatory polyneuropathy, and immunodeficiency with predominant T-cell defect. He ordered an extraordinary number of tests. *Id.*

On July 18, 2005, Dr. Campbell diagnosed petitioner with restless leg syndrome, and noted high thyroid peroxidase serum antibodies, high thyroglobulin serum antibodies, and abnormal lymphocytes natural killer cells activity. Med. recs. at Ex. 17, p. 4.

DISCUSSION

This is a causation in fact case. To satisfy her burden of proving causation in fact, petitioner must offer "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Secretary of HHS, 418 F. 3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

> A persuasive medical theory is demonstrated by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]" the logical sequence being supported by "reputable medical or scientific explanation[,]" *i.e.*, "evidence in the form of scientific studies or expert medical testimony[.]"

In Capizzano v. Secretary of HHS, 440 F.3d 1274, 1325 (Fed. Cir. 2006), the Federal Circuit said "we conclude that requiring either epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect is contrary to what we said in Althen...."

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, at 1149. Mere temporal association is not sufficient to prove causation in fact. Hasler v. US, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984).

Petitioner must show not only that but for the vaccine, she would not have had polyneuropathy and/or CFS, but also that the vaccine was a substantial factor in bringing about her polyneuropathy and/or CFS. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

There are a number of problems with this case. The first problem is that petitioner did not have a neurological disorder or CFS. She did not have demyelinating disease, much less MS, TM, GBS, or CIDP which were the diseases discussed in the Omnibus proceeding on hepatitis B vaccine-demyelinating diseases. She saw an extraordinary number of doctors, including two neurologists, and none opined that she had a neurologic disease. She might have mild carpal tunnel syndrome. She might have compressed an elbow nerve. The only opinion that she had a

neurologic disease comes from Dr. Campbell, who is not a neurologist or an immunologist. The audiologist who thought she might have peripheral pathology is not a medical doctor and the undersigned does not accept medical opinions from persons who are not medical doctors. Domeny v. Secretary of HHS, No. 94-1086V, 1999 WL 199059 (Fed. Cl. Spec. Mstr. March 15, 1999), aff'd, (Fed. Cl. May 25, 1999) (unpublished), aff'd, 232 F.3d 912 (Fed. Cir. 2000) (per curiam) (unpublished) (proffer of dentist's testimony for diagnosis of a neuropathy rejected).

That leaves Dr. Campbell as the sole support for petitioner's allegation that she has a neuropathy. The idea that she has chronic fatigue syndrome, although evaluated by her other medical doctors, is not substantiated by the evidence in the medical records that she had no trouble going to sleep, slept nine hours, and woke refreshed. This not the description of someone with CFS. Her later complaints to Dr. Campbell of sleep disturbance come years after her hepatitis B vaccination.

The undersigned questions Dr. Campbell's conclusions in diagnosing and treating his patients. The Texas Medical Board has filed two complaints against Dr. Campbell of the Center for Immune and Toxic Disorders in Spring, TX, in the context of toxic mold injuries, charging Dr. Campbell with the following: operating below the standard of care, relying on unproven science when making a medical diagnosis, reaching medically unreasonable conclusions regarding a diagnosis that is not recognized or generally accepted in the medical and scientific community, ordering tests that are not appropriate, making medically and scientifically unsupported jumps in logical conclusions which betray a standard of care that is scientifically and medically unsound, making medically unsupported findings and conclusions of "abnormal neurological examination" based on incomplete examinations and failure to perform medically necessary diagnostic testing,

making medically and unsupported findings and conclusions of "demyelinating polyneuropathy" without meeting the medical and diagnostic criteria required before arriving at such a diagnosis, ordering treatment without meeting the appropriate medical and diagnostic criteria, requesting payment at a higher level than warranted, and unprofessional conduct in double billing, all constituting grounds for the Board to revoke or suspend Dr. Campbell's Texas medical license. The Texas Medical Board accused Dr. Campbell of unprofessional and dishonorable conduct that was likely to deceive, defraud, or injure the public. See Second Amended Complaint, page 33, paragraph 5. Both the First Amended Complaint and the Second Amended Complaint are available at: http://www.casewatch.org/board/med/campbell/complaint.shtml.

The second problem in this case is onset. Petitioner initially told Dr. Rosenblum that the onset of her symptoms (extreme fatigue and malaise) occurred three days after vaccination. If she had a demyelinating disease, this would put her in the ballpark (but just in it) for an appropriate temporal relationship. But she told every subsequent physician that her onset of symptoms (and the symptoms increased in variety and scope over time) occurred the day after her vaccination. She moved the date of the vaccination up from June 12, 2002 to June 13, 2002, and she moved the date of the onset of her symptoms back from June 15, 2002 to June 14, 2002. If petitioner insists on maintaining that the onset of her symptoms was one day after vaccination, she will have to provide an expert report substantiating that whatever she has can occur within one day of vaccination.

What petitioner has is panic attacks. She had them two years before vaccination (in 2000) and she had them after vaccination (in 2002 and later). Her doctors gave her numerous tests, all

of which came back normal. Only the dubious Dr. Campbell and the non-medical audiologist found that she had anything wrong (beyond carpal tunnel and a compressed elbow nerve).

Petitioner must file an expert report by **October 13, 2006** or this case will be dismissed. Petitioner is ORDERED TO SHOW CAUSE why this case should not be dismissed by **October 13, 2006**.

IT IS SO ORDERED.

_____ _____

DATE Laura D. Millman
Special Master