In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 98-627V
September 14, 2007
To be Published

BOHN D. DUNBAR,	*	
	*	
Petitioner,	*	
	*	
v.	*	Entitlement; hepatitis B
	*	vaccinations; causation of
SECRETARY OF THE DEPARTMENT OF	*	various illnesses, including
HEALTH AND HUMAN SERVICES,	*	autoimmune hepatitis, POTS,
	*	encephalopathy, lupus-like
Respondent.	*	syndrome, and neuropathy

Clifford J. Shoemaker, Vienna, VA, for petitioner.
Catherine E. Reeves, Washington, DC, for respondent.

MILLMAN, Special Master

RULING ON ENTITLEMENT[1]

Petitioner filed a petition on July 31, 1998 under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that hepatitis B vaccine caused him a lupus-like reaction with demyelinating disease/vasculitis.

[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.

A hearing was held on June 29, 2007. Testifying for petitioner were petitioner,[2] Dr. Joseph A Ballanti, and Dr. Yehuda Shoenfeld (by telephone). Testifying for respondent was Dr. Alan Brenner.

FACTS

Petitioner was born on March 13, 1947.

On August 7, 1976, petitioner went to Haxtun Community Hospital ER after falling and hurting his right shoulder. Med. recs. at Ex. 36, p. 37. He had an x-ray showing no fracture or dislocation. Med. recs. at Ex. 36, p. 38.

On April 27, 1978, petitioner went to Haxtun Community Hospital for pathological examination of tissue from the back of his head. Dr. R.D. Jensen noted that petitioner had a lesion in the back of his head in the area of his first cervical spine for two years, which haircuts irritated. Med. recs. at Ex. 36, p. 36. Dr. Jensen's diagnosis was focal acanthosis and hyperkeratosis, nonspecific. *Id.* Petitioner's physician was R.J. Ridenour. *Id.*

On August 11, 1994, petitioner had his first hepatitis B vaccination. Med. recs. at Ex. 37, p. 1.

On September 23, 1994, petitioner had his second hepatitis B vaccination. *Id.*

On September 26, 1994, three days after his second hepatitis B vaccination, petitioner went to the Occupational Health Program of Baylor College of Medicine and reported to Dr. Ellison Wittels that after his first hepatitis B vaccination, he developed pain under his left arm,

[2] Petitioner's wife Teresa Gilbertson did not testify but she submitted an affidavit. P. Ex. 62. She stated that petitioner's arm was red and sore after his first hepatitis B vaccination on August 11, 1994. He was tired and complained of not feeling well, lasting for about a week. After his second hepatitis B vaccination, he felt badly that day and the next, missing work. On Monday, he went to see a doctor. *Id.*

headache, nausea, and watering of his left eye. Med. recs. at Ex. 20, p. 4. He reported that, after his second hepatitis B vaccination, he had frontal headache, aches and pains, sweats and chills, twitching of his left eyelid, joint aches, and stiffness. Physical examination revealed only conjunctivitis and he was prescribed Benadryl for three to four days. *Id.* Dr. Wittels diagnosed petitioner with an allergic reaction and deemed him able to return to work. Med. recs. at Ex. 20, p. 5.

On November 2, 1994, petitioner saw Dr. Charles H. Miranda, an internist. Med. recs. at Ex. 2, p. 1. He told Dr. Miranda that, after the first hepatitis B vaccination, he had a minor local reaction consisting of erythema and pain around the injection site. After the second hepatitis B vaccination, petitioner said he had severe local pain in his arm, mild erythema, paralysis and weakness from shoulder to elbow of his vaccinated arm, generalized myalgias, fatigue, arthralgias, malar rash, and axillary lymphadenopathy which had since resolved. He complained of increasing fatigue, marked loss of short-term memory, shortness of breath, and dyspnea on climbing two flights of stairs. Petitioner stated he had had previous reactions to influenza vaccinations. He denied any preceding viral prodrome or current visual changes. Dr. Miranda's impression was that petitioner's condition was consistent with systemic lupus erythematosus or a lupus-like drug reaction. *Id.* On physical examination, petitioner was awake, alert, and active. He did not have lymphadneopathy, cyanosis, clubbing, or edema. He had normal cranial nerve testing. His motor strength was 5/5 bilaterally. His sensory examination and cerebellar examination were normal. His deep tendon reflexes were 2+ bilaterally and symmetrical. He complained of arthralgias which were worse in the morning. He was increasingly sleepy and

fatigued during the day. He described marked loss of short-term memory and shortness of breath. He noted bilateral flank discomfort. Med. res. at Ex. 6, pp. 1, 2.

On December 1, 1994, petitioner returned to Baylor Occupational Health with a four- to five-day history of pain and three to four days of feeling tired and waking up tired. Med. recs. at Ex. 20, p. 6.

On December 2, 1994, petitioner had blood taken. Med. recs. at Ex. 40, p. 14. His ALT was 49 (range of normal being 0-45) and his iron was 165 (range of normal being 35-140). *Id.*

On December 23, 1994, petitioner saw Dr. Martin D. Lidsky, a rheumatologist. Med. recs. at Ex. 2, p. 4. He complained of increased fatigue, joint pain, malaise, facial skin eruption, accelerated loss of scalp hair, chilliness, and short-term memory loss. Dr. Miranda found evidence of serum ANA at an elevated titer (which was a false positive, see Ex. 4, p. 1) and the presence of serum antibody to the Smith antigen. He had normal strength. *Id.* The onset of his complaints was early October 1994. He noted decreased muscular strength. He was very angry over the state of his health. Petitioner drank two to four beers at night. On physical examination, he generally looked well. He appeared anxious, alert, and oriented. He communicated effectively. He had no palpable lymphadenopathy. Med. recs. at Ex. 7, pp. 3, 4. He had telangiectasia over the cheeks of his face, male baldness, no edema of the lower limbs, ordinary and normal tandem gait, normal strength (+5/+5) bilaterally, and present and normal reflexes. Med. recs. at Ex. 7, p. 5. His cardiolipin IgG was 48.920 (range of normal being 0.000-23.000). Med. recs. at Ex. 40, p. 24.

On January 16, 1995, petitioner returned to Dr. Lidsky. Petitioner's blood count was normal. He had an elevated serum ALT (SGPT) of 49 units/liter (the normal range being 0-45).

This turned out to be a false positive. His serum ANA titer was 1:160. He did not have elevation of serum antibodies to Smith antigen. Petitioner had elevated serum IgG antibody to cardiolipin. The value was 48.920 with GPL (normal being 0-23). There was no elevation of serum IgM antibodies to cardiolipin. Dr. Lidsky's impression was a possible presence of systemic rheumatic disorder with lupus-like manifestations. *Id.*

On January 27, 1995, petitioner saw Dr. Eugene C. Lai, a neurologist. Petitioner's muscle tone was normal, and his strength 5/5 and symmetrical. Med. recs. at Ex. 2, p. 15. He had a fine reddish malar rash on his face. Dr. Lai's impression was a three-month history of progressive memory decline, visual disturbance, and fatiguability. On physical examination, petitioner had bradyphrenia (fatiguability of interest) and mild short-term memory deficit. He had difficulty with calculation and programming. Dr. Lai's impression was mild encephalopathy that might be related to his connective tissue disease. *Id.*

On January 27, 1995, petitioner had a brain MRI done. Med. recs at Ex. 7, p. 83. The MRI was normal. *Id.*

On February 2, 1995, petitioner saw Dr. Andrew G. Lee, a neuro-ophthalmologist. Med. recs. at Ex. 2, p. 19. Petitioner had intermittent positive visual phenomena associated with photosensitivity and photophobia. *Id.* There was no evidence of anterior segment inflammation, uveitis, or vasculitis. Med. recs. at Ex. 5, p. 1.

On February 14, 1995, petitioner returned to Dr. Lidsky. On physical examination, he was anxious, alert, and oriented. Med. recs. at Ex. 7, p. 33. He communicated effectively. He had telangiectasia on the cheeks bilaterally. He had no palpable lymphadenopathy. The

remainder of his physical examination was normal. He did not have edema of the lower limbs or clubbing of his fingers or toes. *Id.*

On March 1, 1995, petitioner saw Dr. Frank C. Arnett, Jr. Med. recs. at Ex. 12, p. 8. On examination, petitioner's joints revealed no synovitis. His muscle strength was normal. His neurologic state was nonfocal. His fundi were normal. He had some rigidity of his arms and legs and generalized shakiness. Med. recs. at Ex. 12, p. 9.

On March 10, 1995, Dr. Arnett telephoned petitioner because he received all of petitioner's lab results back. Med. recs. at Ex. 12, p. 1. Testing for serologic evidence of lupus was entirely negative. Specifically, his ANA was negative on two occasions. Testing for anti-Sm, RNP, Ro, and La was also negative. He was negative for cardiolipin antibodies, anti-DS-DNA, and lupus anticoagulant. An antiribosomal-P antibody was negative. Dr. Arnett could not substantiate the prior diagnosis of systemic lupus erythematosus. He suspected an initial laboratory error in the reportedly positive test for ANA and anti-Smith in December and/or February. Petitioner had stored serum from that time and offered to provide some to Dr. Arnett to retest. *Id.* In an addendum, Dr. Arnett did a repeat test for ANA from the December 1994 serum which was negative. The anti-Smith was preliminarily negative also. Med. recs. at Ex. 12, p. 2.

On March 15, 1995, petitioner returned to Dr. Lee. Petitioner's eye examination was not suggestive of any specific disorder. He had a completely normal macula, vessels, and periphery. Med. recs. at Ex. 5, pp. 2, 3. His optic nerve was normal. He had no disc edema or vitreous cell in either eye. Petitioner complained of photosensitivity, photophobia, and several episodes of blurry vision. Dr. Lee recommended reading glasses. *Id.*

On April 16, 1995, petitioner saw Dr. Lidsky. Med. recs. at Ex. 7, p. 38. Physical examination showed inflammatory soft tissue swelling involving the proximal interphalangeal joint of the right middle finger. He could not elicit the left gastrocnemius-soleus reflex (above the calf) even on reinforcement. *Id.*

On May 10, 1995, petitioner's sister, Bonnie Dunbar, filled out a VAERS form for petitioner. Med. recs. at Ex. 42, p. 9.

On May 12, 1995, petitioner saw Dr. Lidsky. Med. recs. at Ex. 7, p. 44. Petitioner was overtly depressed. He spoke in a tremulous voice, sighed repeatedly, and had a very sad appearance. Med. recs. at Ex. 7, p. 45. He was oriented and communicated effectively. There was no palpable lymphadenopathy. He had telangiectasia on the cheeks bilaterally. He had male baldness, no edema of the lower limbs, and no clubbing of the fingers and toes. He had normal strength bilaterally, no dysmetria (his muscle control was okay). Dr. Lidsky was unable to elicit the left gastocnemius-soleus reflex. Dr. Lidsky's diagnosis was overt depression. Med. recs. at Ex. 7, p. 46.

On June 14, 1995, petitioner saw Dr. Lidsky. Med. recs. at Ex. 7, p. 54. The left gastrocnemius-soleus reflex was present but diminished. Petitioner appeared anxious and manifested a flat affect. *Id.*

On June 22 and 28 and on July 25, 1995, petitioner saw Robert G. Harper, Ph.D., a neuropsychologist. Med. recs. at Ex. 2, p. 22. Petitioner had some indications of deficits in information processing speed, effortful attention-concentration, and cognitive flexibility on the Wechsler Memory Scale. He scored 116 or above average with no appreciable deficit in mnemonic functioning. He had good motor function within normal, grip strength much above

normal bilaterally, with depression and heightened somatic anxiety, i.e., he perceived he was worse than he was. Med. recs. at Ex. 2, pp. 24, 25. Dr. Harper's impression was an incompletely resolved encephalopathy. Med. recs. at Ex. 2, p. 25.

On July 6, 1995, Dr. Harper opined that 116 on the Wechsler memory scale was above average and indicated no appreciable deficits in mnemonic functioning. Med. recs. at Ex. 7, p. 71. Petitioner performed the California verbal learning test generally within normal limits on all measures. His recall of a temporal ordering of information was unimpaired. His generative naming or rapid word retrieval was within normal. *Id.* The controlled oral word association test showed petitioner approached high average. Med. recs. at Ex. 7, p. 72. Petitioner's motor function was well within normal. His grip strength was much above average bilaterally. His visual tracking and sequencing, and cognitive set shifting appeared grossly well-preserved. Almost inexplicably, petitioner was unable to establish and maintain a computer-defined rule involving sorting cards according to the determinants of form, color, or number. Dr. Dunbar reported minimal somatic distress. He denied appreciable psychological symptomatology. His MMPI profile, however, by contrast reflected psychometrically significant depression and heightened somatic anxiety. Petitioner made considerable use of denial and repression. He had some probable deficits in information processing speed, sustained attention concentration, and certain aspects of concept formation and efficiency in trial and error learning. However, although petitioner complained of memory compromise, formal psychometric assessment showed his learning, recall, and retention of newly-acquired information was generally unimpaired. While it was petitioner's perception that his fine motor control was reduced, his performance was within normal limits and indeed well above average for such parameters as

bilateral grip strength. *Id.* Petitioner's nervousness and apprehension about his diminished abilities contributed to some of his difficulties on some tasks. *Id.*

On August 14, 1995, Dr. Richard D. deShazo, an allergist-immunologist and rheumatologist, reviewed petitioner's records. Med. recs. at Ex. 9, p. 271. All the physicians who saw petitioner concurred he had an untoward reaction to hepatitis B vaccine, although the specific type of reaction was in dispute, one doctor opining petitioner had lupus cerebritis. Causation from hepatitis B vaccine was supported not only by the temporal association with the onset of his illness, but by the fact that he had an unusual syndrome of local inflammation at the site of revaccination. *Id.* The manufacturer's product information notes that neurological reactions to hepatitis B vaccine include peripheral neuropathy, Guillain-Barré syndrome, radiculopathy, transverse myelitis, and Bell's palsy. The psychologist who examined petitioner opined there was objective evidence he had a resolving encephalopathy. Dr. deShazo stated a resolving encephalopathy was the most likely diagnosis in his opinion of petitioner's condition. *Id.* Dr. deShazo concluded petitioner had an episode of encephalopathy caused by hepatitis B vaccine. *Id.*

On September 5, 1995, petitioner saw Dr. James W. Ley, stating he had a vasculitis affecting his eyes. Med. recs. at Ex. 25, p. 10. On examination, petitioner's joints did not show evidence of warmth, swelling, or tenderness to palpation. His range of movement seemed normal in all his joints and he had no pain with passive or active range of movement. Med. recs. at Ex. 25, p. 9. He had no muscle weakness. His fundi appeared normal. *Id.*

On September 19, 1995, petitioner saw Dr. V. Joyce Gauthier, a rheumatologist. Med. recs. at Ex. 4, p. 1. Petitioner gave a history that, shortly after the first hepatitis B vaccination on

August 11, 1994, he developed lethargy the next day with soreness and stiffness in his arm. He recovered although he was tired for several days. He received his second hepatitis B vaccination on September 22, 1994 and his arm became sore. He was fatigued shortly thereafter and went downhill since. He was unable to perform his job. In mid-November, he was referred to an internist at Baylor and had a positive ANA with increasing problems with fatigue and forgetfulness. He received pulse dose steroids in December 1994. *Id.* Petitioner had short-term memory loss and bradyphrenia (sluggish thinking) with a normal MRI. Med. res. at Ex. 4, p. 2. In February 1995, he had a second set of pulse steroids. He was referred to Dr. Frank Arnett, a lupus specialist, who did lupus studies on petitioner that were negative. A retesting of the original bloods showed a lab error was responsible for the ANA tests being positive previously. Petitioner was told to stop taking Prednisone. He had continued fatigue, rash, and memory problems. He had multiple psychological assessments due to his frustration with questionable diagnoses and possible association with hepatitis B vaccine. He was evaluated in July 1995 with psychometrics (psychologic testing) and was felt to have an incompletely resolved encephalopathy. He had tried multiple times to use antidepressants to help with anger and fatigue issues which were unsuccessful throughout 1995. In July 1995, petitioner noticed increased problems with discomfort and functioning in his left leg and more recently complained of some of this in his right leg as well. He was in conflict with his employees compensation and physicians at Baylor. He was seeing Dr. Gauthier for a second opinion. *Id.* He had a history of high arches, a pattern in his family, and mandibular torus (thickening of the bone of the lower jaw), which also ran in the family. Med. recs. at Ex. 4, p. 3. On physical examination, he had a large white bony mass under his tongue, which ran in his family. He had somewhat smaller

musculature on the left leg than on the right and bilateral pes cavus (high arch). There were no abnormalities on rheumatologic assessment in December 1994. Med. recs. at Ex. 4, p. 4. On neurologic examination, his reflexes and sensation were normal. He had prominent vessels on his face bilaterally in the malar region without actual vasculitis at this time. He stated this was different than before the last few years. Dr. Gauthier's impression was a serum-sickness-like reaction to the initial vaccinations which argued for an immunological event. *Id.*

On February 23, 1996, petitioner had a physical examination of his hands. Med. recs. at Ex. 4, p. 30. He did not have any joint swelling, redness, erythema, or tenderness to palpation over the joint. Petitioner complained of achy joint pains involving primarily the metacarpal phalangeal (MP) joints of the left hand, numbers 3, 4, and 5. He had a little bit in the right hand, number 5, and also in the sacroiliac area bilaterally in his lower back. He had some unusual pains down the sides of his fingers, especially the left hand, numbers 3 through 5. Those had stopped. He still complained of poor memory. He still was quite tired and required 12-14 hours of sleep. Exertion resulted in nausea the next day. He still had pain down the left leg and still complained of spots in his eyes. *Id.*

On May 24, 1996, petitioner saw Dr. Sterling West, the clinical director of the Autoimmune Disease Center, University of Colorado Health Sciences Center. Med. recs. at Ex. 4, p. 34. This was an IME at the request of Corvel Corporation. Petitioner saw Dr. Frank Arnett in March 1995 at the University of Texas at Houston for a second opinion for worker's compensation. Med. recs. at Ex. 4, p. 35. His ANA was negative on two different occasions. Repeat testing of saved blood from December 1994 when petitioner first saw Dr. Lidsky also revealed a negative ANA. Petitioner did not have lupus. *Id.* On June 15, 1995, petitioner saw

Dr. Betsy Compton for psychiatric and neurologic testing for worker's compensation. He had an IQ of 117, but petitioner claimed it used to be 140 (but did not have proof). Testing showed no memory problems. Petitioner complained of reduced fine motor control but none was demonstrated on testing. He had significant depression and anxiety. Dr. Robert Harper felt that petitioner's psychologic status affected his performance on cognitive testing. Med. recs. at Ex. 4, p. 37. He had a history of bad headaches as a child. He had ringing in his ears before because of shooting rifles. He had a reaction to horse serum when he received a tetanus shot. He drank two beers a day and occasionally more. Med. recs. at Ex. 4, p. 38. On physical examination, petitioner had male baldness pattern, mild malar erythema with telangiectasis, but no raised or palpable rash in this area. His extremities did not have clubbing, cyanosis, or edema. There was no evidence of synovitis. He had full range of movement of his joints. Neurologically, he had slight tremor of his hands when outstretched at rest. He had intention tremor. Petitioner scored 30 out of 30 on a mental status examination. He refused to do serial 7s. Petitioner's motor, sensory, and cerebellar examinations were normal. His deep tendon reflexes were 2+ bilaterally except for the ankle jerks which were decreased bilaterally. Dr. West was unsure if petitioner could not relax for the examination or if this were a finding. X-rays of petitioner's joints were reportedly normal in the past. *Id.* Dr. West's assessment was that petitioner had a symptom complex of fatigue and arthralgias without objective signs of inflammation. He had mild cognitive deficits with psychologic distress. He had a normal cerebrospinal fluid examination. Petitioner did not have systemic lupus erythematosus. Dr. West suggested he obtain a chronic fatigue syndrome evaluation and a psychiatric evaluation. He had erythematous accentuation of his facial telangiectasis with sun exposure. The rash was not classic for systemic lupus

erythematosus. It was suggestive of sun-damaged skin. Petitioner's history of shooting rifles could have contributed to his hearing loss and dizziness. Dr. West's impression was that petitioner did not have systemic lupus erythematosus or another identifiable autoimmune connective tissue disease. At the time of examination, it was difficult to quantify his fatigue and arthralgias without objective symptoms. Petitioner should never receive any further corticosteroids or narcotics. *Id.*

On August 30, 1996, petitioner was brought to Sterling Regional MedCenter ER by ambulance, complaining of neck and back pain. He had spots in his eyes and numb hands. He was immobilized on a back board. Med. recs. at Ex. 22, p. 225. Petitioner stated his head hit the back window. He complained of being dizzy after ambulating at the scene. He denied pain anywhere else. *Id.*

On October 7, 1996, petitioner saw Dr. James F. Jones. Med. recs. at Ex. 34, p. 106. There was no objective data for any inflammatory process at the current time. Med. recs. at Ex. 34, p. 107. Petitioner had postural orthostatic tachycardia syndrome (POTS). He had a near syncopal episode. POTS syndrome can be associated with many of petitioner's symptoms, particularly the lightheadedness, dizziness, headache, and cognitive problems. The origin of POTS is not clear. It can follow infectious illnesses. Dr. Jones did not feel petitioner's illness was related to chronic fatigue syndrome but more related to POTS and a past exposure following hepatitis B vaccine. Med. recs. at Ex. 34, p. 108.

On October 29, 1996, petitioner went to physical therapy at Haxtun Hospital because of a cervical muscle strain and ligamentous sprain. He was in a motor vehicle accident two months

earlier and was hit from behind. The back of his head broke the rear glass. Med. recs. at Ex. 36, p. 17.

On November 8, 12, and 13, 1996, petitioner was tested by Elizabeth Kozora, Ph.D., a neuropsychologist. Med. recs. at Ex. 34, pp. 94, 100. Although petitioner reported significant difficulties with memory, she did not find evidence for this in formal testing. Med. recs. at Ex. 34, p. 98. His verbal learning and recall across two different types of tests were well within normal limits. *Id.* Petitioner reported mild difficulty in planning and problem solving, but his results were not impaired in those areas. Med. recs. at Ex. 34, p. 99. He did well on tests requiring flexible thinking and he was not perseverative in his thought processes. *Id.* Petitioner reported mild problems with language function but, in formal testing, his receptive and expressive language skills were normal. *Id.* Dr. Kozora concluded that petitioner's overall level of performance suggested relatively intact cerebral functioning. Med. recs. at Ex. 34, pp. 99-100. The variability in his performance suggested that other factors, i.e., fatigue or psychological distress, might be interfering with optimal attentional abilities. Med. recs. at Ex. 34, p. 100.

On November 21, 1996, petitioner saw Dr. Robert A. Bethel, a pulmonologist. Med. recs. at Ex. 34, p. 112. His impression was that petitioner had asthma and dyspnea on exertion of uncertain etiology. *Id.* On examination, there was no lymphadenopathy. Med. recs. at Ex. 34, p. 113.

On November 26, 1996, petitioner saw Dr. Kirsten Bracht. Med. recs. at Ex. 10, p. 13. Nerve conduction studies showed obvious atrophy of the abductor pollicis brevis (APB). Electromyography (EMG) showed no spontaneous activity. Dr. Bracht's impression was

multifocal abnormalities on nerve conduction studies involving especially the right leg. There was no active or chronic denervation seen on EMG. *Id.*

On November 26, 1996, petitioner saw Dr. Bracht for a visual evoked response (VER). He had normal conduction along the central visual pathways. Med. recs. at Ex. 10, p. 15.

On November 26, 1996, petitioner saw Dr. Bracht for an SSEP. He had normal conduction along the central somatosensory pathways (median). Med. recs. at Ex. 10, p. 16.

On November 26, 1996, petitioner saw Dr. Bracht for an SEP. He had normal conduction along the central somatosensory pathways (tibial nerve). Med. recs. at Ex. 10, p. 17.

On December 11, 1996, Dr. Ronald S. Murray wrote a neurological summary. Med. recs. at Ex. 10, p. 12. On November 26, 1996, petitioner had normal evoked potentials of his visual and somatosensory pathways. On EMG and nerve conduction studies, he had multifocal abnormalities on the nerve conduction studies involving the right leg more than the left leg. The findings might be consistent with mononeuritis multiplex or a plexus lesion. *Id.*

On December 12, 1996, Dr. Bethel, the pulmonologist, concluded that petitioner's physiologic exercise test, showing his exercise to be limited, was compatible with cardiovascular disease or deconditioning. Med. recs. at Ex. 34, p. 109.

On January 16, 1997, petitioner saw Dr. Howard D. Weinberger, a cardiologist. Med. recs. at Ex. 34, pp. 101, 104. Petitioner stated he had fairly constant nausea and some dizziness. He had always slept with two pillows, one under his head and one over his head. Med. recs. at Ex. 34, pp. 101-02. He drank less than six light beers per night, but his drinking was heavy in the past. Med. recs. at Ex. 34, p. 102. Dr. Weinberger's impression was that petitioner had

exercise intolerance and fatigue, possibly secondary to post-hepatitis B vaccine symptoms, deconditioning, or possible cardiac etiology. Med. recs. at Ex. 34, p. 103.

On February 15, 1997, petitioner slipped or tripped and fell and landed on the stairs on his tailbone, which had been painful ever since. Med. recs. at Ex. 25, p. 5.

On February 17, 1997, petitioner saw Dr. West. Med. recs. at Ex. 11, p. 65. On physical examination, petitioner did not have active synovitis. He complained of pain in the left thumb area diffusely, but specific palpation of the joints, including his left first CMC joint as well as his Dequervain's tendons were without specific pain. He had an absent left ankle jerk. Petitioner had nondermatomal subjective decreased sensation in his right hand. He had inconsistent tremor of his right hand greater than his left. *Id.* Petitioner's complete blood study was normal. There was no evidence that petitioner had systemic lupus erythematosus or other autoimmune disease. He had a positive tilt table test. EMG showed no evidence of active or chronic denervation. He had mononeuritis multiplex. Med. recs. at Ex. 11, p. 66. He had sun-damaged skin and rosacea. His facial rash was not consistent with connective tissue disease. Med. recs. at Ex. 11, p. 67. He had mild asthma. He did not have heart disease. He had an abnormal exercise test due to deconditioning. He had an IQ of 116, which was the same as in 1995 when he had an IQ of 117. Petitioner's memory and higher reasoning skills were intact although he perceived them to be more abnormal than the test showed. He tended to minimize and deny any psychologic difficulties. He had anxiety and fatigue. Dr. West's assessment was that hepatitis B may have resulted in mild neurologic damage as evidenced by petitioner's abnormal lower extremity EMG and nerve conduction velocities as well as the abnormal tilt table studies which tested autonomic function. *Id.*

On April 27, 1997, petitioner saw Dr. West. Med. recs. at Ex. 34, p. 9. His fatigue is partially due to POTS. This was being treated with Verapamil. *Id.*

On July 21, 1997, petitioner saw Dr. Andrew W. Campbell.[3] Med. recs. at Ex. 45, p. 86. Petitioner had worked for the government for approximately 12-14 years as a research agronomist. Every six months, he was monitored for any exposures with physical examinations and blood tests. Chemicals were in the laboratories to which he was exposed. He used safety equipment such as hoods, goggles, respirators, and radiation shields. Then petitioner entered private consulting and went to Mexico and Alaska since he had expertise in chemical remediation, mine remediation, and detecting low levels of pesticides. He also had a gemstone background. At Baylor, petitioner was exposed to alcohols and acids such as hydrochloric and sulfuric. He had hepatitis B vaccination on August 11, 1994. The next day, he experienced lethargy, soreness, and stiffness in his left arm. He became fatigued. He slowly got better. On September 23, 1994, he had the second hepatitis B vaccination and went to bed with a terrible

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[3] On June 6, 2007, the Texas Medical Board issued a 26-page Final Order in In the Matter of the Complaint Against Andrew William Campbell, M.D., SOAH Docket No. 503-04-5717, License No. G-7790, suspending Dr. Campbell's medical license until February 8, 2008, at which point his suspension will end if he fulfills a number of requirements and pays an administrative penalty of $210,000.00 plus transcription costs. If he satisfies these requirements, he will be placed on probation for five years under the close supervision of another medical doctor for whose services he would have to pay. If he does not satisfy the listed requirements, the Board will revoke his medical license as of February 8, 2008. The Board states that its Final Order constitutes a PUBLIC REPRIMAND (the capital letters are in the Final Order) of Dr. Campbell. Among the Board's findings were that Dr. Campbell failed "to practice medicine in an acceptable professional manner consistent with public health and welfare" (p. 18). The Board stated: "Dr. Campbell's failure to practice medicine in an acceptable manner consistent with public health and welfare includes the failure to treat a patient according to the generally accepted standard of care." (p. 18). Besides calling Dr. Campbell dishonorable, the Board criticized his extensive prescription of intravenous immunoglobulin (IVIG). See Ottenweller v. Secretary of HHS, No. 99-519V, 2007 WL 2241875 (Fed. Cl. Spec. Mstr., July 17, 2007).

case of flu which he described as being comatose. On the fifth day, he went back to work, feeling very sick. He was fatigued and nauseated, with joint pain, a facial rash, and broken capillaries. *Id.*

On July 21, 1997, Dr. Campbell had petitioner's blood tested by Immunosciences Lab, Inc., showing sensitivity to formaldehyde (IgG of 32 when the normal range is 0-16), sensitivity to phthalic anhydride (IgG of 32 when the normal result is 16), lower natural kill cell activity (13.00 when the normal range is 20-50) and a positive rheumatoid factor of 50.0 (when the normal range is 0-20). Med. recs. at Ex. 45, p. 258. However, also on July 21, 1997, Dr. Campbell had petitioner's blood tested by the same laboratory and the total natural killer cells were 261.8, which is normal (the range being 52-864), and the percentage of natural killer cells was 17.0, which is normal (the range being 5.5-20%). Med. recs. at Ex. 45, p. 264. T cells and B cells were also normal. *Id.*

On August 18, 1997, Dr. Campbell wrote an expert report for the federal district court in Texas where petitioner had a civil suit pending. Dr. Campbell wrote that hepatitis B vaccine caused petitioner an unresolved encephalopathy and symptoms of autoimmunity. Med. recs. at Ex. 11, p. 25.

On September 22, 1997, petitioner recounted a motor vehicle accident when his head struck the window of a car and he had a slight concussion and whiplash. In February 1997, he fell and had lumbar complaints. Med. recs. at Ex. 24, p. 420.

On September 29, 1997, petitioner was examined by Dr. Thomas Soper, DO, an internist. Med. recs. at Ex. 11, p. 10. Six to eight hours after his first hepatitis B vaccination on August 11, 1994, petitioner had marked erythema and pain in his left deltoid. Within 24 hours, he had

lethargy and left upper extremity stiffness which never completely resolved. He received his second hepatitis B vaccination on September 22, 1994. Within six to 12 hours, his arm became exquisitely tender. He had erythema at the injection site, some axillary lymphadenopathy, and his arm became nearly paralyzed from shoulder to elbow. He had erythema with malar distribution and fatigue. He began to lose clumps of his hair, had severe frontal and parietal headaches, arthralgias, myalgias, and was forced to remain in bed. *Id.* Petitioner was a collector of weapons. Med. recs. at Ex. 11, p. 16. He was allergic to horse serum as a child. Med. recs. at Ex. 11, p. 17. He used to drink heavily in the past but now drank two to six beers daily. Med. recs. at Ex. 11, p. 18. He was slightly obese, slightly anxious, and overall tremulous. His pulse was 104. Med. recs. at Ex. 11, p. 19. His laboratory studies showed a normal ANA, and a rheumatoid factor of 50 international units/ml. Med. recs. at Ex. 11, p. 21. Dr. Soper's diagnoses were an adverse reaction to hepatitis B vaccine complicated by resolving encephalopathy with significant cognitive dysfunction, natural killer cell defects with recurrent immunosuppression requiring weekly doctor visits, irritable bowel syndrome, borderline obstructive pulmonary disease, emotional complications with obsessive thought patterns, including depression and anxiety, with an overall impairment of 60%. Med. recs. at Ex. 11, p. 22.

On January 20, 1998, petitioner saw Dr. Campbell. Med. recs. at Ex. 45, p. 69. Petitioner's chiropractor Dr. Johnson recommended that he get an MRI of his spine because of a car accident one year previously. Petitioner had the MRI one week before, which revealed one herniated disc on his neck and one on his back. He wanted Dr. Campbell to prescribe St. John's wort because it was helping his depression. *Id.*

On February 9, 1998, Dr. Campbell wrote a letter to the Texas Workers Compensation Board, saying that petitioner had POTS. Med. recs. at Ex. 11, p. 8. He described POTS as an autoimmune disorder of the autonomic nervous systems which was extremely debilitating. It results in an inability of the body to control blood pressure when changing positions. *Id.* Verapamil only partially controlled this. Med. recs. at Ex. 11, p. 9. Petitioner's rheumatoid arthritis factor was elevated as expected with this type of joint pain and subsequent immobility. Dr. Soper reported vasculitis/optic neuritis. Petitioner had not read a book since August 1994 and had constant ringing in his ears since August 1994. There was nothing organically wrong with petitioner's ears. Dr. Campbell also diagnosed petitioner with chronic inflammatory demyelinating polyneuropathy (CIDP) based on myelin-associated antibodies and abnormal neurometric testing. Dr. Campbell stated that petitioner was 100% disabled since August 1, 1995. *Id.*

On February 27, 1998, petitioner went to Dr. James W. Ley at Haxtun Hospital as an outpatient for intravenous gamma immune infusion. Dr. Campbell diagnosed petitioner with five separate autoimmune syndromes: antibody against the myelin sheath of his nervous system; POTS; rheumatoid arthritis; and two syndromes that petitioner was unable to explain to Dr. Ley. Med. recs. at Ex. 36, p. 41. The IVIG would be 35 grams for each infusion. *Id.* Possible side effects of IVIG were mild hip, joint, or back pain; leg cramps; muscle pain; nausea or vomiting; irritability; fatigue; lightheadedness or dizziness; or pain, tenderness, and muscle stiffness at the site of injection. Med. recs. at Ex. 36, p. 53. Petitioner was to alert his doctor if he experienced chills, rash, or sweating. *Id.*

On April 14, 1998, petitioner saw Dr. Soper for an evaluation and Dr. Soper wrote that petitioner was 60% impaired. Med. recs. at Ex. 11, p. 5.

On June 2, 1998, petitioner had a liver panel showing ALT of 93 (range of normal being 7-56), AST of 70 (range of normal being 5-35), and iron of 178 (range of normal being 35-158). Med. recs. at Ex. 45, p. 229.

On June 23, 1998, Dr. Campbell wrote to Dr. Soper that petitioner had CIDP. Med. recs. at Ex. 11, p. 1.

On July 2, 1998, Dr. Soper changed his evaluation of petitioner's whole body impairment rating to 91% based on information from Dr. Campbell on CIDP. Med. recs. at Ex. 45, p. 10.

Some date in July 1998, petitioner saw Dr. Philip J. Pollock, director of Holly Chiropractic Center, for an IME on behalf of Case-Pro, Inc. after petitioner's automobile accident of August 30, 1996. Med. recs. at Ex. 24, p. 402. Petitioner complained of neck pains which were sharp and stabbing at times, and stiffness with grinding sounds. The pain radiated from the center to the left into the left upper trap at the base of his neck. He had radiating pain into the left side of his face and eye. He had loss of range of motion of his neck, especially to his left. Petitioner described his cervical pain as constant burning, stabbing, or sometimes dull. He also complained of low back pain which was dull and constant with occasional sharp stabbing pain, and radiation of the pain from the center across the low back, especially to the left. At night, his low back pain disturbed his sleep. *Id.* Petitioner stated these problems were the result of a motor vehicle accident which occurred August 30, 1996. Med. recs. at Ex. 24, p. 403. Petitioner's head had gone completely through the rear window and knocked the entire glass out of the frame. He was pulled from the pickup in which he was a passenger, and sat down on a

street curb, overcome by nausea and pain. He immediately got a headache and his fingers and feet began tingling. Petitioner stated he was incoherent. He had headaches, dizziness, pain in the neck and back, tingling in his fingertips and feet, nausea, blurred vision, and pain in the back of his head where he had hit the rear window. *Id.* Petitioner fell on the stairs on February 15, 1997. Med. recs. at Ex. 24, p. 404. His feet got tangled up because of his low back pain. *Id.* As a result of the motor accident, petitioner could not walk even for short distances. Med. recs. at Ex. 24, p. 408. Before the motor accident but after his reaction to hepatitis B vaccine, he could work on the computer and ride in a car. After the motor vehicle accident, he could not do that. *Id.* Petitioner denied joint swelling or rheumatoid arthritis. Med. recs. at Ex. 24, p. 409. He had bouts of depression. *Id.* He did not have any difficulty going from a sitting to a standing position when Dr. Pollock and he moved from Dr. Pollock's office to the examination room. *Id.* His cognition appeared normal and he was a good historian. *Id.*

On examination, his left leg exhibited decreased peripheral sensitivity along the L4 and L5 dermatomes. Med. recs. at Ex. 24, p. 410. Petitioner had normal tone, bulk, power, and coordination in the upper and lower extremities. He scored 5/5 in all extremities. He did not have atrophy or fasciculations. *Id.* Dr. Pollock concluded there was a definite alteration of motion in the cervical spine on the March 13, 1997 films likely due to muscle spasm caused by the August 1996 motor accident. Med. recs. at Ex. 24, p. 414. He had spondyloarthrosis of the lumbar spine. He had soft tissue damage in the cervical region. His L5/S1 disc was degenerated, causing dysfunction of the posterior facets and lumbosacral back pain. *Id.* Petitioner had chronic pain due to the motor vehicle injuries. Med. recs. at Ex. 24, p. 415. He also had TMJ dysfunction which might be a focus of pain into the left side of the neck and upper back. *Id.*

Petitioner was able to perform all ranges of motion with resistance and without pain. *Id.* Dr. Pollock recommended acupuncture as a treatment and resistance-type exercises. Med. recs. at Ex. 24, p. 416. Petitioner's IVIG treatments virtually wiped him out. Med. recs. at Ex. 24, p. 417. Over time, Dr. Pollock expected petitioner to have degenerative joint disease, degenerative disc disease, and perhaps disc rupture. *Id.* Because petitioner did not complain of low back pain and leg pain until after his fall of February 15, 1997, Dr. Pollock attributed his low back pain and leg pain to that fall and not to the motor vehicle accident of August 30, 1996. Med. recs. at Ex. 24, p. 419.

On November 20, 1998, petitioner's liver panel showed ALT of 114 (range of normal being 3-36), AST of 106 (range of normal being 22-47), total bilirubin of 1.1 (range of normal being 0-1.0), and direct bilirubin of 0.6 (range of normal being 0-0.3). Med. recs. at Ex. 36, p. 10.

On January 14, 1999, petitioner's liver panel showed ALT of 154 (range of normal being 7-56), AST of 131 (range of normal being 5-35), and iron of 184 (range of normal being 35-150). Med. recs. at Ex. 45, p. 324.

On March 9, 1999, petitioner's liver panel showed ALT of 190 (range of normal being 30-65), AST of 147 (range of normal being 15-37), iron of 164 (range of normal being 35-150), and % transferin sat of 63 (the range of normal being 20-55). Med. recs. at Ex. 29, p. 24.

On May 17, 1999, petitioner telephoned Dr. Campbell's office. He had had IVIG on Thursday, May 13, 1999, and woke Friday morning with severe nausea and vomiting. He wanted to know if he should continue with IVIG. His symptoms were worse. Med. recs. at Ex. 45, p. 44.

On May 28, 1999, petitioner saw Dr. John S. Goff, a gastroenterologist, because in the prior six months, his liver enzymes had moderately increased. Med. recs. at Ex. 29, p. 6. Petitioner drank one liter of vodka per week. He did not have heptomegaly. Dr. Goff wondered if he had autoimmune hepatitis or hepatitis C. *Id.* On May 28, 1999, petitioner's liver panel showed ALT of 372 (the range of normal being 30-65) and AST of 346 (the range of normal being 15-37). Med. recs. at Ex. 29, p. 21. In a letter, Dr. Goff wondered if petitioner's abnormal liver tests were an autoimmune hepatitis related to hepatitis B vaccination. Med. recs. at Ex. 29, p. 27.

On June 4, 1999, petitioner was found to be negative for hepatitis C. Med. recs. at Ex. 29, p. 20.

On June 9, 1999, Karen Snow, Ph.D., released a report showing that petitioner had hereditary hemochromatosis (HH). Med. recs. at Ex. 29, p. 16. One copy of the C282Y mutation was identified (heterozygous for this mutation). The H63D mutation was not detected. *Id.* Petitioner was at minimum a carrier of hereditary hemochromatosis (HH). *Id.* One copy of the HH was described following the test as "characterized by abnormal intestinal iron absorption and progressive iron deposition predominantly in the parenchyma cells of the liver, heart, and certain endocrine organs. Iron deposition can ultimately lead to a variety of clinical complications including cirrhosis, diabetes, cardiomyopathy, arthritis, endocrine dysfunctions, and susceptibility to liver cancer." Med. recs. at Ex. 29, p. 18.

Also on June 9, 1999, petitioner saw Dr. Campbell who ordered numerous tests and charged him $11,550.00. Petitioner's previous balance was $171.00. Med. recs. at Ex. 45 p. 41. Petitioner was found to have hepatitis A serology consistent with past exposure to hepatitis A

virus. Med. recs. at Ex. 45, p. 285. His serology also showed past exposure to hepatitis B virus with immunity to hepatitis B virus. *Id.*

On June 21, 1999, petitioner was telephoned and informed of his hemochromatosis[4] heterozygous state and hepatitis C result. Med. recs. at Ex. 29, p. 7. His Texas doctor had seen this result before with gamma globulin. *Id.*

On July 1, 1999, petitioner's liver panel showed ALT of 200 (range of normal being 30-65) and AST of 139 (range of normal being 15-37). Med. recs. at Ex. 29, p. 14.

On July 23, 1999, petitioner called Dr. Campbell's office to say he was taking a trip to Europe in two weeks. Med. recs. at Ex. 45, p. 40.

On October 22, 1999, petitioner's liver panel showed ALT of 128 (range of normal being 30-65), AST of 80 (range of normal being 15-37), and iron of 171 (range of normal being 35-150). Med. recs. at Ex. 29, p. 15.

On October 29, 1999, petitioner was off gamma globulin and felt better off it. Med.. recs. at Ex. 29, p. 7. He went to an acupuncturist to get Chinese herb combinations to clean out his liver. He functioned normally when he got 12 hours of sleep a night. *Id.* Dr. Goff noted in a letter that petitioner's liver function tests continued to go down. Med. recs. at Ex. 29, p. 26. Dr. Goff suspected petitioner had autoimmune hepatitis. Since petitioner had had abnormal liver enzymes for almost five years, it would be useful to do a biopsy. *Id.*

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[4] Hemochromatosis is "a disorder due to deposition of hemosiderin in the parenchymal cells, causing tissue damage and dysfunction of the liver, pancreas, heart, and pituitary. Other clinical signs include bronze pigmentation of skin, arthopathy, diabetes, cirrhosis, hepatosplenomegaly, hypogonadism, and loss of body hair." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 831.

On December 27, 1999, petitioner's liver panel showed ALT of 88 (range of normal being 30-65) and AST of 47 (range of normal being 15-37). Med. recs. at Ex. 29, p. 12.

On March 2, 2000, petitioner's liver panel showed ALT of 130 (range of normal being 30-65) and AST of 75 (range of normal being 15-37). Med. recs. at Ex. 29, p. 13.

On April 17, 2000, petitioner saw Dr. Campbell who ordered a number of laboratory tests for him, costing $13,404.00. Petitioner's prior balance was $350.00. Med. recs. at Ex. 45, p. 34.

On April 27, 2000, petitioner's laboratory report per Dr. Campbell was released showing he was deficient in vitamins B1, B2 and B6, folate, and glutathione. Med. recs. at Ex. 45, p. 200. Clinical signs of persons with vitamin B1 (thiamin) deficiency were fatigue, mental depression, nausea, and peripheral neuropathy. Alcoholics were at risk for thiamin deficiency. Med. recs. at Ex. 45, p. 206. Clinical signs of persons with vitamin B2 (riboflavin) deficiency were depression, dizziness, photophobia, teary eyes, and loss of visual acuity. Med. recs. at Ex. 45, p. 207. Clinical signs of persons with vitamin B6 (pyridoxine) deficiency were peripheral neuropathy, weakness, irritability, depression, and anxiety. Med. recs. at Ex. 45, p. 208. Clinical signs of persons with folate deficiency were fatigue, paranoia, memory impairment. Alcoholics were at risk for folate deficiency. Med. recs. at Ex. 45, p. 209. Glutathione is an anti-oxidant. Petitioner's deficiency of glutathione in his lymphocytes put him at higher risk for arthritis, aging, and neurodegenerative diseases. Med. recs. at Ex. 45, p. 210.

On August 17, 2000, petitioner saw Dr. Campbell. Petitioner's previous balance was $13,404.00. Med. recs. at Ex. 45, p. 29.

On August 22, 2000, petitioner's liver panel showed total bilirubin of 1.1 (range of normal being 0.0-1.0), ALT of 330 (range of normal being 30-65), and AST of 196 (range of normal being 15-37). Med. recs. at Ex. 29, p. 11.

On February 20, 2001, petitioner had an appointment with Dr. Campbell. He took laboratory tests and a bioscan test costing $5,245.00. Med. recs. at Ex. 45, p. 23. Petitioner's prior balance was $9,061.00. Dr. Campbell charged him $250.00 for that day's visit. Med. recs. at Ex. 45, p. 24. Dr. Campbell diagnosed petitioner with abnormal involuntary muscle movement, arthritis, demyelinating disease, fatigue, generalized pain, hepatitis B vaccine reaction immune mechanism disorder, multiple vitamin deficiency, polyneuropathy, and severe muscular weakness. *Id.* Petitioner complained of fatigue, joint pain, and sparkles in his vision. Med. recs. at Ex. 45, p. 26. He had a facial rash and whole body ache. He stated he had very vivid dreams. He had tinnitus and blurred vision, but his nausea improved. He had vertigo/dizziness, abnormal involuntary movements, memory loss, blurred vision, neuralgia, weakness in his left arm and left leg, and an inability to exercise. He got very ill when he tried to exercise. *Id.*

On February 21, 2001, petitioner had an EEG. Dr. William High, Jr., a neurologist, stated it was normal. Med. recs. at Ex. 45, p. 106.

On February 21, 2001, petitioner had a somatosensory evoked response test done on his median nerves. Dr. High stated the SEPM was normal. Med. recs. at Ex. 45, p. 197.

On February 21, 2001, petitioner had a somatosensory evoked response test done on his tibias which Dr. High stated was normal for a tall person. Petitioner is 6' 3" tall. Med. recs. at Ex. 45, p. 108.

On February 21, 2001, petitioner had a visual evoked response (VER) test done on each eye. Dr. High stated it was normal. Med. recs. at Ex. 45, p. 109.

On February 21, 2001, petitioner had a brain stem auditory evoked response (BAER) test performed. Dr. High stated it was normal. Med. recs. at Ex. 45, p. 110.

On March 12, 2001, petitioner telephoned a nurse at Infinity Infusion Care, Inc., which faxed Dr. Campbell the record of the call, expressing petitioner's concern about elevation of his liver enzymes. Med. recs. at Ex. 45, p. 354. Petitioner stated that the last time he was infused with IVIG, it almost killed him. *Id.*

On March 13, 2001, Dr. Campbell's office wrote petitioner to stop taking any iron supplements immediately. Med. recs. at Ex. 45, p. 356.

On April 2, 2001, petitioner again refused to take IVIG against Dr. Campbell's medical advice because of his previous reaction to IVIG. Infinity Infusion Care, Inc. notified Dr. Campbell's office. Med. recs. at Ex. 45, p. 352.

On September 10, 2001, petitioner saw Douglas S. Jones, a chiropractor. Med. recs. at Ex. 24, p. 2. He had injuries in his cervical and lumbar spine due to a motor vehicle accident on August 30, 1996. His problems were solely due to the car accident. He had neck and back pain and some upper mid-back pain. Med. recs. at Ex. 24, p. 3.

On March 28, 2002, petitioner saw Dr. Campbell. Med. recs. at Ex. 45, p. 16. Petitioner complained of chronic fatigue and chronic diarrhea with pain in every joint. Petitioner rated the pain as 8 on a scale of 1 to 10. He reported that no medication relieved his joint pain. He did not have edema of his joints. He had facial flushing during his assessment. He elected not to take IVIG as Dr. Campbell prescribed on March 7, 2001. He complained of alopecia since the

vaccination. He did not have sleep disturbances. He required 12-15 hours of sleep nightly or he became non-functional. He continued to have blurred vision with bilateral floaters. He had chronic tinnitus. He had a rash on his chest area which he said had frequent exacerbations. The rash did not itch. *Id.* On a form dated March 28, 2002, petitioner checked off symptoms and rated their severity from 0-10: fatigue (8); attention deficit disorder (6); calculation difficulties (6); memory disturbance (5); frequently saying the wrong word (4); depression (4); anxiety (3); personality changes (4); mood swings (4); concentration problems (7); sleep disturbances (2); headaches (1); changes in visual acuity (6); numbness or tingling (6); disequilibria (5); lightheadedness, feeling "spaced out" (6); difficulty moving tongue to speak (1); ringing in ears (5); severe muscular weakness (8); intolerance of bright lights (7); intolerance of alcohol (4); slapped cheek look (8); muscle and joint aches (8); abdominal pain, diarrhea, nausea, intestinal gas or "irritable bowel syndrome" (8); recurrent "flu-like" illnesses, often with chronic sore throat (2); twitching muscles (5); painful lymph nodes (2); severe nasal or other allergies (4); weight gain (5); low grade fevers or feeling hot often (7); night sweats (5); heart palpitations or other rhythm disturbances (8); rashes (5); hair loss (4); chest pain (7); dry eyes and mouth (5); cough (4); cold hands and feet (4); tremors (7); low back pain (7); shortness of breath (5); symptoms worsened by extremes in temperature (8); sore(s) that will not heal (2); dry skin (4); multiple sensitivities to medicine, food, and other substances (8); and excessive thirst (4). Med. recs. at Ex. 45, p. 18. Dr. Campbell charged petitioner $352.00 for the visit. Med. recs. at Ex. 45, p. 15.

On March 28, 2002, petitioner had somatosensory evoked potential response testing (SEPT) done on his tibias which Dr. High interpreted as abnormal showing peripheral conduction delay bilaterally. Med. recs. at Ex. 45, p. 100.

[After the hearing in this case on June 29, 2007, petitioner filed medical records from Dr. Gregory S. Holst and Dr. Paul D. Simmons. Exs. 64, 65.]

On August 12, 2002, petitioner saw Dr. Holst who diagnosed him with chronic autoimmune hepatitis related to hepatitis B vaccination. Med. recs. at Ex. 64, p. 15.

On September 19, 2002, petitioner saw Dr. Holst and received the same diagnosis. *Id.*

On October 28, 2002, petitioner saw Dr. Holst. Petitioner had found out that he had a heterozygote for hemochromatosis. Med. recs. at Ex. 64, p. 14. Dr. Holst noted that patients with this problem showed positive rheumatoid factors. Petitioner was having more problems with chronic musculoskeletal aches and pains. *Id.*

On December 9, 2002, petitioner saw Dr. Holst, who diagnosed chronic autoimmune hepatitis related to hepatitis B vaccination, migraine headaches, and mild exercise induced asthma. Med. recs. at Ex. 64, pp. 13-14.

On January 15, 2003, petitioner saw Dr. Holst with itching and rash. Dr. Holst diagnosed him with irritable bowel syndrome. Med. recs. at Ex. 64, p. 13.

On February 14, 2003, May 20, 2003, and September 10, 2003, petitioner saw Dr. Holst. Med. recs. at Ex. 64, pp. 11, 12. Petitioner had finished phlebotomy under the direction of Dr. Thomas Higginbotham. Med. recs. at Ex. 64, p. 11.

On October 6, 2003, petitioner saw Dr. Holst. Petitioner still had iron overload. Dr. Higginbotham wanted petitioner to continue with at least two more phlebotomy treatments. *Id.*

On May 20, 2003, petitioner saw Dr. Holst. Petitioner wanted to pursue some EDTA therapy because of his chronic iron overload. Med. recs. at Ex. 64, p. 10.

On August 1, 2003, petitioner saw Dr. Holst. Petitioner brought in documentation of his liver tests since the mid-90's which showed that his iron saturation and ferrate had gone up considerably since 2000. He also had a progressive decline in his ALT and AST over the prior two years. Dr. Holst diagnosed chronic autoimmune hepatitis related to hepatitis B vaccine and chronic iron overload. Med. recs. at Ex. 64, p. 10.

On March 2, 2004, petitioner saw Dr. Holst. Med. recs. at Ex. 64, p. 9. Dr. Holst diagnosed him with chronic autoimmune hepatitis related to hepatitis B vaccination, asthma, chronic low back pain and joint aches secondary to chronic autoimmune hepatitis, and iron overload. *Id.*

On May 28, 2004, petitioner saw Dr. Holst. His blood work on March 5, 2004 showed his iron was up again at 278 (normal being between 40-150). His binding capacity was extremely low at 15.3. His transferrin saturation was 95% and ferritin was 30. His liver function tests showed ALT of 89 and AST of 53. Petitioner was discouraged because of fatigue and paresthesia involving his hands and feet. He also had nausea. Dr. Holst scheduled a phlebotomy again. Med. recs. at Ex. 64, p. 9.

On October 1, 2004, petitioner saw Dr. Holst. An iron panel showed his iron at 179, ferritin saturation at 65, and ferritin level at 394. His UIBC and iron binding capacity were low at 98 and 277. Petitioner stated he had a lot more back pain when he was active. Dr. Holst diagnosed him with chronic autoimmune hepatitis secondary to hepatitis B vaccination, chronic iron overload, and chronic low back pain. Med. recs. at Ex. 64, p. 8.

On November 16, 2004, petitioner saw Dr. Holst. A recheck of his iron showed it was up again to 221 mcg/dL. UIBC was 39, iron binding capacity was low at 359, transferrin saturation was high at 85, ferritin was high at 298. Petitioner had more problems with back pain. *Id.*

On September 30, 2005, petitioner saw Dr. Holst. Med. recs. at Ex. 64, p. 7. His iron level was 154, UIBC was 135, iron binding capacity was 288, transferrin saturation was 53, ferritin was 52, ALT was 73, and AST was 59. Med. recs. at Ex. 64, p. 7.

On November 4, 2005, petitioner saw Dr. Holst. His iron level was 374, UIBC 56, iron binding capacity 330, transferrin saturation 83%, and ferritin 35. Dr. Holst diagnosed petitioner with chronic autoimmune hepatitis secondary to hepatitis B vaccination, depression, and chronic iron overload related to hepatitis. Med. recs. at Ex. 64, p. 6.

On March 29, 2006, petitioner saw Dr. Holst. Although his metabolic panel showed all of his liver functions to be normal except for a slightly high AST of 42, and his iron panel was also within normal except for a slightly low iron saturation of 19, petitioner said that he had increasing back pain and tremors. *Id.*

On June 7, 2006, petitioner saw Dr. Holst. His iron level was low at 54. Med. recs. at Ex. 64, p. 5.

On September 8, 2006, petitioner saw Dr. Holst. His iron was low at 45 and his transferrin saturation was also low at 13. Med. recs. at Ex. 64, p. 4.

On November 27, 2006, petitioner saw Dr. Holst. Med. recs. at Ex. 64, pp. 3-4.

On January 15, 2007, petitioner saw Dr. Holst. Med. recs. at Ex. 64, p. 3.

On May 14, 2007, petitioner saw Dr. Paul D. Simmons, who recorded his history as vaccine-induced autoimmune hepatitis from hepatitis B vaccine, hereditary iron overload

syndrome, heterozygosity for hereditary hemochromatosis, classic migraine headaches, adult onset of asthma, and vitamin B12 deficiency. Petitioner lived in a trailer home with 14 cats and his wife. Med. recs. at Ex. 64, p. 2. The second page of this record is at Ex. 65, p. 3.

On June 6, 2007, an iron profile showed 208 (normal is 59-158) and transferrin saturation of 77 (normal is 22-55). A hepatitis profile 8 showed petitioner negative for hepatitis B core antibody and IgM as well as hepatitis A antibody and IgM. Med. recs. at Ex. 61, p. 1.

On June 20, 2007, petitioner saw Dr. Simmons. He reported a right lower visual field distortion similar to a migraine aura. He had some nausea but no vomiting and a slight headache. Med. recs. at Ex. 65, p. 3. His vitamin B12 level was normal. His iron profile was consistent with past results showing a heterozygous hemochromatosis gene iron overload syndrome with total iron of 208, iron binding capacity of 268, transferrin saturation of 77%, and normal ferritin at 44. His hepatitis profile 8 was negative. Dr. Simmons ordered therapeutic phlebotomy. Med. recs. at Ex. 65, p. 2.

On June 20, 2007, a hepatitis B core antibody test was negative as was a test for antibody B core IgM. Med. recs. at Ex. 61, p. 2.

On June 28, 2007, Dr. Joseph A. Bellanti, one of petitioner's experts, examined petitioner. Med. recs. at Ex. 63. Petitioner showed fine involuntary tremor of the hands and fingers of both hands. He had weakness of both arms to passive movement and diminishment of both deep tendon flexor reflexes in both arms, more marked in the left arm. He had weakness of both flexor and extensor muscles of the lower legs and diminished popliteal reflexes bilaterally. Dr. Bellanti opined these findings were consistent with central and peripheral neurologic injury

from hepatitis B vaccinations petitioner received on August 11, 1994 and September 23, 1994. *Id.*

TESTIMONY

Petitioner testified first. Tr. at 4. He is an agronomist who worked for the United States Department of Agriculture Research Service for about 14 years. Tr. at 7. He had always been active: fishing, hiking, backpacking, skiing, shooting, archery, and cutting gems. Tr. at 9. He does not know if he ever had hepatitis A infection. Tr. at 11. He was positive for hepatitis A antibody at the time he was receiving multiple courses of IVIG. Tr. at 11-12. He never had symptoms of hepatitis A infection. Tr. at 12.

When he went to work at his sister's laboratory in Houston August 1, 1994, he was extremely healthy. *Id.* He was born and raised on a farm where he did manual labor and, in 1993, worked in a gold mine in Alaska, running machinery. *Id.* He went to Baylor to train for a position as head of the science department at Alamosa College in Colorado. Tr. at 12-13. He had hoped to become dean of the school. Tr. at 13. At the time he was first given hepatitis B vaccine, the college per Dr. Wittels drew his blood to test for hepatitis B infection and other diseases. Tr. 15-16. He was told he was negative for these illnesses. Tr. at 17.

Petitioner received his first hepatitis B vaccination on August 11, 1994. Tr. at 18. Shortly afterward, his arm got very sore and stiff, and was hot and swollen, persisting for quite a few days. He felt nauseated and had flu-like symptoms. Tr. at 19. He had some swelling and a little bit of visual distortion. He also had more fatigue. *Id.* His symptoms lasted for two weeks and subsided when he received his second hepatitis B vaccination on September 23, 1994, in the afternoon. Tr. at 20. Very shortly after the vaccination, petitioner felt nauseated and quite ill. He was fatigued the next day and felt his whole body was on fire. His hands were swollen and red.

He slept most of the weekend. Tr. at 20-21. Petitioner saw Dr. Elliston Wittels at the college clinic and Dr. Wittels diagnosed petitioner with an allergic reaction. Tr. at 24. He told petitioner to take two aspirin and go back to bed. Petitioner continued to be very lethargic. *Id.*

Petitioner would try to go into work, but he would lie on the floor and try to rest as much as he could. Eventually, his employer fired him. Tr. at 25. He saw Dr. Wittels in November 2004 who recommended petitioner see Dr. Miranda, who thought he had lupus and sent him to a lupus specialist. *Id.* Dr. Miranda told petitioner he had a reaction to hepatitis B vaccine. Tr. at 26. Petitioner saw Dr. Lidsky, the lupus specialist, who diagnosed petitioner with lupus. *Id.* Dr. Frank Arnett tested his antibodies and found they were not positive for lupus. Tr. at 27. Dr. Eugene Lai, a neurologist, diagnosed him with possible vasculitis or cerebritis, while Dr. Andrew Lee, a neuro-ophthalmologist, diagnosed him with conjunctive vasculitis. Tr. at 28.

After his second hepatitis B vaccination, all of petitioner's facial blood vessels broke four or five days later. Tr. at 29. He had visual distortion and his face itched. *Id.* Petitioner had and still has photosensitivity. Tr. at 30. Petitioner applied for and received worker's compensation. Tr. at 34-35. Dr. de Shazo wrote an opinion that hepatitis B vaccine caused petitioner encephalopathy. Tr. at 35-36. Petitioner got a 91 percent disability rating. Tr. at 77.

Petitioner returned to Colorado in 1995. Tr. at 36. He saw Dr. James Ley there. *Id.* He also saw Dr. Joyce Gauthier, a rheumatologist in Seattle. Tr. at 37. She agreed he had reacted to hepatitis B vaccine in the form of serum sickness. *Id.* Petitioner saw Dr. Sterling West in 1996 for an independent medical examination. Tr. at 38. Dr. West was convinced that petitioner had an adverse reaction to hepatitis B vaccine. *Id.* Petitioner had a tilt table test which resulted in his being diagnosed with postural orthostatic tachycardia syndrome or POTS after he saw Dr. Jones,

a chronic fatigue specialist. Tr. at 39. Within a few weeks of his second hepatitis B vaccination, petitioner had a tremendous amount of difficulty standing up because of dizziness and falling. *Id.*

On August 30, 1996, petitioner was in a motor vehicle accident in the cab of a stationary truck which was hit from behind by a truck going 40 to 45 miles an hour. Petitioner's head broke the rear windshield and he had a herniated disc in his lower back and neck problems. Tr. at 40. Petitioner settled for $19,000 for pain and suffering. Tr. at 76.

On February 15, 1997, petitioner tripped on the stairs and fell on his tailbone. Tr. at 43-44. Dr. West concluded on April 27, 1997 that petitioner might have had a post-hepatitis B vaccination reaction resulting in mild neurologic damage because of abnormal lower extremity EMG and nerve conduction velocities as well as POTS and chronic fatigue syndrome possibly related to POTS. Tr. at 45. Petitioner was diagnosed with adult-onset asthma. Tr. at 77-78. In July 1997, petitioner saw Dr. Andrew Campbell in Texas who became his treating physician. Tr. at 46. Dr. Campbell treated petitioner with a 30 treatments of IVIG. *Id.* The IVIG made petitioner feel awful. Tr. at 47.

Because petitioner's liver enzymes were elevated, he was referred in May 1999 to Dr. John Goff, a gastroenterologist. *Id.* Dr. Goff thought petitioner had autoimmune hepatitis. Tr. at 47-48. Dr. Goff thought this was related to the hepatitis B vaccine. Tr. at 74-75. Dr. Snow found that petitioner has one copy of the C282Y mutation which makes petitioner at minimum a carrier of hereditary hemochromatosis. Tr. at 49. In 2007, petitioner's blood was tested and found to be negative on core and surface antibodies to hepatitis B and A. Tr. at 51-52.

Petitioner's fatigue requires him to sleep at least 12 to 14 hours per night with occasional naps. Tr. at 53. He has pain in his joints, back, and hips, and his hands are dysfunctional. *Id.* He had a tremor shortly after the vaccination, as well as tachycardia and visual distortion. *Id.* He also has problems with memory and cognition. Tr. at 54. He can sit before a computer for brief periods of time. Tr. at 57. Petitioner saw Dr. Ley, Dr. Gregory Holst and now Dr. Paul Simmons for his family doctor. Tr. at 70. Petitioner has a rash from his face down his body. He has not worked since the second hepatitis B vaccination. Tr. at 79.

Dr. Yehuda Shoenfeld, an immunologist, testified next for petitioner.[5] Tr. at 81. He has edited a book on the subject of autoantibodies. *Id.* He has written a chapter on vaccines and autoimmunity in another book on autoimmunity. Tr. at 82. His opinion is that petitioner was completely healthy before vaccination and developed an avalanche of autoantibodies after vaccination. He thought petitioner's condition to be the most remarkable case of the association of vaccine and autoimmune disease. Tr. at 83. Some of the immediate side effects were swelling of the limbs. *Id.* Petitioner had an encephalopathy and POTS, showing that his autonomic immune system was involved. Tr. at 85. Petitioner had systemic manifestation including nervous system and liver involvement. Tr. at 86. His opinion is that petitioner's two hepatitis B vaccinations caused his autoimmune conditions. Tr. at 87. Valid theories about how vaccines can trigger these kinds of reactions are molecular mimicry, polyclonal activation, and bystander effect. *Id.* Dr. Shoenfeld opined there was a logical sequence of cause and effect in this case.

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[5] Because Dr. Shoenfeld had an accent and the telephone connection was not a good one, the transcription of his testimony was difficult to understand. The undersigned requested that petitioner's counsel send the pages of Dr. Shoenfeld's testimony to him for correction which counsel did. The corrected pages are petitioner's exhibit 70, with corrections in bolded letters.

Id. The timing between vaccination and onset of symptoms is correct. *Id.* Petitioner does not have lupus but a lupus-like illness. Tr. at 89. He does not believe petitioner has chronic fatigue syndrome. Tr. at 90. He would like a liver biopsy before diagnosing petitioner with autoimmune hepatitis. Tr. at 90-91. Petitioner has antismooth and anti-Smith autoantibodies. Tr. at 92. Dr. Shoenfeld said whatever the virus can cause, the vaccine can cause. Tr. at 94. This is the consequence of an autoimmune reaction. Tr. at 95. Autoantibodies means antibodies against self. Tr. at 96. Dr. Shoenfeld called petitioner's case one of positive rechallenge. Tr. at 98. Petitioner did not have an autoimmune reaction immediately after the first vaccination, but had a much more severe reaction after the second vaccination. *Id.*

Dr. Joseph A. Bellanti, an immunologist, testified next for petitioner. Tr. at 102. He is a professor of pediatrics and microbiology immunology and director of the International Center for Interdisciplinary Studies of Immunology at Georgetown University Medical Center. *Id.* His opinion is that petitioner suffered adverse reactions to his hepatitis B vaccinations. Tr. at 105. Dr. Bellanti agreed with Dr. Shoenfeld that petitioner had an avalanche or a cascade of autoantibody autoimmune attack against various tissues of his body. Although several organs can be involved, predominantly they seem to be the central nervous system and the liver. *Id.* Petitioner's skin involvement was also probably part of the autoimmune attack. *Id.* Petitioner's central and peripheral nervous systems appeared to be involved. Tr. at 107. Petitioner's POTS is evidence of autonomic nervous system dysfunction. It would be more central in the deep parts of the brain referred to as the limbic system which controls involuntary control of heart rate, respirations, whereas petitioner's weakness of his left arm with a greater tremor in that arm may be part of the peripheral system. Tr. at 107-08.

Dr. Bellanti did a quick examination of petitioner the day before the hearing. Tr. at 108. Petitioner had good strength in his arms with a little bit of weakness on the left and an obvious tremor, more on the left. He had decreased reflexes in the left and right arms and decreased deep tendon reflexes in both legs. Tr. at 109. Dr. Bellanti based his opinion of causation of petitioner's physical problems due to hepatitis B vaccine based on the classic immunology of an anamnestic secondary response, a recall phenomenon, i. e., petitioner had a sore arm after his first hepatitis B vaccination and then an exacerbation after his second hepatitis B vaccination. *Id.*

Dr. Bellanti stated that petitioner's subsequent development of immunity that waxed and waned, involving various organs, was caused by the vaccinations as well. Tr. at 110. Petitioner has both autoserum antibodies and autoimmune disease. *Id.* He has autoimmune disease of specific organs and doctors have found autoantibodies in his serum. *Id.* Dr. Bellanti disagreed with respondent's expert Dr. Brenner's initial opinion (in his report) that petitioner actually had the wild virus hepatitis B infection at the time he received his hepatitis B vaccinations. Tr. at 111. Petitioner had no history of infection. He was prescreened at the time he received his first vaccination and had negative titers to hepatitis B. He was not a high-risk individual such as a drug user. And, in June 2007 tests, petitioner had an absence of antibody to hepatitis B core antigen and no antibody to hepatitis B surface antigen. If someone had hepatitis B wild infection, the antibodies to the core and surface antigen would be elevated for many years, but petitioner did not have this, as the 2007 testing showed. *Id.* Petitioner's testing positive for antibody to hepatitis B core antigen in 1999 was due to his receiving IVIG in 1998 and 1999. Tr. at 114, 115. Petitioner had passive antibody in his serum as opposed to active antibody which one

would get from a vaccination. The passive antibody came from his intravenous gammaglobulin, which was also true for his testing positive to hepatitis A in 1999. Tr. at 115.

Dr. Bellanti believes that petitioner has autoimmune hepatitis manifested by the antismooth muscle antibody and the anti-Smith antibody. Tr. at 116-17. Dr. Bellanti testified that in order to have full-blown hemochromatosis, petitioner would need two alleles, but he has only one, which gives him a lesser expression of the disease, which causes iron overload. Tr. at 119-20. Dr. Bellanti did not attribute petitioner's symptoms to his hemochromatosis because autoimmune expressions have nothing to do with it. There might be some fatigue because the iron involves parts of the enzymes that affect brain function, but the autoimmune process is definitely different. Tr. at 120-21, 147. Dr. Bellanti did not think petitioner had chronic fatigue syndrome. Tr. at 122. Dr. Bellanti believed petitioner's rash was due to a vasculitis. Tr. at 131. Dr. Bellanti considered petitioner's hair loss to be alopecia because the hair came out in clumps. Tr. at 133. Petitioner's autoantibody levels fluctuated so that he had both negative and positive antismooth muscle tests. Tr. at 137.

Dr. Bellanti thinks that petitioner's symptoms go beyond the fatigue and malaise described in hereditary hemochromatosis. Tr. at 147. Someone would not get POTS from hereditary hemochromatosis. Tr. at 148. Someone would not get an incomplete or partial encephalopathy from hereditary hemochromatosis. *Id.* Hemochromatosis is a disease of iron overload, affecting key organs such as the pancreas, heart and liver, but it is metabolic metallic poisoning, not an immune response. *Id.* Dr. Bellanti stated petitioner was a carrier but he did not have the disease so he did not have clinical symptoms of hemochromatosis, just too much iron in his blood. Tr. at 149. When petitioner's antibody response to hepatitis B was tested, it was high,

indicating petitioner is a high responder and that might reflect polyclonal B-cell activation. Tr. at 150-52. Over 13 years later, the antigen from the vaccine was eliminated from his body. Tr. at 152. If his high hepatitis B antibody result 13 years ago were due to natural infection, his antibody count would still be high. Tr. at 153.

Dr. Alan I. Brenner, an internist and rheumatologist, testified for respondent. Tr. at 155. For about 10 years, he ran his own immunology lab. Tr. at 157. He does not treat patients with POTS, which is an autonomic neuropathy. Tr. at 157, 158. An article respondent filed on POTS refers to POTS after immunizations as having an immune-mediated pathogenesis. Tr. at 159.

Dr. Brenner's opinion is that petitioner suffers a form of chronic fatigue syndrome with manifestations of POTS, which hepatitis B vaccine was unlikely to have caused. Tr. at 161. Dr. Brenner said he respected Dr. Shoenfeld tremendously, but he thinks there is almost no autoantibody activity in petitioner's medical records. Tr. at 161-62. The results are inconsistent and at a minor level. Tr. at 162. They do not suggest immune-mediated inflammation. They do not mean anything. *Id.*

Dr. Brenner thinks more important is petitioner's liver issue. Although uncommon, heterozygous patients can develop manifestations of hemochromatosis. *Id.* People with hemochromatosis have arthralgia, arthritis, fatigue--all of petitioner's symptoms except for POTS. Tr. at 163, 164. At first, Dr. Brenner stated that it was possible that hemochromatosis explained petitioner's symptoms and then he said it was more likely than the vaccine to be the cause of petitioner's symptoms. Tr. at 164, 165.

Dr. Brenner accepted that petitioner had local reactions to hepatitis B vaccine. Tr. at 167. Petitioner's reaction to his second hepatitis B vaccination lasted as long as his arm remained sore

and swollen. *Id.* There is a difference between the state of autoimmunity and autoimmune disease, which is a progressive process. Tr. at 170. Dr. Brenner denied that petitioner has autoimmune hepatitis. Tr. at 173. He did not have persistent positive ANA or antiliver/kidney mitochondrial antibody. *Id.* Dr. Brenner thinks that petitioner has chronic hepatitis caused by hereditary hemochromatosis. When he is bled, his liver function enzymes come down. Tr. at 174.

Dr. Brenner said petitioner may have had a local reaction positive rechallenge after his second hepatitis B vaccination. Tr. at 176. If petitioner had autoantibodies, which Dr. Brenner denies, petitioner could have had the immediate reaction of arm ache, stiffness, and malaise, and then the continuation of autoantibodies over time so that he had more problems. *Id.* Dr. Brenner was the main author of a paper discussing the death of a servicewoman from lupus due to smallpox vaccination and other vaccines. Tr. at 188, 189. Although he agrees that vaccines can cause lupus, he disagrees that hepatitis B vaccine can cause lupus. Tr. at 188. He could not separate out hepatitis B vaccine from the servicewoman's other vaccinations. Tr. at 189. Epidemiological studies have not shown any causal relationship between hepatitis B vaccine and lupus. Tr. at 190.

Dr. Brenner does not believe that hepatitis B vaccine caused petitioner's chronic fatigue syndrome. Tr. at 192. Hepatitis B vaccine is a weak immunogen. Tr. at 193. There is controversy over whether inflammatory cytokines are involved in chronic fatigue syndrome. *Id.* Cytokines are sort of preimmune. Tr. at 194. Cytokines recruit two subsets of T-lymphocytes and B-lymphocytes. *Id.* They transform plasma cells and make antibodies. It is an ongoing process. It takes time. *Id.* Even though clinical manifestations may wax and wan, significant

immune hyperactivity does not. Tr. at 195. Someone with low antibody titers could have high avidity antibodies. "Avidity" means how closely the antibodies stick together. Tr. at 196. Antibodies alone do not tell someone what is going on. *Id.*

Dr. Brenner denied the significance of the autoantibodies that Dr. Shoenfeld listed in his report on petitioner. Tr. at 197. Dr. Brenner thinks that petitioner has rosacea and male pattern hair loss. Tr. at 198. Hemochromatosis and liver dysfunction could possibly be related to petitioner's mild encephalopathic manifestations. Tr. at 199. Dr. Brenner does not know about POTS. *Id.* He could not find tremor in petitioner's medical records. *Id.* Liver dysfunction is not uncommonly associated with tremor. Tr. at 200.

Dr. Brenner's opinion is that petitioner's hepatitis caused his encephalopathy. Tr. at 201. In lupus, the hair breaks instead of coming up by the roots. Tr. at 206. But petitioner does not have lupus. *Id.* Dr. Brenner disagrees with petitioner's multiple treating doctors who felt that his problems were vaccine-caused. Tr. at 212. Dr. Brenner thinks that Dr. Shoenfeld is one of the leading experts writing opinions, rather than doing research, in autoimmunity. *Id.* Dr. Brenner has no evidence that hepatitis B infection caused petitioner's problem. Tr. at 215. Dr. Brenner admitted that petitioner does not fit the published criteria for a diagnosis of chronic fatigue syndrome. Tr. at 216. He agreed that petitioner does not have chronic fatigue syndrome. *Id.* Petitioner has manifestations that appear to be of that nature. Tr. at 217. Dr. Brenner does not think petitioner is lupus-like. *Id.* He thinks petitioner is chronic fatigue-like. *Id.* Petitioner does not have recurrent sore throats, adenopathy, or fever, but he does have chronic fatigue with arthralgias and myalgias, and is unable to function. *Id.*

Dr. Brenner agreed that petitioner does not have lupus and that, in alopecia, the hair does not break but comes out by the roots. Tr. at 221. He also agreed that alopecia is an immune-mediated disease that vaccines can cause. Tr. at 221-22. He believes the hemochromatosis caused petitioner's hepatitis which caused the encephalopathy which caused his tremor. Tr. at 222. That all this happened right after the vaccinations is coincidence. Tr. at 239.

Dr. Brenner denied petitioner was just a carrier of hemochromatosis. Tr. at 223. Petitioner has one of the two alleles of hemochromatosis. *Id.* Dr. Brenner agreed that petitioner's case does not lend itself easily to diagnosis. Tr. at 236. Dr. Brenner agrees that petitioner had a syndrome consistent with mild encephalopathy and postural orthostatic tachycardia, but not that there is an autoimmune basis for them. Tr. at 237-38. Autoimmune processes are inflammatory by nature and none of petitioner's serology, spinal fluid analysis, and MRIs show any inflammatory process. Tr. at 238.

He disagrees completely with Dr. Shoenfeld's use of the term "cascade" in petitioner's case. Tr. at 239-40. Ten doctors in the record (Drs. Wittels, Miranda, Gauthier, Jones, Weinberger, West, Campbell, Soper, Goff, and de Shazo)[6] thought that the vaccinations caused petitioners' problems, and Dr. Brenner did not blame them for doing so when petitioner had a reaction to the first and second hepatitis B vaccinations. Tr. at 242. But Dr. Brenner thought these doctors' assumptions were based on absolutely nothing. Tr. at 243.

Dr. Brenner agreed that a small percentage of POTS is immune-mediated. Tr. at 245. The article respondent submitted relates POTS to vaccinations. *Id.*

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[6] This was before petitioner filed the records of Dr. Holst and Dr. Simmons who also thought his medical condition was due to hepatitis B vaccination.

Other Submitted Material

Respondent filed an article entitled "The Postural Tachycardia Syndrome: A Concise Guide to Diagnosis and Management" by B.P. Grubb, et al., 17 *J Cardiovasc Electrophysiol* 1:108-12 (2006). R. Ex. I (although marked as H on respondent's cover sheet). Postural Tachycardia Syndrome or POTS can cause "palpitations, exercise intolerance, fatigue, light-headedness, tremor, headache, nausea, near syncope, and syncope. Patients may be severely limited as activities such as housework, bathing, and even meals may exacerbate symptoms." *Id.* at 108. The authors state that the most common primary form of POTS is called "partial dysautonomic whose patients have a mild type of peripheral autonomic neuropathy characterized by an inability of the peripheral vasculature to constrict in the face of orthostatic stress." *Id.* The authors also state that many patients report the abrupt onset of POTS after a febrile illness, pregnancy, immunizations, sepsis, surgery, or trauma. "It is currently felt that this form of POTS has an immune-mediated pathogenesis." *Id.*

Because petitioner filed the medical records of Dr. Holst and Dr. Simmons after the hearing, the experts did not have the opportunity to read these records prior to their testimony. Dr. Holst attributed petitioner's chronic iron overload syndrome to his hepatitis and his hepatitis to autoimmune hepatitis due to hepatitis B vaccination. Dr. Simmons diagnosed petitioner with autoimmune hepatitis due to hepatitis B vaccination and chronic iron overload syndrome due to his hereditary hemochromatosis.

The undersigned ordered Dr. Bellanti to file a supplemental report in light of Dr. Simmons' opinion that petitioner's chronic iron overload syndrome was due to his hereditary heterozygous hemochromatosis. In a report dated August 16, 2007, Dr. Bellanti replied that

carriers of one mutation ordinarily do not manifest symptoms of the disease. P. Ex. 69. Dr. Bellanti thought that petitioner's iron overload syndrome "might" have occurred secondary to hepatitis B vaccination or that his vaccine reactions may have worsened it and made it clinically apparent. P. Ex. 69, p. 2. Respondent declined to supplement Dr. Brenner's testimony.

DISCUSSION

To satisfy his 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 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 vaccine, he would not have had the injury, but also that the vaccine was a substantial factor in bringing about his injury. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

In essence, the special master is looking for a medical explanation of a logical sequence of cause and effect (Althen, 418 F.3d at 1278; Grant, 956 F.2d at 1148), and medical probability rather than certainty (Knudsen, 35 F.3d at 548-49). To the undersigned, medical probability means biologic credibility or plausibility rather than exact biologic mechanism. As the Federal Circuit stated in Knudsen:

> Furthermore, to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program. The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims. The Vaccine Act established a federal "compensation program" under which awards are to be "made to vaccine-injured persons quickly, easily, and with certainty and generosity." House Report 99-908, *supra*, at 3, 1986 U.S.C.C.A.N. at 6344.
>
> The Court of Federal Claims is therefore not to be seen as a vehicle for ascertaining precisely how and why DTP and other vaccines sometimes destroy the health and lives of certain children while safely immunizing most others.

35 F.3d at 549.

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."

The Federal Circuit in Capizzano v. Secretary of HHS, 440 F.3d 1317, 1326 (Fed. Cir. 2006) emphasized the opinions of petitioner's four treating doctors in that case dealing with hepatitis B vaccine causing petitioner's rheumatoid arthritis. The chief special master who originally ruled in the case accepted that hepatitis B vaccine could cause rheumatoid arthritis because of the evidence of positive rechallenge in the medical literature and other cases.

As the Federal Circuit stated in Knudsen, 35 F.3d at 548, "Causation in fact under the Vaccine Act is thus based on the circumstances of the particular case, having no hard and fast *per se* scientific or medical rules." The undersigned's task is to determine medical probability based on the evidence before the undersigned in this particular case. Althen, 418F.3d at1281 ("judging the merits of individual claims on a case-by-case basis").

The Federal Circuit in Knudsen, 35 F.3d at 549, also stated: "The special masters are not 'diagnosing' vaccine-related injuries."

That petitioner's condition may be difficult to diagnose does not prevent his being able to prove causation in fact as long as he fulfills the three criteria described in Althen. See Kelley v. Secretary of HHS, 68 Fed. Cl. 84, 100 (Fed. Cl. 2005) (whether petitioner had chronic inflammatory demyelinating polyneuropathy [CIDP] or Guillain-Barré syndrome [GBS] was irrelevant to his proving entitlement).

Petitioner's case herein is both easy and hard. It is easy in the sense that petitioner clearly had a reaction to both his hepatitis B vaccinations. Respondent's expert Dr. Brenner does not dispute that petitioner reacted to his second hepatitis B vaccination, but declined to admit a reaction to the first because there was no contemporaneous medical record of that reaction. The undersigned accepts petitioner's history given three days after his second hepatitis B vaccination

when he reacted again and dragged himself to the Baylor clinic, telling Dr. Ellison Wittels he had reacted to the first hepatitis B vaccination and now was feeling just as bad. Dr. Wittels noted in the medical records that petitioner had an allergic reaction.

When the undersigned asked Dr. Brenner when petitioner's reaction ended, he stated when his arm stopped hurting. Dr. Brenner ignores, however, that petitioner never recovered his health. Petitioner had more going on than a sore arm. His entire life changed and it changed over time. Before the vaccinations, he was hardy, athletic, active, and involved in strenuous work on farms, in Alaska, and in Mexico. After the vaccinations, he could hardly go to work and had to lie down often. He is still incapacitated.

Although Dr. Shoenfeld referred to petitioner's experience as positive rechallenge in his report, Dr. Bellanti (petitioner's other immunologic expert) called petitioner's experience an anamnestic response. This is a more precise, although related, description. Whereas positive rechallenge means that petitioner experienced the same reaction after each vaccination, an anamnestic response means petitioner's reaction after the second vaccination was similar but far worse. And this is what happened to petitioner. After the first vaccination, he had pain under his left arm, headache, nausea, and left eye watering. After the second vaccination, he had frontal headache, aches and pains, sweats and chills, twitching of his left eyelid, joint aches, and stiffness. His blood vessels dilated on his face down his chest. Even though Dr. Wittels diagnosed petitioner with conjunctivitis, he also wrote that petitioner had an allergic reaction.

Subsequently, petitioner's condition got worse. Dr. Brenner in his own report diagnosed petitioner with mild encephalopathy and POTS. On the witness stand, he thought petitioner had hepatitis from his hemochromatosis and the hepatitis caused his encephalopathy, but he had no

opinion about the POTS. Petitioner's treating physicians Drs. Goff, Holst, and Simmons thought he had autoimmune hepatitis from hepatitis B vaccine.

Dr. Brenner stated he had great respect for Dr. Shoenfeld, the first immunologist to testify on petitioner's behalf. Dr. Shoenfeld, as well as numerous treating physicians, including the worker's compensation doctor (Dr. deShazo) who presumably would be motivated to produce an opinion against granting petitioner worker's compensation but did not, diagnosed petitioner with a mild encephalopathy.

Dr. Shoenfeld stated that petitioner had an avalanche of autoantibodies. Petitioner had numerous illnesses which might be hard to describe but which petitioner himself boiled down to lupus-like. To Dr. Brenner, petitioner is chronic fatigue-like, but does not fulfill all the criteria of classic chronic fatigue syndrome. Dr. Brenner denied petitioner was lupus-like.

Dr. Bellanti, petitioner's second immunologic witness, seconded Dr. Shoenfeld's opinion that petitioner's avalanche of autoimmune diseases was caused by hepatitis B vaccine. Dr. Goff, petitioner's treating gastroenterologist, diagnosed petitioner with autoimmune hepatitis due to hepatitis B vaccination. Dr. Holst and Dr. Simmons also diagnosed petitioner with autoimmune hepatitis due to hepatitis B vaccination. A number of other doctors, including Dr. Bellanti, diagnosed petitioner with neurologic injury due to hepatitis B vaccination. Dr. Lai, a neurologist, in January 1995 diagnosed petitioner with a mild encephalopathy. In addition, petitioner had POTS.

Respondent's article on POTS relates that immunizations can cause POTS and that POTS is an immune-mediated disease. Dr. Brenner has no explanation for why petitioner has POTS (not that respondent has the burden to prove the cause of petitioner's POTS). But both of

petitioner's experts and many of his treating physicians ascribed his lupus-like condition, autoimmune hepatitis, mild encephalopathy, and POTS to hepatitis B vaccine.

The hard part of this case is that petitioner also has heterozygous hemochromatosis which Dr. Simmons, one of his treating physicians, states in the medical records caused his chronic iron overload syndrome. This syndrome causes a number of the symptoms petitioner has, primarily fatigue. But fatigue is a symptom common to many diseases, including POTS. Moreover, when petitioner is bled (phlebotomy is the treatment for hemochromatosis), his symptoms do not seem to ameliorate. Therefore, the undersigned must assume that petitioner's chronic iron overload syndrome does not play a major role in causing petitioner's symptoms compared to petitioner's various conditions which affect his vascular, autonomic nervous, and nervous systems.

Other confounding factors are petitioner's motor vehicle accident on August 20, 1996 and his fall on February 15, 1997. On August 20, 1996, petitioner's head broke the rear windshield of a truck cab in which he was a passenger and he had cervical spine and lower back problems afterwards. In petitioner's fall on February 15, 1997, petitioner injured his coccyx on a staircase. The effect of these accidents on petitioner's current condition is a question for damages, not for entitlement.

Dr. Brenner initially thought that he could attribute all petitioner's symptoms to wild hepatitis B virus infection coincident to petitioner's hepatitis B vaccinations until petitioner's serum tested negative for hepatitis B core and surface antigen in 2007, showing he could not have had wild hepatitis B virus infection in 1994. The reason he had tested positive in 1999 was that Dr. Campbell had, inadvisedly, prescribed IVIG treatments, exposing petitioner to antibodies in the immunoglobulin injected into him that came from other people. At trial, Dr. Brenner

changed his opinion from wild hepatitis B infection to chronic fatigue syndrome, a position from which he retreated in light of petitioner's not satisfying the criteria for the disease. Respondent does not have the burden of showing a known factor unrelated to the vaccinations. The question remains whether petitioner has satisfied his burden of making a prima facie case of causation in fact. He has.

As Dr. Shoenfeld and Dr. Bellanti explained, petitioner was susceptible to whatever in the hepatitis B vaccine caused him to react in multiple ways (nervous system, vascular system, autonomic nervous system, hepatologic system) so that he manifested various conditions and was diagnosed by treating physicians with encephalopathy, POTS, autoimmune hepatitis, neuropathy, and lupus-like syndrome. In his written report, Dr. Shoenfeld described four mechanisms by which the hepatitis B surface antigen could lead to an avalanche of autoimmune diseases: molecular mimicry, polyclonal activation, tissue damages, and bystander activation. P. Ex. 57, pp. 8-11 (he left out tissue damages in his testimony). The undersigned is aware that treating doctors, such as Drs. Arnett and West, did not find petitioner to have any autoimmune abnormalities and Dr. Bellanti testified that merely having an autoimmune abnormality on blood testing did not mean that someone had an autoimmune disease clinically (such as thyroid disease). However, Dr. West still believed that petitioner's mild neurologic damage was due to his hepatitis B vaccinations.

Since the Federal Circuit in Knudsen stated petitioners do not have to prove a specific biological mechanism in order to prevail, Dr. Shoenfeld's thesis and Dr. Bellanti's testimony present a biologically plausible explanation for what happened to petitioner. We can see the beginning of his allergic reaction after the first vaccination, manifested by a more serious

reaction after the second vaccination (the anamnestic response). If he had an autoimmune response, the diagnosis of autoimmune hepatitis due to hepatitis B vaccine by Drs. Goff , Holst, and Simmons are valid conclusions. If he had an encephalopathic response, as numerous doctors, including respondent's expert Dr. Brenner, believed, his treating doctors also attributed it to the vaccination. If he had a neurologic response, Dr. Shoenfeld's thesis that anything the virus can cause, the vaccine can cause as well explains the biologic theory behind causation in fact. Respondent's article on POTS also explains an immune-mediated basis for the relation of immunizations to POTS.

There is a logical sequence of cause and effect manifest because the susceptibility petitioner showed after the first vaccination was consistent in his reaction after the second vaccination magnified by an onslaught of disease entities affecting his mind, vascular system, neurologic system, liver, and balance.

There was a medically appropriate time frame between petitioner's reactions to his hepatitis B vaccinations. Regarding the Federal Circuit's emphasis on respecting the treating physicians opinions (see Capizzano), the undersigned notes that 12 of petitioner's doctors opined that hepatitis B vaccine caused his condition, however they diagnosed his condition: Dr. Ellison Wittels, Dr. Charles Miranda, Dr. Richard deShazo (the worker's compensation physician), Dr. V. Joyce Gauthier, Dr. James Jones, Dr. Howard Weinberger, Dr. Sterling West, Dr. Andrew Campbell, Dr. Thomas Soper, Dr. John Goff, Dr. Greg Holst, and Dr. Paul Simmons.

In addition, although the undersigned does not regard this as a close case, the Federal Circuit in Althen and Capizzano has stated that in close cases, petitioners should prevail.

Petitioner has proved a prima facie case of causation in fact and but for the hepatitis B vaccinations, he would not have had the conditions he currently has (except for any residua from his motor vehicle accident and his fall, and if there are any symptoms from his hereditary hemochromatosis).

CONCLUSION

Petitioner has prevailed on the issue of entitlement. The undersigned encourages the parties to settle damages in this case. A telephonic status conference shall be set soon to discuss how to proceed with damages.

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IT IS SO ORDERED.

September 14, 2007
DATE

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