OFFICE OF SPECIAL MASTERS

June 30, 2003

BERNARD BISSON,	*	
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	*	No. 98-121V
Petitioner,	*	PUBLISHED
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v.	*	
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SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
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Respondent.	*	
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John J. Welch, Jr., Rutland, VT, for petitioner.
Traci R. Manning, Washington, DC, for respondent.

DECISION

MILLMAN, Special Master

On February 17, 1998, petitioner filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986[1] (hereinafter the "Vaccine Act" or the "Act"), alleging that hepatitis B vaccine caused his transverse myelitis (TM). Petitioner has satisfied the requirements for a prima facie case pursuant to 42 U.S.C. § 300aa-11(c) by showing that: (1) he has not previously

[1] The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C.A. § 300aa-1 et seq. (West 1991), as amended by Title II of the Health Information, Health Promotion, and Vaccine Injury Compensation Amendments of November 26, 1991 (105 Stat. 1102). For convenience, further references will be to the relevant subsection of 42 U.S.C.A. § 300aa.

collected an award or settlement of a civil action for damages arising from the alleged vaccine injury; and (2) he received hepatitis B vaccine in the United States.

The court held a hearing in this case on April 4, 2003. Testifying for petitioner were Dr. Sheldon Margulies and Dr. David Rosenstreich. Testifying for respondent were Dr. Paul Safran and Dr. Burton Zweiman.

FACTS

Mr. Bisson was born on October 28, 1937. Before he received two hepatitis B vaccinations in 1993, he had a number of medical problems.

A medical notation dated December 11, 1987 stated Mr. Bisson had been tired for two months. He was allergic to Penicillin. He had a noted lack of energy for the past two months. He fell asleep easily in a chair. He had gained 20 pounds in the prior year. His reflexes were slightly "hung up." Med. recs. at Ex. 3, p. 1.

A medical notation dated December 31, 1992 stated Mr. Bisson had gained 11 pounds in a year. He had left-sided rib cage pain. He reached across the car on December 28th and felt sudden pain in that area. He fell across a car recently and injured his back and left side. Med. recs. at Ex. 3, p. 17. He had a left supraclavicular[2] node, unchanged from the previous examination of December 7, 1992. Med. recs. at Ex. 3, p. 25.

Mr. Bisson received his first hepatitis B vaccination on January 20, 1993. Med. recs. at R. Ex. A. He received his second hepatitis B vaccination on February 24, 1993. Med. recs. at Ex. 2, p. 4. On March 15, 1993, 19 days after vaccination, Mr. Bisson went to see a dentist, Dr. Sally A.

[2] Supraclavicular means situated above the clavicle which is "the bone articulating with the sternum and scapula ... forming the anterior portion of the shoulder girdle on either side; called also collar bone." Dorland's at 1614, 343.

Bishko, for an emergency examination concerning tooth # 30 because it hurt a lot and for a while. She prescribed Percodan. R. Ex. J, pp. 5, 7. On his dental registration form, Mr. Bisson stated he was having discomfort. It had been three years since he had seen a dentist. He had lost some teeth and the extractions had complications. His gums bled when he brushed his teeth. Id. at 4. He felt that his teeth needed work. Id. at 5. He noted on the form that he had had a heart attack in 1985. Id.

Mr. Bisson saw his medical doctor March 19, 1993, 23 days after vaccination. He had a fever of 103° that morning. He had an infected tooth and was on an antibiotic. The fever went up and down all week. His fever did not appear until after the tooth infection was apparent. Med. recs. at Ex. 3, p. 25.

A subsequent medical record dated March 22, 1992 (which should be 1993) stated that his temperature continued to be 102° over the weekend. That morning, it was 100°. He was very weak. Id.

On March 24, 1993, Mr. Bisson went to the Central Vermont Hospital Emergency Department. R. Ex. H. He had had a febrile illness with temperature up to 104° for about one and one-half weeks. Dr. Bruce Talmadge saw him the prior week and diagnosed a viral syndrome with gradual resolution of fever and flu-like symptoms. That day, Mr. Bisson complained of about one day's history of severe bilateral shoulder pain which was worse with shoulder movement. The diagnosis of Dr. Christin Blaski was myalgias/arthralgias probably secondary to a viral syndrome. Id. at 1.

Mr. Bisson telephoned his doctor on March 26, 1993 and reported that, since March 23, 1993, his right shoulder and arm pain had been very bad. He went to the emergency room again on

March 24th. He still got some severe pain in his right arm, and it did not work well. It was hard for him to open a packet. He could not raise his arm. It had a numb feeling. He was very tired and had a headache. He had been afebrile for the prior three to four days, but the pain and disability had worsened. Med. recs. at Ex. 3, p. 27. Mr. Bisson filled out a health questionnaire on March 26, 1993. He stated that he did not suffer from constipation, he did not have constant numbness or tingling in any part of his body, he did not have trouble starting urinating, and he did not have severe pains and aches making it impossible for him to work. Med. recs. at Ex. 3, pp. 29-30.

On March 26, 1993, Mr. Bisson saw Dr. John H. Milhorat, a neurologist. He wrote that Mr. Bisson was in his usual state of good health until several weeks prior when he apparently developed some type of infectious disease process. Prior to that, there was no history of any chills, fever, weight loss or any other telltales of systematic disease. He had general malaise and elevated temperature readings (102-103° and rarely 104°). His illness generally lasted about eight days or so. At one point, an infected tooth was strongly suspected. Mr. Bisson was placed on Erythromycin and the tooth felt better. Dr. Milhorat wrote it was "probably true that the patient had a viral syndrome–with general malaise, a lack of energy and a variety of aches and pains in his muscles which, recently, have been principally located within both his shoulder and his scapular regions and his upper arms–much more so on the right side." Recently, he had variable telltales of hypalgesia and parasthesiae mostly within his right shoulder and right upper arm. A cervical spine series revealed almost complete straightening (he had complete loss more or less of the normal cervical

lordosis), suggesting muscle spasms. Mr. Bisson had negative Babinski[3] signs. Med. recs. at Ex. 3, pp. 66A, 67.

On March 30, 1993, Mr. Bisson had a MRI which showed mild degenerative changes at the C4-5 levels. Med. recs. at Ex. 3, p. 32.

On April 1, 1993, Mr. Bisson had a neurological follow-up. "[T]here were no telltales for a demyelinating disease process."[4] His cervical spine series done on March 26, 1993 revealed no major abnormalities. MRI was negative for any significant pathology, and revealed some minor disc protrusions at C4-5 and C5-6. Dr. Milhorat stated, "I was surprised that his MRI was so normal." His reflexes were trace to +1 in his right upper extremity and +1 ½ or +2 in his left upper extremity. Dr. Milhorat noted no pathoreflexia. Mr. Bisson could walk independently. His signs and symptoms were asymmetrically distributed. Med. recs. at Ex. 3, pp. 69, 69A.

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[3] "In people more than 2 years old, the presence of a Babinski's reflex indicates damage to the nerve paths connecting the spinal cord and the brain (the corticospinal tract)." Medline Plus. http://www.nlm.nih.gov/medlineplus/ency/article/003294.htm. "A Babinski response in an older child or adult is abnormal. It is a sign of a problem in the central nervous system (CNS), most likely in a part of the CNS called the pyramidal [corticospinal] tract." MedicineNet.com. http://www.medterms.com/script/main/art.asp?articlekey=7176.

[4] "Transverse myelitis is a demyelinating (loss of the fatty tissue around the nerves) disorder of the spinal cord. It may occur alone or in combination with demyelination in other parts of the nervous system. Onset of the disorder is sudden. Symptoms may include low back pain, spinal cord dysfunction, muscle spasms, a general feeling of discomfort, headache, loss of appetite, and numbness or tingling in the legs." National Institute of Neurological Disorders and Stroke (NINDS) Transverse Myelitis Information Page. http://www.ninds.nih.gov/health_and_medical/disorders/transversemyelitis_doc.htm

On April 2, 1993, Mr. Bisson had a bone scan of his chest which showed two ribs in the lower rib cage on the left anteriorly with slightly increased activity at the costochondral[5] junction, consistent with recent injury.[6] Med. recs. at Ex. 3, p. 38.

On April 6, 1993, he had an EMG. He gave a history that he likely had a viral illness several weeks previously. Six to eight days previously, he had pains and weakness in all four limbs. His strength was tested and was 4/5 strength in his right upper extremity, 4/5 strength in his right lower extremity, 5/5 strength in his left upper extremity, and 5/5 strength in his left lower extremity. An MRI of his cervical spine showed minor disc protrusions at C4-5 and C5-6. He had fasciculations (muscle twitches) and sensory changes. Possible diagnoses were TM, other myelopathy, or Guillain-Barre Syndrome (GBS). He had negative Babinskis. Med. recs. at Ex. 3, p. 36.

On April 9, 1993, Mr. Bisson complained of more right-sided pain. Med. recs. at Ex. 3, p. 34. On April 13, 1993, he felt numbness and tingling in his legs, mostly in the right leg, but also in the right arm and thumb of his left hand. He had no strength. The impression was TM at the C-4 level, of unknown etiology. Med. recs. at Ex. 3, p. 34. On April 13, 1993, Dr. Milhorat stated that it was much more likely than not that Mr. Bisson's TM was an immune response to his hepatitis B vaccination in late February 1993. The timing was correct and literature describes TM following hepatitis B. The pathologist Dr. Mike Belding suggested it was more likely than not that Mr. Bisson received a recombinant form of hepatitis B vaccine, not of human origin. Med. recs. at Ex. 3, p. 70.

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[5] Costochondral means "pertaining to a rib and its cartilege." Dorland's at 389.

[6] This may be a reference to the injury on Mr. Bisson's left side when he fell across a car and injured his back and left side, noted in the record of December 31, 1992.

On April 13, 1993, a protein count of his CSF was 54, within the normal range of 15 - 60 mg/dl. Med. recs. at Ex. 3, p. 42.

Mr. Bisson returned to his dentist on April 20, 1993 for further treatment of tooth # 30 which had been aching. He had no response to a pulp[7] test.[8] But Mr. Bisson was back on antibiotics and was much better. The dose of PCE (erythromycin particles in tablets) was 333 mg. R. Ex. J, p. 2.

Mr. Bisson telephoned his doctor on April 29, 1993, saying he was taking PCE for his tooth infection and had a red, blotchy rash on his chest, arms, and neck. Med. recs. at Ex. 3, p. 44. On April 30, 1993, his prescription was changed to Tetracycline 500 mg. R. Ex. J, p. 2. He saw the dentist again on May 5th and 7th. He had some swelling and tenderness but no pain. On May 6, 1993, he was on Percodan for his dental pain as well as Tetracycline. He had been off Prednisone since April 28, 1993 and felt better off Prednisone as it depressed him. Med. recs. at Ex. 3, p. 70.

On May 7, 1993, Mr. Bisson saw Dr. Talmadge at the Central Vermont Medical Center Rehabilitation Services for a physical therapy initial evaluation. The date of the onset of his problems was March 24, 1993. He had received his first hepatitis B vaccination in January and his second on February 28th (it should be the 24th). He had a fever until March 14, 1993 for eight consecutive days and then developed pain in his shoulders across the cervical thoracic junction. The pain progressed into the right arm with weakness all the way down to his fingers. He also had pain

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[7] Pulpa dentis or "dental pulp: the richly vascularized and innervated connective tissue of mesodermal origin contained in the central cavity of a tooth and delimited by the dentin, and having formative, nutritive, sensory, and protective functions." Dorland's Illustrated Medical Dictionary, 27th ed. (1988) 1388.

[8] The pulp test is "a diagnostic test to determine tooth pulp vitality or abnormality, usually by means of electric pulp testers or by application of a hot or cold stimulus." Dorland's at 1689. "A minimal positive pulp test as compared to adjacent and contralateral teeth may predict future non-vitality...." http://www.endomail.com/articles/dsk14goodfoundation.html.

and weakness in his arm and thumb. The prognosis was TM in the mid-cervical region with marked weakness in his right upper extremities and slight weakness in his left upper extremity. Med. recs. at Ex. 3, p. 45.

On May 10, 1993, Mr. Bisson had bronchitis. It hurt to cough. His dentist had prescribed Tetracycline for his tooth, but it did not seem to help. Med. recs. at Ex. 3, p. 44.

On May 26, 1993, the dentist wrote that tooth # 30 was asymptomatic. The dentist recommended a crown[9] for it. R. Ex. J, p. 2.

On May 28, 1993, Dr. Milhorat provided Mr. Bisson with some of the latest articles on TM related to immunization and/or parainfectious disease processes, including an article from *The New England Journal of Medicine* and *Archives of Neurology*. Dr. Milhorat stated in his medical records for that visit that Mr. Bisson "has had no autonomic dysfunctions such as bladder incontinence or fecal incontinence." Med. recs. at Ex. 3, p. 72. Dr. Milhorat also stated "there is no history to support the notion that he might have a demyelinating disease." Mr. Bisson did not have positive Babinski responses. Med. recs. at Ex. 3, p. 72A.

On August 5, 1993, Mr. Bisson's occupational therapist Nancy Frey wrote that Mr. Bisson had little movement in his right shoulder but, fortunately, was left-handed. She noted no fasciculations (muscle twitches) referable to his right upper extremity. Med. recs. at Ex. 3, p. 52A.

On September 1, 1993, Dr. Mark Friedman, an internist, wrote a report stating that Merck had eight possible TM cases reported after 34 million doses administered of hepatitis B vaccine. The TM cases followed live or killed virus vaccines, but not genetically engineered vaccine as Mr. Bisson

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[9] An artificial crown is "a restoration ... that reproduces the entire surface anatomy of the clinical crown of a tooth; it may be attached to a prepared tooth stump .. or it may be cemented to the remaining tooth structure." Dorland's at 401.

received. The onset of TM after vaccination was days, not three weeks as in Mr. Bisson's case. He noted that Mr. Bisson was having moderate weakness of his upper and lower extremities without bladder or bowel symptoms Viral infection often precedes the onset of TM and Mr. Bisson's case suggests he had a virus because he had a mildly elevated liver function test, increased monocytes, elevated ESR, fevers, and myalgias. R. Ex. D, pp. 8, 9, 10.

On September 2, 1993, Dr. Milhorat saw Mr. Bisson and noted no pathoreflexia or fasciculations. Med. recs. at Ex. 3, p. 55A. On September 13, 1993, a radiology report showed osteoporotic changes within Mr. Bisson's right shoulder, which was a new finding when compared to a study done five months previously. He had fairly marked osteoporosis of all his bony structures on the right side, most marked within the joint capsules. Med. recs. at Ex. 3, p. 57.

On February 2, 1994, Dr. Friedman wrote that Mr. Bisson's main symptom was a lack of stamina. R. Ex. D, p. 1. Dr. Friedman and Dr. Paul N. Chervin, a neurologist, both examined Mr. Bisson on February 2, 1993. On February 3, 1994, Dr. Friedman wrote a report, stating that Mr. Bisson's gait was essentially normal, based on a videotape that he saw of Mr. Bisson walking with a cane. Mr. Bisson's gait on the videotape was different from the one he demonstrated during the office examination. Med. recs. at Ex. D, p. 4. Dr. Friedman stated he did not believe that Mr. Bisson has a medically disabling condition because of the inconsistency in his gait during the examination and in the videotape, and because of his physical examination. Id.

Dr. Chervin wrote a report dated February 3, 1994 that Mr. Bisson did not have a neurologic abnormality or disability. There was no objective documentation in the medical records that he ever had a myelopathy. R. Ex. B, p. 2. On examination, Mr. Bisson was alert and healthy appearing. He noticed that Mr. Bisson's gait changed from when he put down the cane and went from the

examining table around the examining room (when he ambulated normally) to when the examination was over, and he picked up the cane and shifted his weight from side to side awkwardly with a stiff leg opposing his left arm which held the cane. R. Ex. B, p. 1. There was no muscle atrophy in the shoulders or upper extremities by inspection or measurement. He had normal strength in the supraspinatus, infraspinatus, deltoid, biceps, triceps, brachioradials, wrist extensors, and, in the left hand, normal strength in the intrinsic hand muscles without atrophy or fasciculations. He had limitations of motion in the PIP (proximal interphalangeal) and DIP (distal interphalangeal) joints of the 4th and 5th digits of the right hand, and was unable to oppose his 1st and 5th digits of that hand. He had normal grasp involving the first three digits only because he could not fully flex the 4th and 5th digits. However, when his palm was inverted, and he was asked to flex his fingers, he had approximately 60% flexion of the DIP joints and 45 degrees of flexion of the PIP joints of the 4th and 5th digits. Sensation to pin, temperature, position and vibration were normal in upper and lower extremities. Reflexes were 1+ in the biceps bilaterally, 1+ in the triceps, and the right brachioradial reflex was barely attainable–the left was 1+, knee and ankle reflexes were both 1+, and there was no ankle clonus and plantar responses were downgoing. He had excellent proprioception and vibratory senses in the lower extremities, including the toes. Cerebellar testing was normal. He was able to stand with his eyes closed, arms out in front of him, on either foot without falling and with normal compensatory pelvic tilt. Id.

Dr. Chervin wrote a letter, dated February 3, 1994, stating that the records fail to provide evidence that Mr. Bisson had a myelopathy. There was no objective evidence that he had spinal cord involvement, and in fact a lumbar puncture that Dr. Milhorat performed on April 13, 1993 was entirely normal. Specifically, it did not contain any white blood cells as evidence of inflammation

and there was not a significant elevation of protein in the spinal fluid or other objective evidence that his spinal cord or nerve roots were affected by an infectious process secondary to hepatitis vaccine. Mr. Bisson's EMG did show denervation which was consistent with radiculitis or neuritis, but these were nonspecific findings. Similarly his cervical MRI was normal and did not show inflammation of the cervical spinal cord to support a diagnosis of myelopathy or transverse myelitis. R. Ex. B, p. 3.

On March 3, 1994, Dr. Friedman wrote that Mr. Bisson did not have a medically disabling condition. He had essentially a normal gait and no clear abnormalities on physical examination. R. Ex. D, p. 4. He noted that Dr. Chervin questioned whether Mr. Bisson had TM. Mr. Bisson's lumbar puncture was essentially normal. There was no MRI evidence of TM. His toes were not upgoing on neurological examination. R. Ex. D, p. 5.

On March 15, 1994, Dr. Milhorat wrote that Mr. Bisson was plateauing. He had had TM secondary to an adverse reaction to hepatitis B vaccine, but he could not absolutely prove it. Med. recs. at Ex. 3, p. 63.

A deposition was taken of Dr. Chervin on July 3, 1995 in a workmen's compensation claim. R. Ex. E. Dr. Chervin testified that Mr. Bisson's gait was feigning or psychological. Id. at 11. His gait was not of someone with weakness from nerve involvement or spinal cord involvement. Mr. Bisson used a crutch not in a physiologic way. His lower extremity was not weak. Id. at 12.

Mr. Bisson's neurological examination was normal except for the movement of the joints of his fourth and fifth digits of his right hand. Id. at 15. Dr. Chervin did not know why Mr. Bisson has difficulty with that movement. Id. His spinal tap or lumbar puncture shows no evidence of a cellular process (infiltrates) which would mean inflammation of the spinal cord. Id. at 17. When someone

has inflammation, cells that normally should be within the barrier of the spinal cord's membranes leak out and his protein content becomes elevated. Id. at 17-18. The absence or lack of abnormal spinal fluid when the patient complains of symptoms absolutely rules out myelopathy. Id. at 18. Abnormal spinal fluid is the hallmark of myelitis or inflammation of the spinal cord. Id. At 18-19.

Mr. Bisson's glucose in the spinal fluid was negative and electrophoresis did not detect abnormal subprotein components. Id. at 19. Mr. Bisson's MRI was normal and did not show spinal cord inflammation, or a scar, or evidence of a subacute process. Id. If Mr. Bisson had had transverse myelitis, Dr. Chervin would have expected to see in the spinal fluid white blood cells (the preeminence of mononuclear or monocytes), and very significantly elevated spinal fluid protein which when fraginated, should have an acute phase reactant that electrophoresis could measure. There should be an anatomic documentation of this process, i.e., the MRI. Id. at 20. Thirdly, the EMG should detect denervation which is in a spinal cord distribution. But, Mr. Bisson's EMG showed something wrong with his nerve roots rather than with his spinal cord. So all the criteria one would expect to see to explain his symptoms were negative, based on the examination by his neurologist, the imaging from the MRI, the laboratory basis with his spinal fluid, and the electrodiagnostic basis with his electromyogram. Id. at 21.

Dr. Chervin testified that there is no evidence based on Mr. Bisson's history, his general medical and neurological clinical records, his EMG, spinal fluid examination, or MRI, that his spinal cord was ever involved. Id. He had something wrong with his nerve roots at the fifth and sixth cervical levels maximally. This would interfere with the ability of the nerve roots to produce electricity in some of the upper extremity muscles, but does not involve the spinal cord. Id. at 24.

An injury to the cervical spinal cord would involve not only the arms, but the legs. But Dr. Roomet, who performed the EMG, found no abnormalities in Mr. Bisson's leg muscles. Id. at 25. His findings indicated segmental denervation at the C5-6 levels. A myelopathy or transverse myelitis would have had to involve the spinal cord as well as the nerve roots. Id.

Dr. Chervin testified he thinks that Mr. Bisson had brachial neuritis. Id. at 26. There is no specific etiology which can be identified other than an infection, a bad tooth, pneumonia, or a cold. Id. He does not think that hepatitis B vaccine caused it. Id. He has never heard at a meeting, or in discussion with his colleagues at a clinical conference or read in the literature that hepatitis B vaccine causes brachial neuritis. Id. Among Dr. Chervin's other professional duties, he is an examiner for the American Board of Psychiatry and Neurology. Id. at 28.

Dr. Chervin stated that Mr. Bisson probably had some type of neuritis or inflammation of the nerves affecting his upper extremities, which was transient and resolved. This is a naturally occurring process and usually occurs after some type of bacterial or viral illness when the individual had a fever. Id. at 32-33. Factors dictating that he did not have transverse myelitis are: absence of long tract findings (meaning those tracts which go from the neck all the way down), normal spinal fluid, normal MRI, an EMG which does not clearly place the lesion in the spinal cord, and absolutely no remnants of TM which in any way alter or affect his ability to use his muscles or perceive those feelings which his spinal cord carries up from his lower extremities or down to them. Id. at 34.

Mr. Bisson's dental infection led to a 102° fever and may have set the seeds for his neurologic process. Id. at 36. He took an antibiotic, Erythromycin, and had an abnormal liver function. Erythromycin has a very high incidence of transient changes in liver function. A virus could also cause abnormal liver function transiently. Mr. Bisson's tooth was treated with a very high

dose of Erythromycin and he had a fever of 102°, which may have set this seeds of his neurological syndrome. Id. Whatever Mr. Bisson had in 1993 was unrelated to his hepatitis B vaccination. Id. Dr. Chervin ruled out a diffuse polyneuropathy as a diagnosis in Mr. Bisson's case. Id. at 52.

Mr. Bisson had some sort of neurological problem in March 1993. Id. at 57, 58. His neurological symptoms were weakness, numbness, and tingling. Id. Dr. Chervin would have expected that if, in fact, Mr. Bisson had transverse myelitis, which means a segmental spinal cord interruption in the nerve tracts, there would be some evidence below the level of involvement producing not only symptoms, but also physical findings. Id. at 62. The sine qua non for problems in the lower extremity relating to weakness is a positive Babinski response which is an abnormal response of the great toe when the sole of the foot is tickled on the lateral margin (the great toes would point upward). Id. at 62, 63. But when Mr. Bisson saw Dr. Milhorat in March 1993, his Babinski response was normal. Similarly, he had no weakness or loss of sensation in the lower extremities. He did have findings in his upper extremities. The other major tracts in the spinal cord, i.e., bowel and bladder function, have never been affected in Mr. Bisson's case. Id. at 63.

If Mr. Bisson had had TM, there would have been oligoclonal banding in his spinal fluid (the subclassification of the protein abnormality in the spinal fluid combined with abnormal cells) which would have led to a diagnosis that there was an acute phase reactant, indicating demyelinization. Id. at 65.

Radiculitis and neuritis are symptoms of brachial neuritis. Id. at 74. Numbness, tingling, and weakness are indicative of brachial neuritis. Id. at 75. Numbness, tiredness, and weakness can be due to radiculitis and/or neuritis in the lower extremities. Id. Mr. Bisson had severe pains in his shoulders and upper arms, primarily on the right, and weakness in all extremities. He did not have

symptoms of lower extremity difficulty (motor, paresthesias, strength, sensation, or reflex abnormality) when Dr. Milhorat saw him on March 26, 1993. Id. at 78. Mr. Bisson's normal reflexes, normal sensation, lack of any abnormal reflex, and lack of fasciculations in the lower extremities rule out a problem with lumbar or lumbosacral neuritis, neuropathy, radiculopathy, or radiculitis. He had a problem in his neck and in the mid- to lower cervical region. Id. When Mr. Bisson saw Dr. Milhorat, he did not have symptoms of lower extremity difficulty. He had severe pains in his shoulders and upper arms, primarily on the right, and weakness in all extremities. Possibilities for Mr. Bisson's difficulties with his upper right extremity are cervical spondylosis with a myelopathy, ruptured disk (arthritis of the neck pushing on the spinal cord), tumor, syrinx (a cavity in the spinal cord), and hematomyelia. Id. at 80.

If Mr. Bisson had had nerve root problems, Dr. Chervin would have expected a very significantly elevated spinal fluid protein, which he did not have. Id. at 83.

On July 6, 1995, Dr. Friedman's deposition was taken in the workmen's compensation case. R. Ex. F. Dr. Friedman gave Mr. Bisson a physical examination on February 2, 1994. Id. at 11. Mr. Bisson had mild impairment of his right hand and arm, but was not disabled. Mr. Bisson reported symptoms of lower extremity weakness, buckling when he walked, using a cane for support, being able to walk only 1/4 mile daily, limited stamina, and difficulty with handwriting. Id. at 19-20.

Dr. Friedman testified that Recombivax hepatitis B is an engineered vaccine. It is more purified by using yeast broths. It does not contain any live or killed virus, and has less protein contaminant and is associated with less adverse events and complications. Id. at 23-24. By the summer of 1993, Mr. Bisson's illness had plateaued. Id. at 26. A videotape was taken of Mr. Bisson with him unaware he was being videotaped. Id. at 30. Dr. Chervin and he received their own copies

of the tape. Id. at 31. Mr. Bisson had a febrile illness, a temperature of 103, and aches and pains. This could have been an infectious illness that was missed. Id. at 38. There is no evidence that Mr. Bisson had a spinal cord lesion. Id. at 39. Dr. Milhorat commented that Mr. Bisson had a viral syndrome based on his general malaise (weakness), fever, lack of energy, aches and pains. Id. at 44. Mr. Bisson did not have an autoimmune reaction. Id. Relying on the medical literature, Merck data, and safety reports of drug toxicities, Dr. Friedman opined that genetically engineered hepatitis B vaccine does not cause neurological problems. Id. at 48. The atrophy in Mr. Bisson's right hand shoulder indicates muscle disuse. Id. at 50, 67. Dr. Friedman thinks it unlikely that hepatitis B vaccine caused Mr. Bisson's tooth infection based on his clinical knowledge and common sense. Id. at 71. He does not believe hepatitis B caused any of Mr. Bisson's symptoms in 1993. Id. at 73. Mr. Bisson's elevated monocyte count in January 1993, his elevated liver function test, and elevated sedimentation rate suggest he had a recent viral illness. Id. at 74. Dr. Milhorat did not do any viral titers on Mr. Bisson. Id. at 76, 81.

On July 27, 1995, Mr. Bisson testified in his workmen's compensation claim. R. Ex. K. He stated his tooth started hurting after the first hepatitis B vaccination and resumed hurting after the second hepatitis B vaccination. Id. at 59.

On July 20, 1996, Mr. Bisson had an independent medical examination with Dr. Mark J. Bucksbaum, who noted Mr. Bisson reported a recurrent bursitis of his right shoulder which he had been told had a calcium deposit. Med. recs. at Ex. 7, p. 1. Mr. Bisson reported being continent of bowel and bladder. Med. recs. at Ex. 7, p. 2. He was scored at a high level of perceived disability. Med. recs. at Ex. 7, p. 5.

On September 17, 1996, Sally Bisson, Mr. Bisson's wife, testified in a suit against SmithKline Beecham. R. Ex. L. She stated that Mr. Bisson had a high fever at around the same time that he had a painful tooth in March 1993. Id. at 7.

On January 22, 1997, the dentist noted that saving tooth # 30 was complicated and risky. R. Ex. J, p. 2. In a note dated July 22, 1997, the dentist states Mr. Bisson had gross debridement[10] and would be seeing Dr. Paul A. Levi for periodontal[11] evaluation. Id. Mr. Bisson expressed the wish to wait for treatment and his dentist advised him not to wait too long or he would require more treatment. Id. In a letter dated December 6, 1997, someone wrote a letter from the periodontist's office to Mr. Bisson's dental office, stating that he would present a periodontal treatment plan on December 20, 1997. Mr. Bisson's maxilla[12] was in trouble, but most of his teeth appeared treatable. His mandibular[13] arch was in pretty good shape. Id. at 3. Mr. Bisson's dentist noted on January 19, 1998 that Mr. Bisson was still not ready to proceed with Dr. Levi's recommendation yet. Id. at 2. On April 7, 1998, Mr. Bisson decided to switch dentists from Dr. Bishko to Dr. David Putter. Id.

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[10] Debridement is "the removal of foreign material and devitalized or contaminated tissue from or adjacent to a traumatic or infected lesion until surrounding healthy tissue is exposed." Dorland's at 434.

[11] Periodontics deals with diseases of the periodontium which are "the tissues that invest or help to invest and support the teeth, including the periodontal ligament, gingivae, cementum, and alveolar and supporting bone." Dorland's at 1261.

[12] The maxilla is "the irregularly shaped bone that with its fellow forms the upper jaw; it assists in the formation of the orbit, the nasal cavity, and the palate, and lodges the upper teeth." Dorland's at 987-88.

[13] The mandibula or the mandible is "the horseshoe-shaped bone forming the lower jaw." Dorland's at 977.

Written Submissions

Petitioner filed Exhibit 16, a letter from Dr. Daniel E. Jolly, a dentist, dated May 6, 2003. Dr. Jolly states that Mr. Bisson's dental problem was not secondary to any infectious process and he probably never had an infected tooth or an abscess. Nothing in his medical or dental records supports a diagnosis of an infected tooth and he had no real improvement in his tooth pain for over two months while he was taking antibiotics, contrary to what one would expect.

Petitioner filed Exhibit 20, a letter from Dr. Margulies, dated May 7, 2003, disputing respondent's expert Dr. Saffron's opinion that Mr. Bisson's neurologic injuries arose from an embolus from his heart to his spinal cord, causing an infarction in the cord. Dr. Saffron also testified that the source of the embolus was subacute bacterial endocarditis arising from an infected tooth. Dr. Margulies stated that there is nothing to indicate Mr. Bisson had subacute bacterial endocarditis, which is an infection of a heart valve due to a structural defect, allowing bacteria from an infection elsewhere in the body to lodge in crevices in the valve. Although Mr. Bisson had jaw pain, there was no clinical or x-ray evidence of a periodontal abscess.

Respondent filed Exhibits AA - EE, including a letter dated April 10, 2003 from respondent's expert Dr. Zweiman. Dr. Zweiman states that Mr. Bisson did not have a mental nerve neuropathy because he did not have a numb chin area. At the hearing, petitioner's counsel claimed that Mr. Bisson's tooth pain was due to mandibular nerve neuropathy. The mental nerve is a branch of the mandibular portion of the trigeminal or 5th cranial nerve. Discussing this with a world-famous expert in peripheral nerve disorders, Dr. Zweiman stated that it would be extremely unusual for a neuropathy involving the mandibular nerve to manifest as solely pain in a single tooth area. When

a damaged mandibular nerve is associated with such localized pain, the cause is nearly always due to local trauma or infection in the area of the tooth. R. Ex. AA.

Respondent's Ex. BB is an article by petitioner's expert, Dr. Sheldon Margulies entitled, "Proving Specific Causation under *Daubert*," 44 For the Defense 10-13, 58 (2002). In the article, Dr. Margulies states:

> General causation requires the expert to cite published epidemiological, animal, and laboratory studies, or some other strong evidence of general acceptance in the scientific community, while specific causation requires the plaintiff's history, physical exam, family history, laboratory tests, pathological studies, response to medications, timing between exposure to the agent and symptoms, clinical experience, textbooks, scientific treatises, and based on all this, a differential diagnosis. ...
> Temporal coincidence alone, however, is scientifically insufficient to establish causation.

Id. at 11. Dr. Margulies is identified as a member of the Maryland Bar.

Respondent's Ex. CC is another article by Dr. Margulies, entitled "The Differential Diagnosis. Its Use and Misuse," 44 For the Defense 14-15, 55-56 (2002). He states, "Symptoms are subjective complaints; signs are objective findings on physical exam." Id. at 15.

Respondent's Ex. DD is "Proposed diagnostic criteria and nosology of acute transverse myelitis," by the Transverse Myelitis Consortium Working Group, in 59 *Neurology* 499-506 (2002). On page 503, the authors describe what should occur during the history and physical examination: confirm acute myelopathy, elicit time course and extent of deficits, determine signs, symptoms or prior history, determine if recent history of vaccination or systemic illness. The authors describe TM as follows:

> Acute transverse myelitis (ATM) has an incidence of one to four new cases per million people per year, affecting individuals of all ages with bimodal peaks between the ages of 10 and 19 years and 30 and 39 years. It is characterized clinically by

> acutely or subacutely developing symptoms and signs of neurologic dysfunction in motor, sensory, and autonomic nerves and nerve tracts of the spinal cord. There is often a clearly defined rostral border of sensory dysfunction, and spinal MRI and lumbar puncture often show evidence of acute inflammation. When the maximal level of deficit is reached, approximately 50% of patients have lost all movements of their legs, virtually all patients have bladder dysfunction, and 80 to 94% of patients have numbness, paresthesias, or band-like dysesthesias. Autonomic symptoms consist variably of increased urinary urgency, bowel or bladder incontinence, difficulty or inability to void, incomplete evacuation, or bowel constipation.

Id. at 499.

The authors listed inclusion criteria, including "Bilateral signs and symptoms (though not necessarily symmetric)." Id. at 500. The authors discuss the situation in which someone does not have "objective documentation of inflammation within the spinal cord. Thus a situation in which spinal MRI shows an appropriately located high signal intensity lesion on T2-weighted sequences but no clear-cut enhancement of the abnormality following gadolinium administration could be envisioned. If the CSF were normal, then a diagnosis of ATM would not be possible under the proposed criteria. Further, the clinical findings present in such an individual may not be consistent with a vascular myelopathy either. Nevertheless, labeling such a situation as 'possible ATM' may be the best option at the moment." Id. at 501.

The authors state:

> Clinical features such as fever, meningismus, rash, concurrent systemic infection (e.g., pneumonia or diarrheal illness), immunocompromised state (e.g., AIDS or immunosuppressive medication), recurrent genital infection, radicular burning pain with or without vesicles suggestive of zoster radiculitis, or adenopathy may suggest an infectious etiology for ATM.

Id. at 502.

Respondent filed Ex. DD, an article entitled "Viruses as triggers of autoimmunity: facts and fantasies" by J.L. Whitton and R.S. Fujinami, 2 *Current Opinion in Microbiology* 392-97 (1999).

The authors found that they could protect animals against autoimmune disease through vaccination. "Therefore, the consequence of immunization with self proteins carried by replicating organisms is variable, at present unpredictable, and most likely depends upon the antigen chosen, and the timing and nature of antigen delivery." Id. at 393.

Petitioner filed, under the heading *Adverse drug reaction of the month*, "Hepatitis B vaccine and neurotoxicity," by M. Pirmohamed and P. Winstanley, 73 *Post Grad Med J* 462-63 (1997), in which the authors discuss a man who had a two-day history of progressively worsening vertigo and a one-day history of nausea and inability to close his left eye as well as tinnitus. Before these symptoms, he had had an upper respiratory tract viral infection for five days. Four days before admission, he had received a recombinant hepatitis B vaccination. On physical examination, he had a left lower motor neuron facial nerve palsy and second degree nystagmus with the fast phase toward the right side, suggesting a left pontine lesion. There were no cerebellar signs or any other abnormal neurological signs. MRI of the brain did not show demyelination. The lumbar puncture was normal without oligoclonal IgG. His erythrocyte sedimentation rate was normal. Visual evoked responses were normal. Viral titers were not significant. The patient's vestibular symptoms began improving within one day of admission, and had completely resolved by five days. The facial nerve palsy took two months to resolve. A repeat MRI of the brain three months later was also normal. The authors thought that hepatitis B vaccine was the cause of the facial palsy involving the seventh and eighth cranial nerves, but admitted that cause could not be proved just on the basis of this report. Filing of Jan. 13, 2003.

Petitioner filed, under "Brief Report," an article entitled "Two Episodes of Leukoencephalitis Associated with Recombinant Hepatitis B Vaccination in a Single Patient," by D. Konstantinou, et

al., 33 *Clinical Infectious Diseases* 1772-73 (2001). A woman who received her second hepatitis B vaccination, developed complete right homonymous hemianopia and severe dyslexia four weeks later. Brain MRI revealed a large lesion occupying most of the left occipital lobe, extending into the splenium of her corpus callosum. A craniotomy and biopsy of the lesion were performed. Histologic examination and staining were consistent with demyelinating disease. One week after surgery, her condition markedly improved. Three months after surgery, the woman received her third dose of hepatitis B vaccine. Eleven days after vaccination, she developed left hemiparesis and acute progressive deterioration of vision. She was afebrile after both vaccinations. No testing was performed for oligoclonal IgG bands in her spinal fluid. Brain MRI revealed a new, large lesion in her right parieto-occipital region with the same characteristics associated with the prior lesion. She was treated with dexamethasone and markedly improved during the next three weeks. This unique case presents rechallenge with hepatitis B vaccine which, the authors concluded, strongly suggests causation, although they termed it "possible." Filing of Jan. 13, 2003.

Petitioner filed, under "Clinical Correspondence, an article entitled "Hepatitis B vaccine related myelitis?" by F. Karaali-Savrun, et al., 8 *European J of Neurology* 711-15 (2001. The authors present four cases of partial myelitis following hepatitis B vaccination. In all four cases, MRIs done of the spines revealed lesions. The authors concede it may not be possible to know if the association with vaccine is causal or coincidental. Filing of Jan. 13, 2003.

Petitioner filed an article entitled "Inflammatory polyradiculoneuropathy with spinal cord involvement and let[h]al outcome after hepatitis B vaccination," by E. Sindern, et al., 186 *J of Neurological Sciences* 81-85 (2001). A man developed inflammatory, primary demyelinative polyradiculneuropathy similar to Guillain-Barre Syndrome 9 days after receiving his fourth hepatitis

B vaccine. He had elevated protein of 107 mg/dl in his spinal fluid, which later rose to 181 mg/dl. The vaccine is made by cloning a portion of hepatitis B virus gene coding for the surface antigen into yeast, and the vaccine is produced from cultures of the recombinant yeast strain. The patient's antibodies to hepatitis B surface antigen (HBsAg) were strongly elevated on the 21st day (3100 mU/ml). Four months later, he died due to multiorgan failure with septic shock syndrome and acute respiratory distress syndrome. Neuropathological examination showed severe axonal loss with mild demyelination of peripheral nerves and mononuclear cell infiltrates, predominantly T-lymphocytes, in his nerve roots and spinal ganglia. There were also unusual, perivascular and parenchymal lymphocytic cell infiltrates in the grey matter, especially the anterior horns of the spinal cord. The authors state theirs is the first case of inflammatory polyradiculoneuropathy after recombinant hepatitis B vaccine reported. Filing of Jan. 13, 2003.

Petitioner filed "Postmarketing surveillance for neurological adverse events reported after hepatitis B vaccination. Experience of the first three years," by F.E. Shaw, et al., 127 *J of Epidemiology* 2:337-52 (1988), which deals with plasma-derived, not recombinant, hepatitis B vaccine. The authors could not conclude based on epidemiological evidence that there was any causal association between any neurologic adverse event and the vaccine. P. Ex. 10.

Petitioner filed, under "Letters to the Editor," "No increase in demyelinating diseases after hepatitis B vaccination," by F. Zipp, et al., 5 *Nature Medicine* 9:964-65 (1999). The authors reported that the results of the first population-based controlled study do not support the assumption that hepatitis B vaccine induces demyelination. P. Ex. 11.

Petitioners filed an article entitled "Mental nerve neuropathy as a result of hepatitis B vaccination," by J.F. Maillefort, et al., 83 *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 663-

64 (1997). The authors described a woman who had polyarthralgia, pain in her inferior limbs, and paresthesia in the right lower lip five weeks after receiving hepatitis B vaccine. Three weeks later, she had acute neck pain. After two days, she developed a right hemifacial paresthesia and hyposthesia. One week later, she had low back pain, pain in the knees and shoulders, and pain and paresthesia in the inferior limbs. Examination revealed anesthesia of the skin and mucosa over the distribution of the right mental nerve. Her erythrocyte sedimentation rate was elevated. She was treated with drugs and, two weeks later, the symptoms had completely regressed. The authors believed that hepatitis B vaccine caused the patient's mental nerve neuropathy. P. Ex. 12.

Respondent filed Immunization Safety Review, Hepatitis B Vaccine and Demyelinating Neurological Disorders by K. Stratton, et al. (Institute of Medicine [IOM])(2002). R. Ex. U. In discussing animal models of disease, the authors state, at 9:

> In none of these models, however, has hepatitis B surface antigen been shown to trigger disease.
>
> There is no significant homology between the amino acid sequences of HbsAg–the main component of the hepatitis B vaccine–and the myelin proteins MOG, MBP, and PLP. This makes it unlikely that a T cell-medicated immune response against these CNS autoantigens would be triggered by the hepatitis B vaccine on the basis of molecular mimicry.

In discussing the significance of case reports, the authors state, at 39, 40:

> Case reports are useful for describing the domain of concerns, but the data are usually uncorroborated clinical descriptions that are insufficient to permit meaningful comment or to contribute to a causality argument. ...
>
> VAERS received several reports of demyelinating disease following hepatitis B vaccination from November 1, 1990 through December 31, 2001. ... Reports included 125 cases of MS, 15 cases of brachial neuritis, 83 cases of optic neuritis, 46 cases of peripheral neuritis, 91 cases of GBS, 30 cases of ADEM or demyelinating disease not otherwise specified, and 109 cases of myelitis.

The committee concluded that there was weak support for a biological mechanism operative in humans in response to hepatitis B vaccine to produce demyelinating disorders. Id. at 83. The committee also concluded that the evidence was inadequate to accept or reject a causal relationship between hepatitis B vaccine and TM or between hepatitis B vaccine and brachial neuritis. Id. at 84.

Respondent filed "Surveillance for Safety After Immunization: Vaccine Adverse Event Reporting System (VAERS) – United States, 1991-2001," by W. Zhou, et al., 52 *MMWR* SS-1 (Jan. 24, 2003). R. Ex. Y. The authors state at 1:

> VAERS is a passive surveillance system: reports are voluntarily submitted by those who experience them, their caregivers, or others. ... [D]etermining causal associations between vaccines and adverse events from VAERS reports is usually not possible.

Respondent filed an article entitled "Hepatitis B vaccine and central nervous system demyelinating diseases," by N.A. Halsey, et al., 18 *Ped Infect Dis J* 1: 23-24 (1999). R. Ex. Z. The authors state "there is no evidence whatsoever of a link between hepatitis B virus infection and CNS demyelinating disorders...." Id. at 24. "Altogether evidence in favor of an increased risk after vaccination is weak and does not meet the criteria for causality." Id.

Under 42 U.S.C. § 300aa-12(d)(3)(B)(1), a special master "may require such evidence as may be reasonable and necessary." An article published in April 2003 is directly on point with the issue in this case: does hepatitis B cause demyelinating illness. The court filed "Vaccinations and Risk of Central Nervous System Demyelinating Diseases in Adults," by F. DeStefano, et al., 60 *Arch Neur* 504-09 (2003). This is the first epidemiologic study, to the authors' knowledge, to evaluate several

adult vaccines and determine if there is a causal association with demyelinating diseases. Id. at 508.

Using a large population-based case-control study, the authors determined "that hepatitis B vaccine is not causally associated with demyelinating diseases," which result they found consistent with accumulating evidence.[14] Id. at 507. The authors used 440 case subjects and 950 control subjects matched on HMO, sex, and date of birth. The adults ranged in age from 18 to 49 years of age. Id. at 505.

TESTIMONY

Dr. Sheldon Margulies testified first for petitioner. Tr. at 25. He is a board-certified neurologist. Tr. at 26. He examined Mr. Bisson on January 18, 1999. Tr. at 27. Dr. Margulies recounted Mr. Bisson's history. He received two hepatitis B vaccinations in early 1993. Tr. at 28. In early March 1993, shortly after the second vaccination, Mr. Bisson had fever and fatigue. He had a presumed tooth abscess (collecting pus) and was on antibiotics which did not relieve the pain until mid- or late May. There was no numbness associated with the tooth pain and the fever slowly resolved. Id.

Mr. Bisson's neurological symptoms in March 1993 affected his arms and legs. The diagnosis eventually was transverse myelitis with possible involvement of the peripheral nervous system. His neurologic symptoms still persist. He has a lot of difficulty with his right hand. He fatigues easily and uses a cane often because his walking is affected. He had a disturbance of his

[14] "An analysis of a US pharmacy benefits management database did not find a statistically significant association between claims for hepatitis B vaccination and subsequent claims for treatment of CNS demyelinating disorders. ... Two European case-control studies found relative risks around 1.5 that were not statistically significant for onset of demyelination within 2 months to 1 year of hepatitis B vaccination." [citations omitted] 60 *Arch Neur* at 507.

SGOT (liver function test). He has weakness in his right leg, with difficulty rising from a chair, and incoordination of his right hand. His central nervous system was affected with bladder and bowel disturbance and back pain (affecting the spinal cord). Tr. at 29. One would expect leg spasticity, but Mr. Bisson did not have any. One would also expect hyperreflexia, but Mr. Bisson was hyporeflexic. Dr. Margulies' opinion was that Mr. Bisson probably had TM with peripheral nervous system features of a demyelinative injury. He has no reflexes in his legs now. Tr. at 30.

Dr. Margulies admitted it was extremely unusual to have both a peripheral nervous system disease and a central nervous system disease. Tr. at 32. The nerve supplying the jaw is the trigeminal nerve whose terminal branch is the mental nerve. If Mr. Bisson had numbness, he would have a mental neuropathy. Dr. Margulies attributes Mr. Bisson's tooth problem to the trigeminal nerve without extending it to the branch or mental nerve. There was irritation or inflammation there. Tr. at 35.

Normally, in TM, the patient has inflammation at one level of the spinal cord, and is paralyzed below that point with hyperreflexia and spasticity. Tr. at 36. Mr. Bisson had involvement of both central and peripheral nerves, liver dysfunction, fever, and trigeminal neuropathy after his hepatitis B vaccination. Tr. at 37. Dr. Margulies testified these problems cannot be coincidental and independent but must have some common cause. The liver contains SGOT (which is an enzyme) that leaked into the blood stream, indicating a mild inflammation from fever. Tr. at 38. Mr. Bisson told Dr. Margulies when he was examining him that he had trouble urinating and defecating in 1993.

The undersigned asked, in light of Mr. Bisson's normal MRI and absent reflexes instead of hyperreflexia, what was it that permitted Dr. Margulies to diagnose transverse myelitis. Tr. at 39.

Dr. Margulies began by saying he was not there at the time, but it may have been the fact that Mr. Bisson had some bowel and bladder disturbance. He did not recall the basis for the diagnosis of transverse myelitis at the time. Tr. at 40.

The medical records noted fever which indicates inflammation. Id. The undersigned asked Dr. Margulies that, if Mr. Bisson did not have anything wrong with his bowel and bladder in 1993, would he still opine that Mr. Bisson had TM. Tr. at 41. Dr. Margulies chose to defer to Mr. Bisson's treating doctors. Tr. at 41-42.

The reason TM does not show up in epidemiologic articles is it is so rare. Tr. at 43. Dr. Margulies' opinion is that hepatitis B vaccine was an insult to Mr. Bisson's immunological system which attacked multiple sites in the nervous system affecting myelin. Tr. at 44.

Mr. Bisson then testified that at the end of March and early April 1993, he could not defecate and found it difficult to urinate.[15] He had a lot of pain, lasting a month. He still has some problems defecating. Tr. at 47. He could not explain why there is no notation in any of his medical records that he had problems with his bowel and bladder. Tr. at 48.

Dr. Margulies stated that Mr. Bisson's illness was monophasic. The first hepatitis B vaccination primed Mr. Bisson's immune system. The second hepatitis B vaccination had an anamnestic effect. The central nervous system elements were his TM in the upper thoracic region, affecting his arms, legs, and the lower cervical region as well. The peripheral nervous system elements were the trigeminal nerve (the fifth cranial nerve) affecting tooth # 30 and brachial neuritis, which is extremely rare. Tr. at 56-57.

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[15] This is directly contrary to Dr. Milhorat's record of May 28, 1993 that Mr. Bisson did not have any autonomic dysfunction such as bladder or bowel incontinence and Mr. Bisson's reporting to Dr. Bucksbaum on July 20, 1996 that he was continent in bowel and bladder.

On cross-examination, Dr. Margulies admitted that Mr. Bisson was on Erythromycin at the time he took his liver function test which was abnormal, and Erythromycin causes liver dysfunction. There was no diagnostic test of peripheral nervous system involvement done. Tr. at 59. An EMG did not show any evidence of peripheral nervous system involvement. Tr. at 61. He did not have any Babinski response, which is what one would expect in a central nervous system problem. Tr. at 62.

Dr. Margulies wrote an article published in the October 2002 "Voice of the Defense Bar," in which he stated that specific causation cannot be based on general causation, and that one needs epidemiological, animal, or scientific studies to prove causation in the courts. Dr. Margulies was referring to what the courts require. Tr. at 69. Dr. Margulies is a lawyer. Tr. at 71. He left Johns Hopkins in 1999 and is at the Uniformed Services Medical School, and about to join the staff at Howard University Medical School. Tr. at 75.

He admitted that TM occurs spontaneously and without an apparent preceding event in one-third of the cases. Tr. at 77, 78. One would like to see symmetry in TM, but Mr. Bisson's involvement was in his right arm and right leg, as well as the upper thoracic and lower cervical regions. Tr. at 86. Tests did not indicate his problems were at the thoracic level about at the C5-C6 level. Tr. at 87. A herniated disc could press against C5-C6. Tr. at 99. Tests indicated denervation consistent with radiculitis or neuritis. Tr. at 95. The timing of three weeks between the second hepatitis B vaccination and Mr. Bisson's onset convinced him of causation since it was a reasonable time for the process to occur. Tr. at 92. Dr. Margulies is not familiar with recombinant vaccines. Tr. at 94. If someone had an asymmetric lesion, you would expect him to have asymmetric symptoms. Tr. at 100-01.

Dr. David Rosenstreich testified next for petitioner. Tr. at 102. He is a professor medicine, microbiology, and immunology at the Albert Einstein College of Medicine and Montefiore Medical Center. Tr. at 103. He directs the Division of Immunology and Allergy, teaches students in lectures and rounds, and has patients. He is board-certified in internal medicine and in allergy and immunology. Id. He testified that Mr. Bisson did not have any adverse effects from his first hepatitis B vaccination in January 1993. Tr. at 106. On February 24, 1993, he had his second hepatitis B vaccination, and 10 to 12 days later, his tooth hurt. Id. He saw a dentist, who diagnosed an abscess and prescribed Erythromycin. The dental records provide no evidence that Mr. Bisson had a tooth abscess, but he had persistent tooth pain. Id.

Mr. Bisson had a fever of 102 to 103° F that persisted, plus weakness, pain, and numbness. He was diagnosed with TM. Dr. Rosenstreich relies on Dr. Milhorat's clinical judgment that Mr. Bisson had quadriparesis, worse on the right, at the C-4 level. Tr. at 107. Dr. Rosenstreich's opinion is that Mr. Bisson had an immunological reaction to hepatitis B, causing disseminated neurological inflammation of the nerves in his spinal cord and, he guesses, in his peripheral nervous system as well. Tr. at 108. The basis for his opinion is the temporal relationship between hepatitis B and Mr. Bisson's symptoms, his high fever in the absence of any other source of infection (which indicates inflammation), elevated ESR (erythrocyte sedimentation rate) which indicates systemic inflammation, and the clinical picture that is consistent with neurological inflammation. Tr. at 109.

The erythrocyte sedimentation rate measures inflammation in the body. The liver produces inflammatory proteins which clump blood, sending the ESR up. The ESR should be 20 and Mr. Bisson's was 35. Tr. at 110. In some way, Mr. Bisson's immune system was activated. There are two ways this could happen: (1) the humoral immune system, involving antibodies; and (2) the cell-

mediated immune system, involving T lymphocytes or T cells. Id. The T cells release cytokines that attract other cells causing various immune responses. Tr. at 111. Inflammation can occur anywhere in the body. In the liver, it releases elevated liver enzymes. Id. In nerves, it can damage the myelin sheath. Id. One can have elevated antibodies which interact with hepatitis B antigen, attracting white blood cells (the inflammation) which cause damage. Tr. at 111-12. In the absence of pathologic findings, he could only speculate which process (humoral or cell-mediated) activated Mr. Bisson's immune system. It is an unusual case. Tr. at 112. It was not investigated, but it is biologically plausible. Tr. at 113, 114.

Dr. Rosenstreich testified that Mr. Bisson had an immune reaction to hepatitis B # 1 and an excessive reaction to hepatitis B # 2, which destroyed nerve parts. This is a biologically plausible mechanism, consistent with human disease patterns. Mr. Bisson was in good health prior to his hepatitis B vaccination. There was no evidence of tooth abscess, and he did not respond to the antibiotics. Tr. at 119.

Ten to twelve days is enough time for the inflammatory process because the immune system needs one to two weeks to become stronger. Id. An increase in activation and development of antibodies or T cells occurs during this time, attracting white blood cells and the effect of them. Tr. at 120. The IOM Report stated that epidemiologic evidence neither supports nor rejects causation. That is because cases are so rare and so much vaccine is administered. It is harder to show an increase in TM cases until many, many more immunizations are given. Tr. at 121-22.

Dr. Rosenstreich has had a handful of vaccine-immunological cases with problems related to hepatitis B vaccine, but nothing like this. He occasionally sees people with reactions to rubella vaccine, not more than ten over the last 23 years. Tr. at 122-23. He tends to see skin rashes or

urticaria (hives) from hepatitis B vaccine, and polyarteritis nodosa (vasculitis) from the disease hepatitis. Tr. at 123. He usually sees people who do not respond to hepatitis B disease. Id. The solution is to keep giving them hepatitis B vaccine. Tr. at 124. It usually takes three vaccinations to get a strong response. Tr. at 125. The first gets the immune system going and the second produces an anamnestic response. Id.

The VAERS reports list 125 cases of MS (multiple sclerosis) and 109 of myelitis. MS is normally a much more common disease than myelitis, but the number of adverse vaccine reports of MS was almost equal for the two diseases. He wondered if the vaccine caused myelitis. Tr. at 126. The Konstantinou article was the most cogent literary proof to Dr. Rosenstreich showing that hepatitis B vaccine causes demyelinating disease since, in a case of rechallenge, a woman who received her second hepatitis B vaccination had leukoencephalitis, which occurred as well after receiving her third hepatitis B vaccination. Tr. at 127.

Dr. Rosenstreich's opinion of causation is based on his whole assessment: the temporal relationship after the second hepatitis B vaccination (when one would expect a hyperimmune response), the expectation of an immune response after two weeks, the high fever (very pronounced for a man his age), mental neuropathy, TM, increased sedimentation rate, and many reports in the medical literature, especially the Konstantinou article. Tr. at 128-29.

On cross-examination, Dr. Rosenstreich admitted that one can have an elevated ESR with any inflammation affecting the body as a whole. Tr. at 137. The abscess was not found or else it was tiny and would not have elevated Mr. Bisson's ESR. Id. There is no evidence that Mr. Bisson has a genetic predisposition to react to hepatitis B. Tr. at 138. Dr. Rosenstreich said he has experience with abnormal vaccine reactions. Id. In 30% of TM cases, there is no apparent

antecedent event. Tr. at 139. He knows that the disease hepatitis can cause vasculitis, which is an immunologically-mediated destructive disease. Tr. at 143.

It is perfectly plausible that a vaccine, which is just an antigen, can cause an excessive immune reaction. Tr. at 144. He admits that biological plausibility can never prove causality. Id. But it is one of the factors that helps support a diagnosis of causality. Tr. at 145. In the Konstantinou article, the demyelination was in the woman's brain rather than in the spinal cord (as with Mr. Bisson), but this is immunologically the same process. Tr. at 150. There are no data as to what immunologic process is taking place. Tr. at 152. The immune response attacks or causes inflammation in parts of the nervous system. Id. Regarding Mr. Bisson's tooth pain, in the absence of signs of an abscess, he interprets this as a neurologically-mediated pain. Tr. at 153. He interprets that, because of hepatitis B vaccine, Mr. Bisson became hyperimmune and various parts of his nervous system were attacked, including his trigeminal nerve (giving him tooth pain), his spinal cord (giving him TM), and perhaps his brachial plexus (giving him brachial neuritis). Id.

The VAERS reports included reports of tooth problems and myelitis, which are just temporal associations. Tr. at 157. Medical literature does not show a statistically significant increased incidence of demyelinating diseases among recipients of hepatitis B vaccine, but one would need an enormous number of patients to see an effect. Tr. at 169.

The original hepatitis B vaccine was plasma-derived. Patients with circulating hepatitis virus would give blood, from which the virus was purified, inactivated, and used as a vaccine. The new hepatitis B vaccine is recombinant, consisting of a manufactured protein from one of the hepatitis viruses. It is a surface protein on the outside of the virus, not a whole virus as the original vaccine. Tr. at 185-86.

Dr. Paul Safran testified for respondent. Tr. at 190. He is board-certified in internal medicine and neurology. He has a special certificate in neurologic rehabilitation. Tr. at 191. He has treated 200 TM patients over 35 years. He has had 20 patients with symptoms like Mr. Bisson which he puts in the idiopathic category. Transverse myelitis requires inflammation across the spinal cord. There are no cases of peripheral nervous system disease with TM. It does not exist. Tr. at 191-93.

Dr. Safran testified that Mr. Bisson did not have trigeminal neuropathy, TM, or BPN. Tr. at 193. He called this "a sad day for neurology." Id. In neurology, one does parsimony of diagnosis, i.e., a single diagnosis to describe someone's condition. Tr. at 194.

The diagnosis of trigeminal neuropathy is foolish. Tr. at 195. The mental nerve has nothing to do with teeth. Local pain in one tooth (tooth # 30) is never a part of trigeminal neuropathy. Id. The spinal cord has white and gray matter. Id. The white matter consists of tracts going up and down the body in which a problem can affect numbness, pain, temperature, coldness, and vibration sense. Id. The exiting fibers leave the spinal cord to make up the peripheral nervous system, which has a completely different structure than the CNS. There would have to be two different sets of antibodies to different antigens for there to be both a CNS and PNS problem following vaccination, which he regards as foolish. Id. In an article concerning someone who died of GBS (a peripheral nerve disease), the authors were struck with axonal involvement, which is central. Dr. Safran said that he attributes the axonal involvement to the dying-back phenomenon, reflecting the severity of the peripheral nerve injury. Tr. at 222-24.

TM is generally symmetric and is almost never asymmetric. Tr. at 197. Mr. Bisson's problems were peculiarly asymmetric. Id. The EMG found a problem at the C5-C6 level. He has a cervical spinal cord involvement. Tr. at 196.

Mr. Bisson has a history of heart attack. Erythromycin makes transaminase. The first worry is embolism from the heart. Erythromycin causes an irregular heart beat. The tooth infection led to embolism that went to the spinal cord. Tr. at 197. Dr. Safran said Mr. Bisson received shocking care. No MRI of the brain and no evoked potentials were done. Id.

Dr. Margulies is the only person who did not find reflexes when he examined Mr. Bisson; others have. Hung up reflexes are generally slow, so they were probably hard to elicit. There is no evidence that Mr. Bisson had a peripheral neuropathy. Tr. at 198. He got a fever from his tooth infection. No one did a blood culture. Tr. at 199-200. Dr. Safran's opinion is that Mr. Bisson did not have TM or brachial plexus neuritis. Tr. at 200. He had a tooth infection in tooth no. 30 which led to fever and an infectious process leading to an embolism. Id. An embolism is a clot in the heart. Tr. at 201. Dr. Safran testified that there is only one lesion here that makes any sense, and it is probably at the C-4 level. Id. Dr. Safran testified that the embolism left Mr. Bisson's heart and went to his spinal cord. Even if he had TM, it was atypical in that it was asymmetrical. The pain in Mr. Bisson's tooth went on for a long time. Tr. at 202. With root canal problems, the pain goes on for a long time. Id. Mr. Bisson's tooth pain affected a single, particular tooth and there is no nerve disease Dr. Safran knows of that can do that. Id.

The peripheral nervous system has a different structure and a different antigenicity than the CNS. Tr. at 203. Mr. Bisson did not have brachial neuritis. Id. His EMG was limited to his C5-C6 level. The brachial plexus covers a much wider area than C5-C6. If the brachial plexus is afflicted, the patient has abnormalities in a wider area than that. The hallmark of brachial plexus problems is almost always involvement of a muscle called the serratus anterior, which causes a winging of the scapula. Id. That was not described as occurring here. Id. A lesion at the C4 level can cause an arm

problem referable to C5-C6, which would explain the weakness and reflex, and is also more consistent with ultimately what happened to Mr. Bisson's hand. Tr. at 203-04.

Mr. Bisson has osteoporosis because he has reflex-sympathetic dystrophy which he suffered as a consequence of injury within the spinal cord affecting those nerve roots. In reflex-sympathetic dystrophy, the limb swells and becomes painful. The bones reabsorb in the part that is afflicted. Tr. at 204. Mr. Bisson's osteoporosis is not generalized but only in part of the hand. Id.

As for the bowel and bladder problems that Mr. Bisson claimed, narcotics (Percodan and Codeine # 3) caused them. His spinal cord affliction was not sufficient to cause his bowel and bladder problems. Tr. at 205. The lesion would have had to affect both sides of the spinal cord for there to be bowel and bladder problems. Tr. at 206. There were no objective findings of weakness in his legs even though Mr. Bisson claimed weakness. Tr. at 205. Mr. Bisson's sensory examination was normal and his reflexes intact. He did not have weakness. Id.

Dr. Safran testified that Mr. Bisson had an inflammation that affected the spinal cord, but was not the usual kind of TM one sees after a viral illness. Tr. at 206. He probably had a small stroke in his spinal cord from an embolism which damaged some of the roots going in his right arm. Tr. at 206-07. The embolism dissolved over time. Tr. at 207. The nervous system does not regenerate. Myelopathy causes damage in the spinal cord. His endocarditis comes from his tooth infection. If he had mental neuropathy, he would have been numb at the tip of his jaw. Tr. at 218. There is a single, unifying diagnosis in this case, which is the tooth infection. Tr. at 208, 222. The dental records indicate swelling and tenderness, meaning ongoing inflammation. Tr. at 214.

Dr. Safran cannot attribute demyelinating diseases to hepatitis B, based on his knowledge of the general neurologic community and the medical literature. Tr. at 224-25. Here, the mental nerve

was not involved and Erythromycin causes liver enzyme elevation. There is no evidence that Mr. Bisson's peripheral nervous system is involved at all. Tr. at 225. Anything causing inflammation, including a tooth infection, can cause the sedimentation rate to rise. Tr. at 226. As for the almost equal rate of MS and myelitis that the IOM reported, most cases of myelitis will turn out to be MS. Tr. at 227. Dr. Safran's opinion is that Mr. Bisson did not have TM, but had myelopathy (some damage to the spinal cord). Tr. at 230. The trigeminal nerve is not a peripheral nerve, but a cranial nerve. The brachial plexus is a different structure than the peripheral nerves. Tr. at 233.

On cross-examination, Dr. Safran admitted that something happened to Mr. Bisson's spinal cord in March 1993. Tr. at 236. Dr. Chervin diagnosed Mr. Bisson with BPN. Mr. Bisson's endocarditis was subacute. Tr. at 261. As for the Konstantinou article, it is a unique event, but there was no lumbar puncture done to look for immunoglobulin banding or evoked potentials. Tr. at 270. The patient could have had MS. There is a different structure to the PNS and the CNS. No immunologist would say that the same challenge has caused both PNS and CNS conditions. Id. The cells that coat the nerves in the central nervous system are oligodendrocytes, but in the peripheral nervous system, they are Schwann cells. Tr. at 271. The same antigen will not produce two different antibodies. Id.

Dr. Burton Zweiman testified next for respondent. Tr. at 283. He is board-certified in internal medicine, and allergy and immunology. Id. He has been on the editorial board of several journals and, from 1988-93, was the editor of the *Journal of Allergy and Immunology*. Tr. at 284. For 25 years until 1998, he was chief of the Allergy and Immunology Division. Id. He has done neuroimmunologic research on PNS and CNS demyelinating diseases. Id.

There is a single case report in the literature of mental neuropathy. Tr. at 286. It concerned a 20-year-old woman with sensory neuropathy involving a number of nerves, including mental neuropathy with numbness of her lower jaw. Id. Practically all cases of mental neuropathy have numbness of the chin and lower jaw. The terminology that Dr. Rosenstreich used in this case is inappropriate (i.e., that Mr. Bisson had mental neuropathy). Id.

TM occurs at a rate of one to four cases per million people. Tr. at 288. One of the peaks of incidence is from ages 10 to 19 years, a time when hepatitis B vaccine is frequently given. Tr. at 289. Dr. Zweiman stated there is no evidence of cross-reactivity between recombinant hepatitis B vaccine and CNS components. Tr. at 292-93. In a very small minority of cases, the immune complex can be pathogenic by enlisting the help of the complement system that attracts leukocytes (white blood cells) which do damage. However, that does not cause CNS demyelinating disease. Tr. at 293. "Complement" is a complex of proteins present in the blood plasma that will bind to immune complexes. When they bind, they form potent chemotactic factors that attract white blood cells. Tr. at 308.

Occasionally, one gets a vasculitis (inflammation of the blood vessels) which can lead to stroke in the PNS. That can cause a peripheral neuropathy, but it is ischemic because one has lost blood supply at the nerve. It can affect multiple nerves, causing mononeuritis multiplex because of the multiple peripheral nerves involved, but this is not a primarily demyelinating neuropathy. It is damage to isolated areas in the nerve. Tr. at 294, 309.

With recombinant hepatitis B vaccine, we are dealing with a protein from the surface of the hepatitis virus, which is very different from the earlier vaccine made from plasma containing the whole virus. Tr. at 295. If someone has a hyperresponse to vaccination, he just makes a lot more

antibodies. Tr. at 296. The antibody does not cross-react with and bind specifically to CNS components. Tr. at 297.

We do not have evidence that Mr. Bisson experienced a T-cell mediated response because he did not have an increased number of leukocytes in his cerebral spinal fluid (CSF). Id. Dr. Zweiman contrasted this case with someone with acute disseminated encephalomyelitis (ADEM) which follows active infections and the early rabies vaccines. You get a leukoencephalitis, such as described in the Konstantinou article, in which the patient has a pronounced inflammatory reaction causing white-cell damage in the nervous system. It is nearly always characterized by a prominent inflammatory cell response in the CSF. In addition, you find increased levels of protein in the CSF. Mr. Bisson had neither a prominent inflammatory response nor elevated level of protein in his CSF. Tr. at 298, 371.

The Konstantinou article dealt with leukoencephalitis, a diffuse disease involving the surface of the brain with damage to the white matter. Transverse myelitis is a localized disease involving a particular segment of the spinal cord. Tr. at 299. As for molecular mimicry, there is no evidence of any shared components between the hepatitis B antigens in the recombinant vaccine and the central nervous system. Tr. at 307-08. There are no cross-reacting antibodies to a CNS component. Tr. at 309-10, 312. There are no immune complexes causing demyelination. If cytokines respond to immunization, there is fever and achiness which are transient and benign. There is no ready entrance to the CNS because of the blood-brain barrier. An embolus does not get into the CNS. It blocks a blood vessel and causes a stroke that affects the CNS, causing localized damage. Tr. at 310. With five million new cases of hepatitis B virus infection every year, which induces a stronger

immune response than the vaccine, one does not see any increase in CNS demyelinating disease. Tr. at 321.

Dr. Zweiman stated that the authors of the Konstantinou article did not do immunologic studies to investigate whether there was molecular mimicry. Tr. at 373. Mr. Bisson did not have peripheral nerve disease. Tr. at 348. The skin, joints, and kidney are the most common lodging place of immune complex. Tr. at 351. The recombinant hepatitis B vaccine is manufactured in yeast which does not induce an adverse immune response. Tr. at 358, 359.

DISCUSSION

Petitioner is proceeding on a theory of causation in fact. To satisfy his burden of proving causation in fact, petitioner must offer "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect." Grant v. Secretary, HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Agarwsal v. Secretary, HHS, 33 Fed. Cl. 482, 487 (1995); see also Knudsen v. Secretary, HHS, 35 F.3d 543, 548 (Fed. Cir. 1994); Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993).

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, 956 F.2d at 1149.

Petitioner must not only show that but for the hepatitis B vaccine Mr. Bisson would not have had the injury, but also that the vaccine was a substantial factor in bringing about his injury. Shyface v. Secretary, HHS, 165 F.3d 1344 (Fed. Cir. 1999).

The evidence in this case is very much a battle of the experts. Petitioner's expert neurologist, Dr. Margulies, testified that Mr. Bisson had transverse myelitis as well as trigeminal neuropathy,

brachial neuropathy, and peripheral nervous system disease. Petitioner's expert immunologist, Dr. Rosenstreich, testified about the possible causal mechanisms explaining how Mr. Bisson contracted both CNS demyelinating and PNS diseases from recombinant hepatitis B vaccine. Respondent's expert neurologist, Dr. Safran, testified that Mr. Bisson did not have TM or BPN, but did have a myelopathy (not a demyelinating disease) at the C-4 level which affected the C5-C6 nerve roots, as depicted on EMG. Respondent's expert immunologist, Dr. Zweiman, testified that there is no basis for concluding that there is biological plausibility for recombinant hepatitis B vaccine causing demyelinating diseases or both CNS and PNS diseases.

In addition to the live testimony, the records provides the examinations and depositions of Dr. Chervin, a neurologist, and Dr. Friedman, an internist. They had the opportunity to examine Mr. Bisson together as well as to watch a videotape of Mr. Bisson walking and unaware he was being filmed. The film showed Mr. Bisson walking normally. In fact, when they were examining him, when he walked around the examining table, he also walked normally. But when the examination was over, and he picked up his cane, he proceeded to shift his weight heavily from side to side. The impressions and analyses of Dr. Chervin and Dr. Friedman were of special interest to the undersigned, not only because they examined Mr. Bisson in 1994, but also because they were exposed to the difference between what Mr. Bisson was asserting were his symptoms (and are duly recorded in the neurologist Dr. Milhorat's notes) and what his condition actually was.

The undersigned finds the neurologist Dr. Chervin's medical reports and testimony quite persuasive. He examined Mr. Bisson in 1994 and concluded that he did not have anything wrong neurologically. The internist Dr. Friedman's examination, report, and testimony reach the same

conclusion. Dr. Chervin opines that Mr. Bisson did have brachial neuritis, but he recovered from it by the end of summer 1993.

The primary reason for Dr. Chervin's opinion that Mr. Bisson did not have TM is that his MRI was normal (a result that surprised Mr. Bisson's treating neurologist, Dr. Milhorat) and his CSF showed no signs of inflammation. The undersigned cannot fathom how Mr. Bisson could have TM with a normal MRI and CSF. The proposed criteria for diagnosing TM which respondent submitted as an exhibit mention particularly an abnormal MRI and cells in the CSF (oligoclonal bands and increased protein), although someone in the beginning stage of TM might have a normal MRI, but then a subsequent MRI would be abnormal.

The undersigned also cannot fathom how Mr. Bisson could have TM with "no telltales for a demyelinating disease process" (to quote Dr. Milhorat on April 1, 1993), since TM is a demyelinating disease.

The undersigned further does not understand how Dr. Milhorat diagnosed Mr. Bisson with TM when Dr. Milhorat consistently noted in his records that Mr. Bisson did not have a demyelinating disease. Dr. Milhorat changed his initial cause for Mr. Bisson's TM from a viral illness or his tooth infection to the hepatitis B vaccination based on temporality (the timing was right). But the timing for what is at issue here.

In the Konstantinou article, the unfortunate woman had a demyelinating lesion in her brain after her second and third hepatitis B vaccinations. The article suggests rechallenge, a strong factor in the authors' reaching an opinion of causation. But Mr. Bisson did not have a demyelinating illness, and, therefore, the Konstantinou article is irrelevant in this case.

There is no credible evidence in this case that recombinant hepatitis B vaccine gave Mr. Bisson a viral infection from which he got TM because recombinant hepatitis B vaccine does not contain the virus. It contains surface antigen, a protein, combined with yeast.

There was a great dispute over whether Mr. Bisson's infamous tooth # 30 indicated a tooth infection or a symptom of a neuropathy due to the vaccine. Initially, petitioner said it was a mental neuropathy, which requires numbness of the jaw or chin that Mr. Bisson did not have. Subsequently, petitioner alleged it was a trigeminal neuropathy. But the dental records say something else. Mr. Bisson did not see a dentist for three years when he saw Dr. Bishko with pain in tooth # 30. She gave him a pulp test to which he had no response, indicating that the tooth was non-vital or dead. She recommended a crown for it. He needed periodontal work. His maxilla was in bad shape. But Mr. Bisson, consistent with his prior avoidance of tooth maintenance, chose not to do the periodontal treatment and switched to another dentist five years later. It is extraordinary that a man seeing a dentist on an emergency basis would take no action to ameliorate the condition of his teeth other than take months of antibiotics. I find petitioner's expert Dr. Jolly's report analyzing the dental records to be inadequate. There is more in these records than Dr. Jolly recognizes on paper.

Dr. Chervin's neurological testing of Mr. Bisson showed no abnormality except in two fingers. His opinion was that Mr. Bisson was fabricating his symptoms. Mr. Bisson does have degenerative changes at the C5-C6 level of his spine, as well as osteoporosis. He had previously injured the ribs on his left side due to a fall. He complained to the doctor years before vaccination that he had no energy. Some symptoms that Mr. Bisson complains about now were present before his vaccination.

One of the bases for Dr. Margulies' opinion that Mr. Bisson had TM was his difficulty with bladder and bowel, according to the history Mr. Bisson gave him at his examination of him. At the hearing, Mr. Bisson stated that he had bladder and bowel problems in 1993. (These could be due to the months of antibiotics he was taking, according to Dr. Rosenstreich.) But the contemporaneous medical records state explicitly that Mr. Bisson did not have bowel or bladder incontinence in 1993 or 1996 (see Dr. Milhorat's record of May 28, 1993 and Dr. Bucksbaum's record of July 20, 1996). Again, Mr. Bisson is fabricating symptoms.

Well-established case law holds that information in contemporary medical records is more believable than that produced years later at trial. United States v. United States Gypsum Co., 333 U.S. 364, 396 (1948); Burns v. Secretary, HHS, 3 F.3d 415 (Fed. Cir. 1993); Ware v. Secretary, HHS, 28 Fed. Cl. 716, 719 (1993); Estate of Arrowood v. Secretary, HHS, 28 Fed. Cl. 453 (1993); Murphy v. Secretary, HHS, 23 Cl. Ct. 726, 733 (1991), aff'd, 968 F.2d 1226 (Fed. Cir.), cert. denied sub nom. Murphy v. Sullivan, 113 S. Ct. 263 (1992); Montgomery Coca-Cola Bottling Co. v. United States, 615 F.2d 1318, 1328 (1980). Contemporaneous medical records are considered trustworthy because they contain information necessary to make diagnoses and determine appropriate treatment:

> Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.

Cucuras v. Secretary, HHS, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Mr. Bisson's history of medical symptoms is not credible seen in the light of his videotaped walk and walk around the examining table before Drs. Chervin and Friedman (compared to his complaints and walking with a cane) and his assertion of bowel and bladder problems in direct

contradiction to his medical records' citing no difficulties. Dr. Chervin found no objective sign of neuropathy in Mr. Bisson.

Even if Mr. Bisson had had brachial neuritis, as Dr. Chervin testified, there is no evidence before me that hepatitis B vaccine caused it. Brachial neuritis is not a Table injury for hepatitis B vaccine. Moreover, by the end of summer 1993, Mr. Bisson had recovered. The Vaccine Act requires that the vaccine injury last more than six months in order for petitioner to recover damages. 42 U.S.C. § 300aa-11(c)(1)(D)(i). Since he had his second hepatitis B vaccination in late February 1993, he would have had to have brachial neuritis beyond August 1993 to exceed six months. There is no credible evidence in this case that hepatitis B caused Mr. Bisson to have brachial neuritis or that his brachial neuritis lasted more than six months after vaccination. Respondent's experts did not conclude that he had brachial neuritis, and Dr. Margulies threw in the diagnosis as part of his collection of diagnoses for Mr. Bisson (trigeminal neuropathy, TM, PNS injury, and BPN).

The undersigned does not take seriously Dr. Margulies' testimony that the same antigen, here hepatitis B vaccine, causes both central and peripheral nervous system disease in the same person. In my experience hearing cases dealing with neuropathies, persons with CNS disease do not have PNS disease, and vice versa.

TM is a central nervous system disease, which would require overactive reflexes (hyperreflexia). Mr. Bisson's reflexes are either normal (on the left) or underactive (hyporeflexive). He never had positive Babinski responses which are typical of CNS disease. In the positive Babinski response, the big toe goes upward when the sole of the foot is stroked. This by itself is indicative of why TM is not an appropriate diagnosis for Mr. Bisson's problem, although that never seems to

have occurred to Dr. Milhorat. Furthermore, Mr. Bisson's symptoms were asymmetric and TM typically is symmetric.

Dr. Safran decried this case, saying it was a sad day for neurology. His depiction of the state of neurology that day is probably accurate.

Because all the indicia of TM are missing in this case and there are positive findings that contradict a diagnosis of TM, petitioner has failed to meet his burden of proof that he had TM. He may have had brachial neuritis. But the proof is weak on that issue and what credible evidence there is suggests that his brachial problems resolved before six months after vaccination. Moreover, there is no credible proof that hepatitis B caused Mr. Bisson's shoulder problem, whether or not it was BPN. The undersigned does not know the cause of the nerve root problems at the C5-C6 level of Mr. Bisson's spine. But he apparently is in far better shape, i.e., walking and bowel and bladder functions, than he is willing to recognize.

Petitioner has not satisfied his burden of showing that hepatitis B vaccine was a substantial factor in causing whatever is wrong with him.

CONCLUSION

Petitioner's petition is dismissed with prejudice. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment in accordance herewith.

IT IS SO ORDERED.

_____ _____

DATE

Laura D. Millman
Special Master