OFFICE OF SPECIAL MASTERS
No. 99-320V
September 12, 2006

DEBRA MAY,	*	
	*	
Petitioner,	*	
	*	
v.	*	Hepatitis B vaccine followed three or four days later by CIDP; causation?
	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

ORDER TO SHOW CAUSE[1]

Petitioner filed a petitioner on May 18, 1999, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that she received hepatitis B vaccine on April 26, 1993, May 26, 1993, and October 26, 1993. Petition, ¶ 3.

Petitioner had chronic inflammatory demyelinating polyneuropathy (CIDP) whose onset was May 29-30, 1993. Med. recs. at Ex. 1, p. 9.

[1] Because this order contains a reasoned explanation for the special master's action in this case, the special master intends to post this order on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and move to delete such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

Respondent is ORDERED TO SHOW CAUSE by **October 20**, **2006** why this case should not proceed to damages.

FACTS

Petitioner was born on November 24, 1951.

On October 31, 1989, petitioner saw her doctor. She had been involved in an auto accident the prior Tuesday, October 24, 1989, and complained of pain in her neck and across her pelvis. She had intermittent numbness in both hands or tingling of her fourth and fifth fingers. She had a headache at the base of her neck., bruised ribs, and spasm in her left back. Med. recs. at Ex. 7, p. 88.

On December 5, 1989, petitioner saw her doctor, stating that one week after the auto accident, she started getting spasm and pain under her right ribs. *Id.*

On December 12, 1989, petitioner saw her doctor, complaining of right shoulder and knee pain with swelling. She had a Baker cyst behind the right knee. *Id.*

On May 8, 1990, petitioner saw her doctor, complaining that she was exposed to a chronic carrier of hepatitis B. Med. recs. at Ex. 7, p. 89.

On July 2, 1990, at the request of Dr. Brian D. Zurcher, Dr. Rudy Kachmann saw petitioner who complained of posterior cervical pain, bilateral shoulder pain, and numbness in both arms. Med. recs. at Ex. 11, p. 21. She said she had been involved in two separate accidents. The first occurred in 1988 when a drunk driver hit her. She had some headaches and mild cervical pain which cleared. In October 1989, she was involved in another automobile accident. She had neck pain. She had a 50% limitation of motion on flexion, extension, and rotation of the cervical spine. She had numbness involving the C6 nerve root bilaterally. She had depressed

biceps reflex bilaterally. *Id.* A cervical disc problem accounted for her persisting numbness. Med. recs. at Ex. 11, p. 20.

On August 13, 1990, petitioner said she had pain in her neck, headaches, pain around her right knee, and spasm and tenderness in the muscles of the base of her neck. *Id.*

On January 17, 1991, petitioner saw her doctor, complaining of pain in her neck and headache. She seemed to have spasm in the muscles of her right neck and shoulder. *Id.*

On October 19, 1992, petitioner saw her doctor, complaining of bilateral shoulder pains. She also had severe headaches and complained that her right three fingers went numb. She had a strong family history of osteoarthritis. Her pain and decreased range of motion of her neck began with her automobile accident in October 1989. She had trauma to her left hip in June 1992 which was still painful and tender. Med. recs. at Ex. 7, p. 32.

On November 9, 1992, an MRI of petitioner's left shoulder was normal. Med. recs. at Ex. 7, p. 85.

On November 20, 1992, an MRI of petitioner's cervical spine suggested muscle spasm. Med. recs. at Ex. 7, p. 84.

On January 22, 1993, petitioner saw her doctor, complaining of pain in the left side of her head. Med. recs. at Ex. 7, p. 90.

On April 26, 1993, petitioner received her first hepatitis B vaccination. Med. recs. at Ex. 12, p. 2.

On May 26, 1993, petitioner received her second hepatitis B vaccinaton. *Id.*

On June 1, 1993, petitioner saw her doctor, complaining of an upper respiratory infection for four weeks associated with rattling in her chest and some neck pain. She also complained of

numbness in her fingers, and neck and back pain. She said she had been doing a lot of lifting in her job. She had not been getting a lot of sleep. Med. recs. at Ex. 2, p. 11. On examination, she had definite muscle spasm at the base of her neck and on the top of her shoulders, left more than right, with some tenderness over the base of her cervical spine. There was no obvious difference in muscle strength bilaterally and no change in sensation to touch. The doctor diagnosed acute sinusitis with possible acute bronchitis, and paresthesias of the hands with neck and back pain. *Id.*

On June 4, 1993, petitioner had an MRI done of her lumbar spine. Dr. Jeffrey R. Bessette's impression was she had a tiny disc protrusion or herniation at C5-C6 on the right laterally. Med. recs. at Ex. 3, p. 35.

On June 9, 1993, petitioner went to Parkview Memorial Hospital Emergency Care Center, complaining of numbness in all her extremities since Monday, June 7, 1993. Prior to that time, her fingers were numb since a motor vehicle accident in 1989. Her condition was made worse with use of her hands or certain positions. She stated her symptoms occurred five days after her second dose of "Hib" vaccine. Med. recs. at Ex. 7, p. 6.

On June 9, 1993, Dr. Joseph Vukovich examined petitioner. Med. recs. at Ex. 11, p. 7. Her husband stated she had numb hands and legs for the last week. She described numbness to her thumb, index and middle fingers of both hands going up to her wrists. She said both forearms got a lot of cramping. She complained of numbness which was almost stocking/glove from her knees to her toes. She said she had had this for a week. She also complained of aches to her shoulders, hips, back, and neck. She has had neck problems since her auto accident in

1989. At that time, she had discomfort in one of her arms. She received her second hepatitis vaccination approximately 7-10 days previously. *Id.*

On examination, she had full range of motion to her neck, but some discomfort on palpation of her lumbar paravertebral and sacral muscles. Med. recs. at Ex. 11, p. 8. She had good strength in her arms and legs. Pinprick sensation was somewhat decreased. Dr. Vokovich diagnosed paresthesias. *Id.*

On June 12, 1993, petitioner went to Fort Wayne Neurological Center and filled out a form. Med. recs. at Ex. 3, p. 24. She wrote she had constant numbness in both hands and her symptoms began on May 31, 1993.

On June 25, 1993, petitioner saw Dr. C. Joe Ottinger. He states that petitioner's problems began around May 29-30, 1993 when she noticed a lot of aching and discomfort through her shoulders and neck. Petitioner did an excessive amount of lifting at a nursing home. Med. recs. at Ex. 3, p. 18. She had had problems like this before because she was in an automobile accident in 1989 and had a significant neck injury. Two days after her May 1993 symptoms, she noted that her hands felt numb most of the time. She also had a deep aching pain along the ulnar aspect of the left arm beginning on June 3, 1993. Her feet felt numb much of the time which she first noticed on June 1, 1993, but the symptoms seemed to subside. Since that time, her feet have felt numb so much that she cannot run. The posteriolateral aspect of both lower extremities from the knees to the ankles ached. *Id.*

She had run low-grade fevers over the last couple of weeks and had a great deal of lethargy. She had trouble sleeping at night. She had twitching around the right eye. She was

treated from June 1-6 for sinusitis with Cipro, and it was around that time she first noticed the discomfort. Med. recs. at Ex. 3, p. 19.

On physical examination, she was tender in her low to mid-thoracic region and along the calf muscles. Med. recs. at Ex. 3, p. 19. She had a slight fasciculation in the muscles around the right lower eyelid. She had normal muscle mass, tone, and strength. Her reflexes were 2-3+. Her sensory examination was intact. Med. recs. at Ex. 3, p. 20. She walked normally although she had mild difficulty with tandem walking. Dr. Ottinger's impression was diffuse and scattered myalgias, possible cervical and upper extremity muscle strain from heavy lifting, and paresthesias in the extremities. He needed to rule out carpal tunnel syndrome, peripheral polyneuropathy, and possible demyelinating disease. *Id.*

On July 8, 1993, petitioner had an EMG and nerve conduction velocity test. Med. recs. at Ex. 2, pp. 3-6. Dr. Ottinger wrote that the results were surprisingly abnormal, showing marked slowing of distal latencies of virtually all nerves examined and other areas of rather marked slowing as well. The findings suggested the presence of fairly widespread although somewhat scattered areas of demyelination with more involvement distally than proximally. Petitioner could have bilateral carpal tunnel syndromes, but Dr. Ottinger was more concerned that she had a systemic demyelinating reaction. With the history of symptoms beginning sometime shortly after a hepatitis B immunization, the possibility of a demyelinating reaction related to the immunization was apparent. Med. recs. at Ex. 3, p. 34.

Also on July 8, 1993, petitioner saw Dr. Kachmann, complaining of posterior cervical pain, bilateral shoulder pain, and numbness in both arms and legs, and the bottom of her feet. Med. recs. at Ex. 5, p. 7. She received hepatitis B vaccine on May 28 and the symptoms began

about a week later. EMG that day by Dr. Ottinger indicated diffuse neurogenic changes consistent with neuritis from the hepatitis shot. On examination, petitioner had normal knee reflexes. Motor, sensory, and reflex examinations were normal. She had some diffuse stocking-type numbness. Dr. Kachmann tended to agree that probably she had diffuse mild sensory neuritis from the hepatitis vaccine. Her MRI of the brain was normal. An MRI of the cervical spine indicated a minimally bulging disc, which was of no great consequence. *Id.*

On July 14, 1993, petitioner returned to her doctor, complaining of pain in her arms, legs, and hip. She said the neurologist and surgeon said it was probably a polyneuritis which might be related to hepatitis B vaccine. Med. recs. at Ex. 2, p. 11. The doctor diagnosed an apparent polyneuropathy although she had pretty good strength. *Id.*

On August 3, 1993, Dr. Ottinger reported to SmithKline Beecham that one of his patients (D.M.) received Engerix-B and experienced numbness of her feet and hands and aching in her shoulders and neck. Med. recs. at Ex. 4, p. 29.

On September 17, 1993, petitioner saw Dr. Mark J. Tatara, an internist. Med. recs. at Ex. 5, p. 44. Petitioner complained of occasional pain in the lateral portion of her palms, previously the entire palm, associated with pain in her forearms. She had weakness of her upper extremities with minimal exertion. Her left hip and knees hurt with some numbness in her nose and feet. *Id.*

On physical examination, her extremities showed no signs of focal neurologic deficit. Med. recs. at Ex. 5, p. 46. She had normal gait and normal cognitive function. Dr. Tatara felt whether petitioner had a neurologic illness and whether hepatitis B vaccine caused it was out of his specialty. She did have gastroesophageal reflux disease. She had osteoarthritis of her hip,

having injured it while wrestling with her husband. She was obese. *Id.* She also had chemical hyperthyroidism although she was clinically euthyroid. *Id.*

On September 30, 1993, Dr. Ottinger saw petitioner for a follow-up EMG and nerve conduction study for her previous findings of diffuse demyelinating peripheral neuropathy. Med. recs. at Ex. 3, p. 30. Dr. Ottinger commented, "There is at least some strong reason to believe that the patient may have suffered some sort of autoimmune demyelinating reaction secondary to [hepatitis B vaccination]." *Id.* The EMG and nerve conduction study still showed prolongation of the distal sensory latencies of the median and ulnar nerves and the posterior tibial and common peroneal nerves, but they were much improved over the prior study done in July 1993. Med. recs. at Ex. 3, p. 31. There also continued to be some mild slowing on the nerve conduction studies in some focal areas, but this was also significantly improved. The EMG was improved in that the only muscle showing any significant abnormality was the extensor digitorum brevis in the left lower extremity. *Id.* Dr. Ottinger's impression was that petitioner was showing resolution of her peripheral polyneuropathy although she was not normal yet. *Id.*

On October 26, 1993, petitioner received her third hepatitis B vaccination. Med. recs. at Ex. 12, p. 2.

On March 11, 1994, Dr. Thomas J. Born wrote a letter to an insurance claims representative. Med. recs. at Ex. 2, p. 2. He notes that four or five days after petitioner received hepatitis B vaccine on May 26, 1993, she developed diffuse myalgias including the lower back and lower extremities. A neurologic examination in late June showed no specific abnormalities other than mild difficulty tandem walking. However, an EMG done on July 8, 1993 showed demyelinating changes in multiple nerves. This result definitely could be consistent with an

acute idiopathic polyneuropathy. These polyneuropathies are usually caused by a deranged immune response to exposure to viral antigens. Dr. Born stated that hepatitis B vaccine was the likely cause for petitioner's symptoms. A reasonable person would consider it likely. *Id.*

On June 6, 1994, petitioner saw Dr. Robert M. Worth, a neurosurgeon, at Indiana University School of Medicine. Med. recs. at Ex. 5, p. 41. Petitioner stated her symptoms began on May 30, 1993 with back pain in the mid-thoracic region. She received hepatitis B vaccine in mid-May [it was actually May 26th]. Initially, she attributed her back and shoulder pain to lifting which she did as a geriatric nurse. The next day, however, she began to develop bilateral numbness in the fingers and toes and became progressively weaker. By the second week of June, she found it difficult to get out of bed. She also complained of visual loss, hearing loss, insomnia, lethargy, low grade fever, maxillary pain, and pruritus. After Dr. Ottinger diagnosed demyelinating polyneuritis, she underwent physical therapy and, over the months, her lethargy, myalgia, arthralgia, and weakness gradually decreased.. She continued to have some weakness and paresthesiae. *Id.*

On physical examination, she had diffuse weakness in individual muscle groups in both legs. Her deep tendon reflexes were 1+ and symmetrical. The remainder of her neurological examination was essentially normal. *Id.* She was a not a candidate for surgery. Med. recs. at Ex. 5, p. 42.

On October 5, 1994, petitioner saw Dr. John C. Kincaid, a neurologist, for a second opinion. Med. recs. at Ex. 1, p. 9. In May 1993, petitioner said that she had a fairly abrupt onset of malaise, and aching and pain in her shoulder and hips. She received hepatitis B vaccine April 26, 1993, and a second one on May 26, 1993. Petitioner connected the symptoms to the second

vaccination. The generalized fatigue persisted and worsened over several months. She was eventually bed bound. *Id.* In June 1993, she developed tingling in her fingertips and toes. On June 25, 1993, she saw Dr. Ottinger, a neurologist, who seemed to think nothing was wrong with her. *Id.*

On physical examination, petitioner's muscle bulk, tone, and strength were normal, except for the ankle muscles which were slightly weak. Reflexes were present throughout at a 2+ level. Med. recs. at Ex. 1, p. 12. Dr. Kincaid's impression was that petitioner's history was very suggestive of an acquired peripheral neuropathy which her July 8, 1993 EMG showed to be demyelinating. The time course fit best with CIDP. Dr. Kincaid noted, "It is a very reasonable conclusion that her neuropathy was a result of the hepatitis B vaccine acting in an immunological stimulating way." *Id.*

On April 26, 1995, petitioner returned to Dr. Kincaid. She continued to have soreness and heaviness in the lower legs that seemed to be mainly in the knee and medial leg area. She had some discomfort in the wrist area and feelings of numbness in the fingers that impaired her grip somewhat. Med. recs. at Ex. 6, p. 13. She dates the onset of her hand complaints to very shortly after hepatitis B vaccination. On physical examination, she had normal median and ulnar strength. Foot and leg strength were normal. Reflexes and sensation were normal in the lower extremities. Nerve conduction was done and showed mild carpal tunnel bilaterally. Ulnar conduction and peroneal motor conduction in the right leg were normal. Dr. Kincaid's impression was carpal tunnel syndrome and normal peripheral nervous system in the remainder. Her achiness and fatigue might be due to residua from GBS or from deconditioning. *Id.*

On April 26, 1995, Dr. Kincaid performed motor nerve and sensory nerve conduction studies, which showed mild bilateral median neuropathy at the wrists, but no generalized neuropathy. Med. recs. at Ex. 6, p. 12.

On May 22, 1995, petitioner returned to the neurosurgeon Dr. Worth, complaining about bilateral carpal tunnel syndrome. Med. recs. at Ex. 6, p. 10. He suggested she wear volar wrist splints. She wondered if carpal tunnel syndrome was related to GBS but Dr. Worth said he did not know of any such cases. *Id.*

On June 13, 1995, Dr. Allan H. Ropper, a neurologist at St. Elizabeth's Medical Center, responded to petitioner's letter. He stated that, to his knowledge, there was no connection between carpal tunnel syndrome and GBS. Med. recs. at Ex. 9, p. 15.

On October 17, 1996, petitioner had an EMG which Dr. Mark V. Reecer stated showed mild bilateral carpal tunnel syndrome, but no evidence of peripheral neuropathy, and no evidence of residua from her prior demyelinating disorder. Med. recs. at Ex. 10, p. 1.

On October 16, 1997, petitioner was in an elevator which fell seven floors. She had neck, shoulder and right hip pain. She also had a headache and had whip lash on the right side in 1989 with an auto accident. Med. recs. at Ex. 7, p. 27.

DISCUSSION

This is a causation in fact case. To satisfy her burden of proving causation in fact, petitioner must offer "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen

v. Secretary of HHS, 418 F. 3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

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

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

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

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

In Gilbert v. Secretary of HHS, No. 04-455V, 2006 WL 1006612 (Fed. Cl. Spec. Mstr. March 30, 2006), the undersigned ruled that hepatitis B vaccine can cause GBS and CIDP, and did so in that case. The onset interval after hepatitis B vaccination was three weeks. Respondent's expert, Dr. Roland Martin, testified that the appropriate onset interval, if a vaccination were to cause an acute demyelinating reaction, would be a few days to three to four

weeks. Stevens v. Secretary of HHS, No. 99-594V, 2006 WL 659525, at *15 (Fed. Cl. Spec. Mstr. Feb. 24, 2006).

Here, petitioner's onset of numbness was approximately three days although her histories vary. Three days would put her in the temporal framework that respondent's Dr. Martin conceived was barely appropriate for a demyelinating reaction to vaccination.

There are some complicating factors here. First, she had numbness, pain, and headaches before she received hepatitis B vaccination from her auto accidents in 1988 and 1989, primarily the second accident. Secondly, her CIDP was so mild that, initially, her treating physician did not diagnose her with a demyelinating polyneuropathy until he saw the results of her EMG and nerve conduction study. That she still complains of pain and numbness is attributable either to her carpal tunnel syndrome (which is unrelated to CIDP) or her prior automobile accident. Her subsequent EMG and nerve conduction studies support that she has recovered completely from her peripheral neuropathy.

One could argue that her cold of four weeks duration during the month of May 1993 (about which she complained on June 1, 1993) which preceded and followed her second hepatitis B vaccination on May 26, 1993 is just as likely a cause of her CIDP as her second hepatitis B vaccination. Curiously, after she received her third hepatitis B vaccination on October 26, 1993, she did not have a relapse of her CIDP. This case is the opposite of a positive rechallenge case because, when rechallenged, petitioner remained free of her prior CIDP.

However, the Federal Circuit, in Capizzano, supra, stated that the opinions of treating physicians was important in evaluating the persuasiveness of petitioner's evidence. In Capizzano, petitioner's allegation of vaccine causation of her rheumatoid arthritis was supported

by four of her treating doctors. 440 F.3d at 1326. In the instant case, Drs. Ottinger, Kachmann, Kincaid, and Born, four of petitioner's treating doctors, opined that hepatitis B vaccine had caused her demyelinating polyneuropathy. The first three doctors are neurologists.

The undersigned is of the opinion that the evidence, so far, weighs in petitioner's favor and that an inexpensive settlement would be appropriate herein.

Respondent is ORDERED TO SHOW CAUSE why this case should not proceed to damages by **October 20, 2006**.

IT IS SO ORDERED.

September 12, 2006
DATE

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