In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. [redacted]V
March 31, 2008
To be Published
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JANE DOE/13,	*	
	*	
Petitioner,	*	
	*	
v.	*	Entitlement; hepatitis B vaccinations; transverse myelitis after second vaccination; ultimately MS
	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

Clifford J. Shoemaker, Vienna, VA, for petitioner.
Chrysovalantis P. Kefalas, Washington, DC, for respondent.

MILLMAN, Special Master

RULING ON ENTITLEMENT[1]

Petitioner filed a petition on May 14, 1999, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that hepatitis B vaccinations administered in August

[1] Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and move to delete such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access. Petitioner filed a motion to redact on April 1, 2008. The undersigned grants petitioner's motion with this redacted Ruling on Entitlement.

and October 1992 caused her unspecified injury, later diagnosed as multiple sclerosis (MS).

On January 29, 2008, a hearing was held. Testifying for petitioner was petitioner, her ex-husband [name redacted], and Dr. Carlo Tornatore, a neurologist. Testifying for respondent was Dr. Arthur P. Safran, a neurologist.

FACTS

Petitioner was born on February 19, 1965.

On July 19, 1979, petitioner went to Centre Hospitalier de Verdun in Montreal with an infection in her left leg. Med. recs. at Ex. 1, p. 5.

On October 27, 1981, petitioner went to Centre Hospitalier de Verdun, having had mono twice that year. Med. recs. at Ex. 1, p. 2. She was diagnosed with pharyngitis.

On August 12, 1992, petitioner received her first hepatitis B vaccination. P. Ex. 29, p. 1.

On September 2, 1992, petitioner received her second hepatitis B vaccination. *Id.*

On February 12, 1993, petitioner saw Dr. Basil M. Yates, a neurosurgeon. Med. recs. at Ex. 28, p. 60. Petitioner told Dr. Yates that she went skiing at the end of November or early December 1992 and, about two weeks later, she began to feel a numbness in her left leg. She said she fell a few times while skiing but was not aware of hurting herself. She saw Dr. Ramon Garcia-Septien, her family doctor, who gave her Roaxisal and pain medication. A CT scan was done of the lumbar and sacral spines, showing a central disc at L5-S1. An EMG dated January 14, 1993 showed bilateral carpal tunnel syndrome, mild distal sensory neuropathy of both ulnar and radial nerves, and mild motor neuropathy of the right radial nerve. An EMG of the legs was normal. Petitioner stated she had a lot of muscle spasms in both legs, more on the left. Occasionally, her lower back bothered her. A couple of days previously, she sprained her back.

She stated that the pain went into the back of her knees from her low back but not below the knees. She had complete numbness of her left foot and some numbness of her right foot. She favored her left leg, putting most of the weight on her right leg because her left leg felt weak. She also complained of numbness in both hands, worse on the left, and just recently, she began to feel pain in the back of her left shoulder. Sometimes, her left posterior neck hurt and the neck pain went down her back but not into her shoulders or arms. *Id.* Petitioner noted numbness in her hands for years, but did not know the onset. Med. recs. at Ex. 28, p. 61. For several years, she had been a mechanic, a painter, and an upholsterer. The prior semester, she was in a nursing program and strained her back. On physical examination, her reflexes were 2+ in the knees and Achilles tendon. She had a sensory diminution on the left from T8-T9 down. She also had some urinary incontinence if she did not go to the bathroom frequently. She strained with bowel movements. *Id.*

On February 23, 1993, petitioner had a thoracic spine MRI done. Med. recs. at Ex. 28, p. 63. There was a focal area of abnormal signal intensity in the thoracic cord at the T8 and T9 levels without associated mass effect. *Id.*

On March 1, 1993, petitioner had a brain MRI done. Med. recs. at Ex. 28, p. 64. It was unremarkable. There was no evidence of a demyelinating process in the brain parenchyma and no area of abnormal enhancement or space-occupying lesions. *Id.*

On March 17, 1993, petitioner saw Dr. Nobel J. David, a neurologist. Med. recs. at Ex. 3, p. 5. Petitioner had a gradually increasing syndrome of difficulty with her left leg, including changes in sensation, and a sensory level on the left up to her navel or slightly above with diminution to pinprick. Her reflexes were somewhat exaggerated on that side and her toes were

upgoing bilaterally. She had diminished vibratory sensation in her legs. There were no cranial nerve findings and her brain MRI was free of any hyperintense white matter signals. The thoracic MRI showed a hyperintense signal within the cord. He diagnosed petitioner with demyelinating disease with a solitary lesion. *Id.*

On March 18, 1993, petitioner was admitted to Jackson Memorial Hospital with a history of carpal tunnel syndrome presented with complaints of numbness and weakness of the bilateral lower extremities, on the left more than the right. Med. recs. at Ex. 2, p. 17. Petitioner stated that the onset of her lower back pain was in August 1992. She later developed mild numbness in both lower extremities which gradually became progressive and worsened since December. She also felt weakness of the bilateral extremities, on the left more than the right. Petitioner also complained of numbness, weakness, and mild pain in both hands for a long time, status post-carpal tunnel syndrome. *Id.* Petitioner complained of an intermittent headache and intermittent blurry vision. She was unable to walk properly for long distances since that time. A CT scan of the lumbar/sacral spine showed a central disc at L5-S1. An EMG showed bilateral carpal tunnel syndrome and mild distal sensory neuropathy of both the ulnar and radial nerves. She also had mild nerve deadening of the right radial nerve. The EMG studies were normal in the lower extremities. An MRI of the thoracic spine showed focal areas of abnormal signal intensity at T8-T9 without mass effect. A brain MRI on March 23, 1993 was negative. *Id.* Petitioner's reflexes were 3+ and her plantars were down. On spinal tap, petitioner had a mildly elevated protein of 56. Med. recs. at Ex. 2, p. 18.

On March 18, 1993, petitioner told the doctor that she had numbness and weakness of both lower extremities and bilateral carpal tunnel syndrome. Med. recs. at Ex. 34, p. 6. She

started having lower back pain in August 1992 and later developed mild numbness of both legs which gradually became progressive and got worse since December. She also felt weakness of both lower extremities. She complained of numbness and weakness with mild pain of both hands for a long time. Petitioner also complained of headaches on and off and blurred vision on and off. She said she was unable to walk for long distances. A CT scan of her lumbar spine was done which showed a central disc at L5-S1. She had an EMG done which showed bilateral carpal tunnel syndrome, mild distal sensory neuropathy of both ulnar and radial nerves, and mild motor neuropathy of the right radial nerve. The EMG studies were normal in the lower extremities. She had a thoracic spine MRI done which showed focality of abnormal signal at T8-T9 but no mass effect. MRI of her brain was negative. *Id.*

On March 19, 1993, a fourth-year medical student named Mintz recorded that petitioner reported a seven-year history of leg numbness with exacerbations and remissions. She also had a history of carpal tunnel syndrome for two years. Med. recs. at Ex. 34, p. 8. She had worked as a painter, reupholsterer, and mechanic. In August 1992, she began to develop lower back pain, leg weakness, and gait abnormalities. CT scan diagnosed a herniated disc. *Id.* The diagnosis was MS. Med. recs. at Ex. 34, p. 9.

On March 20, 1993, petitioner had a consultation with Dr. Subhi Eldeiry, a family practice doctor. Med. recs. at Ex. 34, p. 17. She had a history of bilateral carpal tunnel syndrome and presented with weakness in her legs beginning in August 1992 with progressive numbness which worsened since December 1992 with numbness, weakness, and pain in both hands. *Id.* Dr. Eldeiry's impression was demyelinating disorder.

On March 22, 1993, a fourth-year medical student notes that petitioner had carpal tunnel syndrome and bilateral leg weakness/numbness for six to ten months. Med. recs. at Ex. 34, p. 13.

On April 7, 1993, petitioner saw Dr. David, the neurologist. Med. recs. at Ex. 3, p. 3. Petitioner had only a solitary spinal lesion. Therefore, instead of calling her illness MS, he called it a demyelinizing plaque. *Id.*

On June 23, 1993, petitioner returned to Dr. David. Med. recs. at Ex. 3, p. 1. Petitioner was improving from demyelinating disease. She had a single lesion. Dr. David said she was in good remission. *Id.*

On July 15, 1994, petitioner saw Dr. Paul L. Ginsberg, another neurologist. Med. recs. at Ex. 4, p. 24. She told him that she began to notice numbness of her left leg in October 1992. The entire leg was involved and the numbness went to her abdomen. The numbness occurred intermittently. She complained also of urinary incontinence and hesitancy. A spinal tap showed multiple oligoclonal bands, suggesting MS. She did better after discharge from Jackson Hospital, but recently developed more weakness and numbness in her legs. She was also fatigued. *Id.* On physical examination, petitioner did not show definite weakness. Med. recs. at Ex. 4, p. 25. She was spastic in the lower extremities. She had bilateral Babinski signs. Dr. Ginsberg diagnosed probable MS. *Id.*

In a letter dated January 10, 1995 from Dr. Ginsberg to Dr. Elisabeth Cohn, Dr. Ginsberg wrote that petitioner called him a few days earlier to say that around Christmas, her right leg had gotten weaker, and she was using a cane. She came in for examination and she had slightly lower extremity hyperreflexia with bilateral Babinski signs. She had decreased vibratory perception in her feet. She had a suggestion of a sensory level to the mid-thoracic region

bilaterally. Med. recs. at Ex. 2, p. 2. Dr. Ginsberg suspected that petitioner had had another exacerbation of her MS. *Id.*

On October 27, 1998, petitioner saw Dr. Brian Steingo, a neurologist. Med. recs. at Ex. 11, p. 22. She told him that her symptoms started within a month of a hepatitis B vaccination. She had initial numbness from the waist down to the toes and also weakness and could barely walk. She was treated with steroids and was eventually back to normal without any problem walking. Six months later, she had an exacerbation. Her legs were again weak and she lost bladder control. *Id.* To date, she had about six exacerbations, the last in January 1998 until that point. Before that, she had gone 14 months without exacerbation. Over the prior days, her symptoms flared. Her head was foggy and she could not think and felt depressed and weak. She had back pressure. She was not incontinent and had no visual symptoms or dizziness. There was a lot of stress at home. She quit smoking in 1992. *Id.* On examination, petitioner's deep tendon reflexes were markedly hyperactive with clonus at the ankles and bilateral plantar extensor responses. Med. recs. at Ex. 11, p. 23.

On October 31, 2001, petitioner had a brain MRI which showed gyriform area of bright signal intensity surrounding a sulcus in the left frontal/anterior parietal lobe measuring approximately 2 cm in maximal length without enhancement, which was not a typical appearance for a demyelinating plaque associated with MS. Med. recs. at Ex. 8, p. 89. The brain MRI was otherwise unremarkable. *Id.*

On November 21, 2002, petitioner saw Dr. Douglas Arnold, a neurologist at McGill University Health Centre. Med. recs. at Ex. 28, p. 39. Her first MS symptoms occurred in 1992 when she developed numbness below the waist after receiving a hepatitis B vaccination. Med.

recs. at Ex. 28, p. 51. In a handwritten note, he states this occurred in October 1992. Med. recs. at Ex. 28, p. 41. Her second attack was in 1993 when she developed transverse myelitis at T8-T9. Med. recs. at Ex. 28, p. 51. In handwritten notes, he stated this occurred in March 1993. Med. recs. at Ex. 28, p. 41. On examination, she had moderately severe quadriparesis. Med. recs. at Ex. 28, p. 52.

On April 26, 2004, petitioner had a brain MRI done which showed hyperintense signal involving the medulla particularly at the level of the restiform bodies mainly evident on the T2 and proton density images. Med. recs. at Ex. 28, p. 54. There was an abnormal increased signal intensity involving the immediate subcortical white matter (U-fiber) in the left superior frontal gyrus. There were a few lesions with an increased signal intensity at the level of the left peritrigonal white matter. The lesions were demyelinating. Med. recs. at Ex. 28, p. 55.

On May 31, 2005, Dr. Jack P. Antel, a neurologist at McGill, wrote Dr. D. Arnold. Med. recs. at Ex. 28, p. 58. Petitioner dated her illness to about 12 years previously when a week after hepatitis B vaccination, she became aware of numbness and perhaps weakness of the lower legs. She recovered from this over some months but, over the following years, she developed progressive weakness and loss of leg function. About four to five years ago, she became aware of arm involvement which seems to have progressed. Her relapses often involve generalized weakness rather than focal loss of neurologic function with recovery. Her initial MRIs in the 1990s showed a spinal cord lesion about which her MRIs in 2004 did not comment although they also showed lesions in the brainstem and cerebral white matter. *Id.* On physical examination, petitioner had nystagmus, markedly reduced muscle movement in the arms, and no voluntary use of the legs. There was some increased tone in the left arm on flexion of the elbow which was

less apparent on the right. Reflexes were difficult to elicit in the arms but at least 2+ in the legs with toes upgoing. Dr. Antel wondered if there were a superimposed element of disuse that evolved over the years to explain the marked impairment of motor and sensory functions in the limbs but not more developed spasticity in the arms. *Id.* There was an issue of the mismatch between the extent of disease on MRI and the amount of clinical disability that she developed. Med. recs. at Ex. 28, p. 59.

On June 14, 2005, petitioner had a brain MRI done. Med. recs. at Ex. 28, p. 53. There were no new lesions since the April 26, 2004 brain MRI. An MRI of the cervical spine dated June 14, 2005 showed severe spinal cord atrophy from C3 to C6. *Id.*

TESTIMONY

Petitioner's ex-husband, testified first for petitioner. Tr. at 3. They had a church wedding ceremony on August 15, 1992, three days after petitioner's first hepatitis B vaccination. Tr. at 5. Petitioner at the time was very active and going to nursing school. Tr. at 6. After the vaccination, petitioner was lethargic and could not think clearly. She also had back pain. Tr. at 9.

Petitioner and her now ex-husband had a honeymoon in Acapulco where petitioner because severely ill with malaise, dizziness, and back pain. They returned to the United States on August 19, 1992. Tr. at 10. Her symptoms waxed and waned. Tr. at 11.

On September 2, 1992, petitioner had her second hepatitis B vaccination. Tr. at 12. Within 24 hours, she had numbness in her feet extending to her rib cage. Tr. at 13-14. She saw her nursing professor who recommended she see her doctor, Dr. Garcia-Septien. Dr. Garcia-Septien ran tests and diagnosed petitioner with a disc problem. Tr. at 14.

During September, October, and November, petitioner's symptoms waxed and waned. *Id.* At the end of November 1992, they went on a skiing trip which he had won. Petitioner had numbness but her muscles worked. Tr. at 15. In December 1992, Dr. Garcia-Septien ordered new tests. Tr. at 16-17. Petitioner's carpal tunnel syndrome existed before her hepatitis B vaccinations. Tr. at 25. Her work as an upholsterer, construction worker, and painter exacerbated the carpal tunnel syndrome. Tr. at 24-25.

Petitioner testified next. Tr. at 34. She was very healthy and active before August 1992. Tr. at 35. After her first hepatitis B vaccination on August 12, 1992, she became very lethargic and had a hard time concentrating. She also had low back pain. She thought she had flu-like symptoms from the hepatitis B vaccination. Tr. at 36. On August 15, 1992, she had the church wedding and went on her honeymoon on August 16, 1992. *Id.* She contracted a bad urinary tract infection and was urinating blood. She cancelled the honeymoon to come back early and her sister got her an antibiotic. She still had fogginess and could not concentrate. Tr. at 37.

On September 2, 1992, she received her second hepatitis B vaccination. *Id.* Within 24 hours, her feet became numb. This numbness gradually rose during the week to her rib cage. Tr. at 38. She telephoned Dr. Garcia-Septien and saw him. He ran a battery of tests and diagnosed a slipped disc. Her lower back hurt. The symptoms gradually became more intense. *Id.*

At the end of November 1992, she went on a skiing trip and fell because her legs were weak. Tr. at 39. Before Christmas 1992, she saw Dr. Garcia-Septien and had more tests and an EMG. He referred her to Dr. Yates, who ordered an MRI. She saw Dr. David and he told her the MRI showed a lesion. Tr. at 40.

Petitioner stated she had had hand numbness all her life, since she was a teenager. Tr. at 43. It was due to repetitive motion. Tr. at 44. Her whole hand became numb. Tr. at 48. She saw Dr. Yates in February 1993. The hospital record stating she had had leg numbness for seven years was incorrect and should have said seven months. Tr. at 53.

In 1994, she told Dr. Ginsberg that the onset of numbness in her left leg was October 1992, but she thought she had received the vaccination in October 1992 when she told him that. Tr. at 62, 63. Every member of her family has had carpal tunnel syndrome. Tr. at 65.

Dr. Carlo Tornatore testified next for petitioner. Tr. at 79. He is director of the Georgetown MS Center which sees 1,500 patients a year. Tr. at 80. It is the largest MS center in the mid-Atlantic region. Tr. at 81. His opinion is that petitioner's second hepatitis B vaccination caused petitioner transverse myelitis (TM) which led to multiple sclerosis (MS). Tr. at 81-82. Both the TM and MS were due to hepatitis B vaccinations. Tr. at 82. Part of the basis of his opinion is the striking temporal relationship between hepatitis B vaccination and onset. *Id.*

On August 12, 1992, after her first hepatitis B vaccination, petitioner had flu-like symptoms and back pain which Dr. Tornatore termed constitutional symptoms. *Id.* Her urinary tract infection on her honeymoon was not due to the vaccine, but was honeymoon cystitis. Tr. at 82-83. Her fuzzy headedness was part of her constitutional symptoms. Tr. at 83.

To Dr. Tornatore, the second hepatitis B vaccination was critical because she developed numbness in both feet that quickly rose to her rib cage. *Id.* Dr. Charcot, the father of MS, described this classic history 150 years ago. *Id.* Petitioner's numbness starting in her feet and going up to her mid-rib cage indicates a spinal cord problem. Tr. at 83-84. Petitioner had the right symptom complex after the second hepatitis B vaccination for a thoracic spinal cord

syndrome. Tr. at 84. It progressed and waxed and waned from October through December. *Id.* Her lower back pain started in August 1992 and she developed mild numbness in both legs which became progressive and worsened since December. *Id.* Her legs also felt weak. *Id.*

Dr. Tornatore testified that petitioner's carpal tunnel syndrome is a red herring in the case. *Id.* In October 1992, the numbness in petitioner's left leg spread to the entire leg and then intermittently to the abdomen. Tr. at 85. She saw Dr. Douglas Arnold, who is a very well-respected neurologist, and told him onset of her numbness was October 1992. *Id.* The transverse myelitis was the beginning of petitioner's MS. Tr. at 89. She also saw Dr. Jack Antel, a premier MS expert in Canada, telling him that onset of numbness and perhaps weakness was one week following hepatitis B vaccine. *Id.* Someone could have significant disease of the spinal cord but the MRI would relatively not look so bad. Tr. at 91. Dr. Tornatore stated that many points in the record indicate an October time frame as the onset of petitioner's symptoms. Tr. at 92.

To Dr. Tornatore, the 24-hour onset that petitioner and her ex-husband claim is not too quick an onset but is consistent with causation because the first hepatitis B vaccination primed petitioner's immune system and, when petitioner received the second hepatitis B vaccination, her immune system was already primed. Tr. at 93. This is molecular mimicry, i.e., the immune cells recognize not only the vaccine, but also the antigens on nerves and myelin that resemble those in the vaccine. Tr. at 93-94. To Dr. Tornatore, both biologically and temporally, it made sense that the vaccinations caused petitioner's MS. Tr. at 95. It was after the second vaccination that petitioner had a neurological reaction. *Id.*

Dr. Tornatore admitted that the histories were not always consistent since petitioner told Dr. Steingo that her symptoms occurred within a month after vaccination and told Dr. Yates that

her numbness began in December after skiing. Tr. at 96-97. That petitioner was worse in December is consistent with all the histories. Tr. at 98. The records in 1993 state that onset was in October 1992. Tr. at 101. Even an onset of one month after the second hepatitis B vaccination would still be clinically appropriate for causation. *Id.* Timing depends on how primed her immune system was. A very primed immune system results in a quick response. Tr. at 102. If petitioner's onset of neurologic symptoms were a week or a month would fit within his reasoning. Tr. at 108. Dr. Tornatore did not relate the back pain petitioner complained about starting in August 1992 to any neurologic component or transverse myelitis. Tr. at 103. Petitioner had lumbar spine disc disease which makes perfect sense as the cause of her back pain. *Id.* It is also the wrong area (because not in the thoracic spine) so it is a red herring. *Id.*

There are errors in the medical records, such as the fourth year medical student writing that petitioner's toes were downgoing (which would mean no central nervous system disease) and later upgoing. Tr. at 100-01. However, toes can fluctuate up and down. Tr. at 105. Dr. Tornatore said that petitioner's urinary tract infection in August 1992 could have worsened petitioner's MS but she did not have neurological symptoms at that time. Tr. at 111-12. Her neurological symptoms began in October 1992 after her second hepatitis B vaccination. Tr. at 109.

Dr. Arthur P. Safran testified for respondent. Tr. at 113. He sees 75 MS patients a month and has run an MS clinic for 28 years. Tr. at 115. His opinion is that hepatitis B vaccine did not cause petitioner's MS. Tr. at 117. The basis of his opinion is: (1) timing (he relies on Dr. Yates' record of petitioner's history of onset of leg numbness in December 1992, two months after her second hepatitis B vaccination); and (2) her prior history of hand numbness which he felt carpal

tunnel syndrome would not explain. Tr. at 118. Dr. Safran believes that petitioner does not have just carpal tunnel syndrome because she said the back of her hands was numb as well which never happens in carpal tunnel syndrome. *Id.* Her radial, medial, and ulnar nerves on EMG were abnormal. Tr. at 119. Carpal tunnel syndrome would not affect those nerves. Tr. at 120.

Dr. Safran stated that lesions in the neck can cause numb hands, but an MRI of petitioner's cervical spine was not done. *Id.* He thinks she has a cervical spine abnormality. *Id.* The reflexes in her arms were just as brisk as those in her legs. *Id.* Damage in the spinal cord increases the reflexes. *Id.* When people pressed over petitioner's carpal ligament, she did not report any symptoms. Tr. at 120-21. Steroid treatment improved her hands. Tr. at 121. Dr. Safran believed that petitioner had MS as a teenager when her hands got numb. Tr. at 122. He did not believe that hepatitis B vaccine significantly aggravated her MS. Tr. at 123. Since she went skiing in December 1992, whatever sickness petitioner had after the hepatitis B vaccination was not a major intervention. *Id.*

Dr. Safran regards numbness up to the rib cage to be a hallmark neurologic emergency, not a subtle event, and demands urgent, immediate, emergency attention. Tr. at 124. This was not what the primary doctor was thinking when he ordered imaging studies of the lumbar spine for back pain and EMGs for carpal tunnel syndrome. Tr. at 124-25. Referring to Dr. Yates' report, Dr. Safran put onset of numbness in December, three months after the second hepatitis B vaccination. Tr. at 126. This conflicts with Dr. Tornatore's testimony that the temporal association between vaccination and onset is strong. Tr. at 127. Dr. Safran mentioned that bladder infection exacerbates underlying multiple sclerosis. Tr. at 129. Dr. Yates is a neurosurgeon and not the typical doctor to treat or diagnose MS. Tr. at 132.

The undersigned asked Dr. Tornatore to respond to Dr. Safran's testimony. Tr. at 148. He stated that it would be unusual for a 15 year-old to have cervical spinal cord MS. *Id.* If she had it, by the time she received hepatitis B vaccine 12 years later, she would have been walking with a cane, but petitioner had no problem. Tr. at 149. Dr. Tornatore described petitioner's MS as progressive, going from transverse myelitis to MS. *Id.* If she had had MS when she went on her honeymoon, her urinary tract infection would have significantly aggravated it on the honeymoon. Tr. at 151. He said that an EMG clearly showed carpal tunnel syndrome. Tr. at 148.

Dr. Safran resumed testifying by saying that petitioner had both MS and carpal tunnel syndrome starting when she was a teenager. Tr. at 152. The undersigned asked Dr. Tornatore if petitioner's abnormal radial, medial, and ulnar nerves were explained by carpal tunnel syndrome. Tr. at 153. He replied that petitioner has a family history of carpal tunnel and she also was involved in a few professions where she used her hands a lot. Tr. at 154. Dr. Safran disagreed, stating that the radial and ulnar nerves do not go through the carpal tunnel. Tr. at 155. Dr. Tornatore said that all the nerves can be compressed even if they all do not go through the carpal tunnel. Tr. at 157.

DISCUSSION

This is a causation in fact case. To satisfy her burden of proving causation in fact, petitioner must offer by preponderant evidence "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Secretary of HHS, 418 F. 3d 1274, 1278 (Fed. Cir.

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

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

In Capizzano v. Secretary of HHS, 440 F.3d 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 transverse myelitis and MS, but also that the vaccine was a substantial factor in bringing about her transverse myelitis and MS. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

In Stevens v. Secretary of HHS, No. 99-594V, 2006 WL 659525 (Fed. Cl. Spec. Mstr. Feb. 24, 2006), the undersigned ruled that hepatitis B vaccine can cause transverse myelitis and did so in that case. The onset interval after the first hepatitis B vaccination was 12 or 13 days. The onset interval after the second hepatitis B vaccination was one week. 2006 WL 659525, at *17.

In Werderitsh v. Secretary of HHS, No. 99-319V, 2006 WL 1672884 (Fed. Cl. Spec. Mstr. May 26, 2006), the undersigned ruled that hepatitis B vaccine can cause multiple sclerosis and did so in that case. The onset interval after vaccination in Werderitsh was one month. Petitioners' expert Dr. Byers testified in the Omnibus proceeding on hepatitis B vaccine and demyelinating diseases that an appropriate temporal interval between vaccination and disease was from four to 30 days. Respondent's expert Dr. Martin testified in the Omnibus proceeding that an appropriate temporal interval for an immune reaction would be a few days to three to four weeks.

Although, in the instant action, petitioner's histories of onset of her symptoms range from one week to one month after hepatitis B vaccine, she and her ex-husband testified that onset of her feet numbness was within one day of her second hepatitis B vaccination. There are no medical records to substantiate this account. There are also no medical records to substantiate petitioner's and her ex-husband's testimony that she became fuzzy headed and could not think clearly after the first hepatitis B vaccination. Petitioner testified that she knew she was not the same after the first hepatitis B vaccination. However, she did tell the doctors that her back pain began in August which is when she received her first vaccination.

Petitioner's ex-husband's testimony of petitioner's symptoms on their honeymoon just after the first hepatitis B vaccination differs from petitioner's testimony. They had a church wedding three days after petitioner received her first hepatitis B vaccination. Petitioner's ex-husband clearly and emphatically emphasized that petitioner felt so bad after her first hepatitis B vaccination that they had to cut their honeymoon short because of those bad symptoms. On the

other hand, petitioner testified that they had to cut their honeymoon short because she developed a urinary tract infection and had blood in her urine.

The undersigned cannot accept that petitioner had fogginess, lack of clear thinking, or any symptom besides back pain after the first hepatitis B vaccination because none of the medical records supports it. The Vaccine Act does not permit the undersigned to hold that symptoms that are alleged but unsupported by the medical records or medical opinion actually occurred. 42 U.S.C. § 300aa-13(a)(1). Petitioner's expert Dr. Tornatore did not rely on these alleged symptoms in his opinion supporting petitioner's allegations and testified that petitioner's first neurologic symptoms (omitting the pre-existing carpal tunnel syndrome) occurred after her second hepatitis B vaccination. The undersigned does accept that petitioner's back was bothering her in August 1992.

The medical histories that petitioner gave to various doctors were that within one week or one month of her second hepatitis B vaccination, she had onset of numbness. That onset puts petitioner's transverse myelitis, ultimately diagnosed as MS, within the appropriate temporal interval that Dr. Byers and Dr. Martin described during the Omnibus hepatitis B vaccine-demyelinating diseases hearing.

If, however, the undersigned were to accept petitioner's and her ex-husband's testimony that the onset of her numbness began within 24 hours of her second hepatitis B vaccination, Dr. Tornatore's testimony that her first hepatitis B vaccination primed her for a speedier onset after her second hepatitis B vaccination is biologically plausible. The undersigned accepted a one-day onset after a second hepatitis B vaccination in Augustynski v. Secretary of HHS, No. 99-611V, 2007 WL 3033614, at *4 (Fed. Cl. Spec. Mstr. Sept. 28, 2007) in which Dr. Tornatore described

the same biologically plausible theory. Petitioners' expert Dr. Byers in the Omnibus proceeding also testified that a one-day onset can occur but only when people had a very strong immune boost fairly shortly before the subsequent vaccination, resulting in preformed antibodies that built up to a fairly high concentration. Omnibus tr. at pp. 102-03; quoted in Augustynski, 2007 WL 3033614, at *3.

Thus, whether the onset of petitioner's transverse myelitis in the instant action was, per the medical histories, one week or one month after petitioner's second hepatitis B vaccination, or per petitioner's and her ex-husband's testimony, within one day, the undersigned arrives at the same conclusion: petitioner prevails because her expert has given a biologically plausible theory connecting the vaccine with her injury, a logical sequence of cause and effect, and a medically appropriate time frame between vaccination and onset..

Respondent's expert Dr. Safran refused to countenance any history but the one petitioner gave to Dr. Yates in February 1993. That history reflects solely her skiing trip at the end of November with leg numbness in December. But, this ignores petitioner's testimony that she had previously seen Dr. Garcia-Septien (whose records are unavailable) in the fall of 1992. He regarded her symptoms as indicative of a disc problem. Moreover, Dr. Yates is a neurosurgeon, presumably the appropriate doctor to see for back surgery for a disc problem, but maybe not as nuanced in diagnosing demyelinating diseases, which a neurologist, but not a neurosurgeon, would treat.

Of importance also is that petitioner's next history after talking to Dr. Yates was in March 1993, just one month later, and all her subsequent histories are consistent that her back pain began in August 1992 and that she had gradual numbness over the months which worsened in

December 1992. Dr. Tornatore, petitioner's expert, considers the onset of petitioner's neurological symptoms (excluding her pre-existing carpal tunnel syndrome) to be October 1992, which is one month after her second hepatitis B vaccination. There are medical records that support his opinion.

The Federal Circuit states that, in a close case, the special master is to rule that petitioner prevails. Close calls are to be resolved in favor of petitioners. Capizzano, 1440 F.3d at 1327; Althen, 418 F.3d at 1280. *See generally*, Knudsen v. Secretary of HHS, 35 F.3d 543, 551 (Fed. Cir. 1994). If this is a close case because of the discrepancy between the history petitioner gave to Dr. Yates in February 1993 and all the remaining histories, starting in March 1993 and afterward, petitioner prevails. The undersigned holds that petitioner's onset of neurologic symptoms manifesting her transverse myelitis occurred in October 1992.

Dr. Safran's opinion that petitioner had the onset of MS when she was 15 years old when her carpal tunnel syndrome including hand numbness began does not seem credible. Dr. Safran stated she had more nerves testing abnormal than he could accept as being part of carpal tunnel syndrome. Dr. Tornatore strongly disagreed that petitioner had more than carpal tunnel syndrome at the age of 15 and opined that if she had gone the next 12 years until she received hepatitis B vaccine with only carpal tunnel syndrome symptoms, she could not have had MS. Moreover, if she had had MS for those 12 years, Dr. Tornatore expected that her urinary tract infection on her honeymoon in August 1992 would have exacerbated her MS symptoms and that, by the time she received her first hepatitis B vaccination, she would have been walking with a cane.

The undersigned is not constrained to hold that petitioner's MS began when she was 15 years of age. The years petitioner spent doing work that involved her hands (painter, mechanic, reupholsterer) plus her family history of carpal tunnel syndrome combine to justify Dr. Tornatore's opinion that her MS did not begin before her hepatitis B vaccinations.

Petitioner has proved a prima facie case that hepatitis B vaccine caused her transverse myelitis leading to multiple sclerosis and that, but for the vaccine, she would not have had transverse myelitis and MS.

CONCLUSION

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

IT IS SO ORDERED.

March 31, 2008 (reissued April 2, 2008)
DATE

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