OFFICE OF SPECIAL MASTERS
No. 99-313V
September 8, 2006

JENNIFER GARLAND,	*	
	*	
Petitioner,	*	
	*	
v.	*	Hepatitis B vaccine followed
	*	four months later by MS;
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	too long for causation
	*	
Respondent.	*	

ORDER TO SHOW CAUSE[1]

Petitioner filed a petitioner on May 17, 1999, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that she received hepatitis B vaccine on November 12, 1992, December 18, 1992, and May 25, 1993.

Petitioner has multiple sclerosis (MS) whose onset was September 21, 1993. Med. recs. at Ex. 8, p. 31.

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[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.

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

FACTS

Petitioner was born on March 13, 1960.

On September 18, 1987, petitioner went to St. Elizabeth Hospital Medical Center, complaining of back pain. Med. recs. at Ex. 7, p. 5. It had begun the day before after lifting at work. She also had numbness. *Id.* Dr. J.P. Brown's impression was thoracic spine strain and petitioner was advised to avoid heavy lifting. Med. recs. at Ex. 7, p. 7. She had some numbness over the right shoulder and leg region but denied weakness in the upper or lower extremities. She was treated in the recent past for episodes of back pain. Back examination revealed minimal spasm among the thoracic spine, particularly on the right. There were no objective sensory or motor findings. She walked without difficulty. *Id.*

On May 1, 1989, petitioner complained of right knee pain. Med. recs. at Ex. 7, p. 2.

On September 4, 1990, petitioner was diagnosed with right knee tendonitis. *Id.* She went to the Emergency Department of Lafayette Home Hospital. Two years previously, she had fluid behind the right knee but no problems since. She complained of pain for two days behind the right knee which radiating to the thigh and the calf. She had intermittent sharpness with tingling in her right toes. She had no swelling. She had a burning sensation in her foot. She had good range of motion. The diagnosis was tendonitis in the right knee. Med. recs. at Ex. 7, p. 9.

She received her hepatitis B vaccinations on November 12, 1992, December 18, 1992, and May 25, 1993. Med. recs. at Ex. 2, p. 2.

On June 28, 1993, petitioner saw Dr. Nicholas F. Hrisomalos, a retinal specialist, for photopsias[2] and film she noted in her right eye over the prior week. Examination showed vitreous floaters in each eye with an annulus[3] appearing on the right. There was no vitreous hemorrhage or pigment. The macula in the right eye had some conspicuous pigmentary changes and drusen.[4] Peripheral retinal examination of the left eye showed peripheral cystoid degeneration but no significant retinal tear, hole, or detachment. In the right eye, there was a patch of lattice degeneration inferiorly and early developing traction inferiorly temporally. Superiorly, there was another area of light without traction. Dr. Hrisomalos's impression was high myopia with posterior vitreous detachment and some peripheral retinal changes in the right eye. No treatment was recommended. Med. recs. at Ex. 4, p. 4.

On August 2, 1993, petitioner returned to Dr. Hrisomalos, complaining that the film, sparklers, flashing lights, and distorted vision were just the same or worse. Her headaches were less and her vision was still slightly blurred but not worse. She reported some possible changes in her color vision. Angiography was performed which showed a small area in the macula inferior nasally which looked like a small laquer crack. There was no evidence of subretinal neovascularization or other change. He called petitioner and recommended she check her central

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[2] Photopsia is "an appearance as of sparks or flashes due to retinal irritation." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1431.

[3] An annulus is "a ring or ringlike structure...." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 93.

[4] Drusen (German for "bumps") are "hyaline excrescences in Bruch's membrane (lamina basalis choroideae); they usually result from aging, but sometimes occur with pathologic conditions...." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 565. Basal lamina of choroid is "the transparent inner layer of the choroid, which is in contact with the pigmented layer of the retina." *Id.* at 993.

vision daily and report any distortion, and check her peripheral vision for any sign of retinal detachment. Med. recs. at Ex. 4, p. 3.

On September 21, 1993, at 7:54 p.m., petitioner went to Lafayette Home Hospital Emergency Department, complaining of pain in her medial right leg proximal and distal to her knee. It started at noon that day. She stated it was tender to touch. She was at work and tried to walk the pain out for about 20 minutes. The pain went away and she felt lightheaded as if she would pass out, but she did not. She came to the hospital and felt better. She had a history of phlebitis in her right leg. Her left inner thigh felt like it was on fire. On examination, her gait was normal and her squat was normal. There was no heat or redness on either leg. She was diagnosed with a vasovagal episode and leg pain. Med. recs. at Ex. 8, p. 31.

On September 22, 1993, Dr. Anna L. Welch worked petitioner into her schedule because of pain in her left leg with numbness. She had had trouble off and on for years with both legs and had a history of phlebitis. She had pain and burning in the medial left thigh. She had shortness of breath last night and went to the emergency room. Her deep tendon reflexes were normal. Her left thigh was tender to palpation but not red or warm. Med. recs. at Ex. 6, p. 14.

On September 23, 1993, Dr. Welch noted that petitioner could return to work. *Id.*

On September 27, 1993, Dr. Welch noted petitioner's legs were numb and her feet cold. She had difficulty ambulating and slid down a hill one week ago on her right buttock. She had no deep tendon reflex on the right. Her left leg was cooler than her right leg. *Id.*

On September 29, 1993, petitioner had an MRI of her lumbar spine which was normal except for mild scoliosis and early dehydration of the L5-S1 intervertebral disc due to age. Med. recs. at Ex. 1, p. 13.

On September 30, 1993, she saw Dr. Michael A. Sermersheim, a neurologist, on referral from Dr. Welch, complaining of clumsiness, numbness and weakness of her lower extremities for about 10 days. Med. recs. at Ex. 1, p. 17. Initially she felt it more in the left lower extremity, but she very quickly started experiencing the sensation in both lower extremities. *Id.* She denied any recent illnesses. *Id.* She had never experienced this sensation before in her life. She had never had any other transient neurologic deficits, specifically no visual disturbances, numbness and tingling in the upper extremities, or personality changes. She was basically healthy and had no significant health problems in the past. *Id.*

On October 1, 1993, petitioner had a nerve conduction study and right peroneal F-wave latency test. Petitioner had complained of 10 days of numbness and tingling in her lower extremities. The study was essentially normal. Dr. Sermersheim stated she had mild delay in the posterior tibial distal latency which was of uncertain clinical significance. There was no suggestion of peripheral neuropathy or Guillain-Barré Syndrome in the study. Med. recs. at Ex. 8, p. 27.

On October 14, 1993, petitioner had a brain MRI which was abnormal due to increased T2 signal in the posterior parietal white matter bilaterally and in the medial left brachium pontis. The primary consideration would be MS. Med. recs. at Ex. 1, p. 15.

On October 20, 1993, Dr. Sermersheim wrote a letter to Dr. Welch to update her on petitioner. Petitioner's lumbar puncture and brain MRI were most consistent with the diagnosis of MS. Med. recs. at Ex. 1, p. 3.

On October 13, 1994, petitioner saw Dr. Catherine I. Hatvani who, in reviewing petitioner's history, stated that petitioner had MS with some involvement of the lower

extremities and not much involvement of her vision or upper extremities. Med. recs. at Ex. 16, p. 27. She had headaches associated with tension. She had tension and pain in the back of the neck associated with work-related tension. *Id.*

On December 17, 1999, petitioner saw Dr. Hamid S. Hamdi, a neurologist, complaining of sudden onset of loss of vision in her left eye, decreased visual acuity, and burning sensations and hyperesthesias in both lower extremities. On examination, Dr. Hamdi did not see any relative afferent pupillary defect. The fundi appeared normal on the left side. The right side showed some atrophy. Petitioner had a patchy loss of sensation in all extremities. Her strength, tone, and deep tendon reflexes were normal. His impression was left optic neuritis. Med. recs. at Ex. 17, p. 10.

On December 17, 1999, at Lafayette Home Hospital, Dr. Hamdi wrote that petitioner had a history of MS diagnosed in 1993 when she presented with right optic neuritis. However, no record in 1993 diagnosed petitioner with right optic neuritis. Med. recs. at Ex. 17, p. 16.

On January 25, 2000, petitioner had a brain MRI which was compared to the MRI she had on October 24, 1993. (That should be October 14, 1993.) Dr. Douglas M. Dunco's impression was interval decrease in the left bracium pontis signal abnormality with stable deep white matter foci of signal abnormality in the parietal regions and with new lesions in the centrum semiovale bilaterally, with an acute lesion in the temporooccipital region. The findings were consistent with MS. Med. recs. at Ex. 17, p. 15.

On September 29, 2000, petitioner suffered cardiac arrest and associated hypoxia with memory and other cognitive difficulties following the cardiac arrest. Med. recs. at Ex. 12, p. 24.

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

In Werderitsh v. Secretary of HHS, No. 99-310V, 2006 WL 1672884 (Fed. Cl. Spec. Mstr. May 26, 2006), the undersigned ruled that hepatitis B vaccine can cause MS and did so in that case. The onset interval after hepatitis B vaccination was several days to a week after Mrs. Werderitsh's first vaccination. She had symptoms of transverse myelitis a month after her second vaccination. Respondent's expert, Dr. Roland Martin, testified that the appropriate onset interval, if a vaccination were to cause an acute 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, Ms. Garland's onset of MS was September 21, 1993, four months after her third hepatitis B vaccination on May 25, 1993. (Her retinal problems in June 1993 were not related to a neurologic condition and she was never diagnosed with optic neuritis in 1993.) Four months is too long to be a medically-appropriate temporal relationship to posit causation. The undersigned doubts that petitioner will locate an expert to opine that her MS was caused by a vaccination that she received four months earlier.

Petitioner must file an expert report stating that hepatitis B vaccine was a substantial factor in causing her MS by **October 13, 2006** or this case will be dismissed. Petitioner is ORDERED TO SHOW CAUSE why this case should not be dismissed by **October 13, 2006**.

IT IS SO ORDERED.

September 7, 2006
DATE

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