In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 02-1344V
June 12, 2007

CYNTHIA JOHNSON,	*	
	*	
Petitioner,	*	
	*	
v.	*	Hepatitis B vaccinations followed seven weeks later by symptoms diagnosed as encephalomyelitis
	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

ORDER TO SHOW CAUSE[1]

Petitioner filed a petition dated October 7, 2002, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that hepatitis B vaccine administered on October 19, 1999 caused her an adverse reaction of neurological-demyelinating injury, specifically, acute encephalomyelitis, and tinnitus. In petitioner's affidavit (Ex. 26), petitioner

[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.

states that the onset of her symptoms was approximately four weeks later when she had a flu-like illness that lasted about three days with fever, headache, and muscle achiness. P. Ex. 26, p. 2. The medical histories petitioner gave, however, uniformly say onset was seven weeks after her second hepatitis B vaccination. She mentions having a viral illness about the same time

Petitioner received a second hepatitis B vaccination on November 23, 1999. *Id.* Petitioner asserts that about four to six weeks afterward, she had weakness, and heaviness and achiness of both arms. *Id.* This followed with right arm pain and weakness with continual numbness and tingling of three of her fingers. Ultimately she had visual problems and tinnitus. Her brain MRI was normal. A cervical MRI was abnormal. Two of her neurologists, Dr. Panzara and Dr. Botsford, opined that hepatitis B vaccine caused her condition.

Petitioner has given a history of symptoms following the first vaccination to any medical treater. She has consistently given a history of symptoms beginning in mid-January 2000, which would be seven weeks after her second hepatitis B vaccination.

Petitioner is ORDERED TO SHOW CAUSE by **August 31, 2007** why this case should not be dismissed.

FACTS

Petitioner was born on July 30 1951.

On January 11, 1988, petitioner saw her doctor with probable early right otitis media. Med. recs. at Ex. 36, p. 1. She had tender anterior cervical lymphadenopathy. *Id.*

On April 12, 1988, petitioner saw physician's assistant E. Caton, complaining of stiffness in her neck and pain in the back of her neck for the prior three or four days. She had been under

a lot of stress and strain. Her father had recently died. It was painful to hyperextend or rotate her neck. She had pain on swallowing occasionally. *Id.*

On April 9, 1991, petitioner saw Dr. Keith D. Jorgensen, an ear, nose, and throat specialist, because of dizzy spells since December 1990. Med. recs. at Ex. 7, p. 4. Audiological evaluation showed a high frequency sensory hearing loss in the left ear to about 30dB. *Id.*

On April 11, 1991, Dr. Jorgensen wrote a letter to Dr. Michael Romanowsky. His impression was possible hydrops and inhalant allergy. He put petitioner on salt restriction, fat and spicy food restriction, decreased caffeine and alcohol, and prescribed Meclizine 12.5 mh. Med. recs. at Ex. 10, p. 5.

On October 19, 1999 and November 23, 1999, petitioner received hepatitis B vaccine. Med. recs. at Ex. 1, p. 1.

On February 28, 2000, petitioner saw her doctor, complaining of about six weeks of right arm pain and numbness in her first, second and third fingers, putting onset in mid-January 2000. Med. recs. at Ex. 12, p. 4. She felt occasional weakness. The doctor diagnosed her with paresthesias/dysesthesias in the right hand consistent with a C-6 distribution with the thumb, index, and third fingers, and the lateral forearm, progressing proximally. *Id.*

On March 8, 2000, petitioner saw Dr. Jack F. Bowers, an ophthalmologist. Med. recs. at Ex. 4, p. 11. Petitioner had blurriness of vision in her left eye for about one week. She had a numb right arm that began six weeks earlier (the third week of January). *Id.*

On March 15, 2000, petitioner had a brain MRI done because of numbness in the shoulder and the middle of the right arm to the right hand with cloudiness of vision of the left

eye. Med. recs. at Ex. 3, p. 4. Her MRI was normal. There was no evidence of demyelination. *Id.*

On March 18, 2000, petitioner had an MRI done of her cervical spine with gadolinium because of dysthesias in the right hand with clouded vision of the left eye for the last six weeks, putting onset at the end of January 2000. Med. recs. at Ex. 3, p. 5. Petitioner had degenerative changes of the cervical spine with a tiny central disc herniation at C6-C6. Med. recs. at Ex. 3, p. 6. She also had several foci of non-enhancing, non-expansile increased T2 signal in the spinal cord. They very likely reflected a demyelinating process, according to Dr. Arthur Zerbey. *Id.*

On March 22, 2000, petitioner saw Dr. Michael Panzara, a neurologist, with Dr. Scott Plotkin for an opinion on possible MS. Petitioner had progressive onset of paresthesias in the left upper extremity and blurry vision in her left eye. She had a hepatitis B vaccination several weeks before the onset of her symptoms. Dr. Panzara diagnosed petitioner with encephalomyelitis. The vaccine might or might not be related but it was possible. Med. recs. at Ex. 16, p. 12. Dr. Plotkin describes petitioner as having no significant medical history who noted the onset of right arm numbness eight weeks previously. It began in her neck and radiated down to her first, second, and third fingers. It was exacerbated in the shower. Med. recs. at Ex. 16, p. 13. Three and one-half weeks previously, she had onset of blurry vision in her left eye. Her ophthalmological examination was normal without evidence of optic neuritis. *Id.* Dr. Plotkin diagnosed petitioner with both clinical and radiologic evidence of demyelinating disease of her spinal cord. He proposed a tentative diagnosis of transverse myelitis. Med. recs. at Ex. 16, p. 14.

On April 6, 2000, petitioner saw Dr. Peter J. Grillo, a neurologist. Med. recs. at Ex. 3, p. 7. The history petitioner gave was that she developed aching in her arms in January 2000. She

began to have some shooting pain from the right shoulder to the right hand with some feeling of numbness at the thumb, index finger, and middle finger. She had occasional discomfort in the right leg. She had a surging sensation briefly. About a month previously (early March 2000), petitioner began to have visual symptoms in the left eye. She noted blurring and dimness of color. All her symptoms worsened in a hot shower. She recalled having a viral illness in November, several weeks before the onset of her symptoms. She also had a vaccination against hepatitis B at the same time. Her optic fundi showed sharp disk margins. *Id.* Dr. Grillo supported the diagnosis of TM. Med. recs. at Ex. 3, p. 8.

On April 13, 2000, petitioner had blood drawn which showed a positive hepatitis B surface antigen antibody, rating 11.0 when 10.0 or greater indicated immunity. Med. recs. at Ex. 1, p. 4.

On May 4, 2000, petitioner saw Dr. Daniel R. Botsford, a neurologist. Med. recs. at Ex. 4, p. 2. She recalled having a flu-like illness or viral-like illness after receiving hepatitis B vaccine. She had a booster vaccination on November 23, 1999. Toward the end of January 2000, she began experiencing heaviness in both arms with aching and numbness radiating to the first three digits of her right arm. On March 3, 2000, she became aware of color desaturation in her left eye. A cervical spine MRI showed three demyelinating lesions between C3 and C6. Since April 25, 2000, she has had some pain between her shoulders and some resurgence of paresthesias in her back and neck and sometimes into her right leg and arm of 30-60 seconds duration. *Id.*

On September 15, 2000, petitioner had an MRI of her brain done because of possible optic neuritis in her left eye. Med. recs. at Ex. 16, p. 6. She had non-enhancing increased T2

signal within the cervical cord at the C2 to C5 levels and left optic nerve as it entered the optic foramen. The findings were suggestive of MS with left optic neuritis. *Id.*

On September 19, 2000, petitioner saw Dr. Panzara for follow-up. Med. recs. at Ex. 12, p. 17. Motor examination revealed normal bulk and town. Her power was 5/5 throughout. *Id.* Dr. Panzara's assessment was that petitioner appeared to be recovering very well from her episode of encephalomyelitis post-vaccination. Med. recs. at Ex. 12, p. 18.

On December 5, 2000, petitioner saw Dr. Jorgensen regarding her history of tinnitus. Med. recs. at Ex. 7, p. 1. Petitioner had visited the office in 1991 for dizzy spells. On November 18, 2000, petitioner began having tinnitus in the right ear. The right ear felt full. She was noted to have a right ear infection. Petitioner had an audiogram in 1991 which revealed similar asymmetry of her hearing at 4000 Hz. *Id.*

On January 8, 2001, petitioner had an auditory brainstem evoked response study which was normal bilaterally providing no evidence of retrocochlear pathology for either ear. Med. recs. at Ex. 7, p. 5.

On January 9, 2001, petitioner returned to Dr. Jorgensen, having had an ABR the day before which was entirely normal. Med. recs. at Ex. 7, p. 3. There was no evidence of retrocochlear pathology for either ear. Dr. Jorgensen's impression was tinnitus, probably post-vaccination and encephalomyelitis-related. *Id.*

On May 2, 2001, petitioner saw Dr. Robert A. Levine, an eye and ear specialist. Med. recs. at Ex. 11, p. 18. Petitioner developed right upper-extremity paresthesias in January 2000. She had hepatitis B vaccine in October 1999 and in November 1999. In February 2000, she developed decreased vision in her left eye. In March 2000, she had a brain MRI which was

unremarkable but a cervical spine MRI showed abnormality between C3 and C6, at the level of the posterolateral right spinal cord, just above the C4-5 level. A third lesion was in the C5 level. In March 2000, Dr. Panzara noted a desaturation for the left eye and six beats of clonus at the right ankle. In September 2000, petitioner had another cervical MRI and the same lesions were seen but felt to be less edematous. A brain MRI showed some abnormality consistent with left optic nerve demyelination. Visual evoked potentials were done in July 2000 and noted a delay consistent with optic nerve demyelination on the left. *Id.* On November 9, 2000, petitioner irritated her ear canal with a steel nail file, but had no persistent symptomatology. On November 18, 2000, she developed unilateral right tinnitus and had some fullness of her right ear with achiness. She was reevaluated on November 24, 2000 and felt to have otitis media of the right ear and treated with Augmentin. Three days later, her otitis media resolved. She described chronic upper cervical and right trapezius and periscapular pain. *Id.* Dr. Levine found the etiology of petitioner's right ear tinnitus uncertain and could be multifactorial. Med. recs. at Ex. 11, p. 19. Because she had demyelinating lesions in her right posterolateral mid-cervical region and diminished vibratory sensation of the lower extremities, it was possible that the demyelinating cervical lesion might in some way relate to her unilateral right tinnitus. *Id.*

On May 31, 2001, petitioner saw Dr. Richard Straub, an orthopedic surgeon. Med. recs. at Ex. 18, p. 1. She had a long history of a reaction to a hepatitis vaccine which caused some neurologic complications. She was in physical therapy for some neuralgia and noted some crepitance in the area of her scapular thoracic region on the right. She had full range of motion of the shoulder without pain. She had a lipoma there. *Id.*

On February 20, 2002, petitioner had an MRI of her brain done. Med. recs. at Ex. 17, p. 2. Her MRI was essentially normal. It was not significantly different than the MRI of March 26, 2001. *Id.*

On February 21, 2002, petitioner had an MRI of her cervical spine done. Med. recs. at Ex. 17, p. 3. There was no evidence of new abnormal foci of increased signal in the cervical spinal cord. The lesions seen on the prior study were somewhat less conspicuous on this study. *Id.*

On February 22, 2002, petitioner saw Dr. Panzara for follow-up of her post-vaccination encephalomyelitis. Med. recs. at Ex. 17, p. 1. She did not have any new symptoms. *Id.*

On October 9, 2002, petitioner saw Dr. Peter Degnan for an integrated medicine consultation. He suggested vitamins. Med. recs. at Ex. 9, p. 6.

On March 19, 2003, petitioner had another MRI of her brain done. Med. recs. at Ex. 15, p. 2. She had no significant white matter abnormality or abnormal enchancement. There was no change from the February 20, 2002 brain MRI. *Id.*

On March 21, 2003, petitioner saw Dr. Panzara for a follow-up of her post-vaccination encephalomyelitis. Med. recs. at Ex. 15, p. 1. She remained stable after the prior episode. Her MRI and examination did not suggest multiple sclerosis (MS). *Id.*

On July 16, 2003, petitioner had an MRI done of her thoracic spine with and without contrast. Med. recs. at Ex. 21, p. 9. It was normal. Med. recs. at Ex. 21, p. 10.

On March 8, 2004, petitioner had an MRI of her cervical spine done. Med. recs. at Ex. 25, p. 3. She had faint increased signal within the spinal cord at C3-4 which was unchanged

since the last examination of July 2003. The abnormal spinal cord foci at C4 and C5 on the July 2003 examination was not apparent on the present examination. *Id.*

Also on March 8, 2004, petitioner had an MRI of her brain done. Med. recs. at Ex. 25, p. 4. She had a normal brain MRI without significant change since her last examination of February 2002. *Id.*

On April 9, 2004, petitioner saw Dr. Panzara for follow-up. Med. recs. at Ex. 25, p. 1. She was stable with fluctuations referred to her cervical spinal cord lesions. *Id.*

On May 9, 2005, petitioner had a brain MRI done. Med. recs. at Ex. 31, p. 4. It was normal. *Id.*

Also on May 9, 2005, petitioner had an MRI done of her cervical spine. *Id.* There was no evidence of a new lesion. The lesions seen did not enhance. Med. recs. at Ex. 31, p. 5.

On May 19, 2005, petitioner saw Dr. Tanuja Chitnis. Med. recs. at Ex. 31, p. 2. She had a single episode of demyelination following hepatitis B vaccine. She received her first vaccination in October 1999 and her second in November 1999. She stated that, in January 2000, she began experiencing electrical-like sensations or surges in her right hand. In February 2000, she experienced blurry vision in her left eye and subsequent ringing in her right ear. In April 2000, she had myoclonic jerks on the right side. In 2003, she had urinary urgency but this was related to infection. Dr. Panzara thought petitioner had ADEM. Family history was positive for MS and a male paternal cousin was recently diagnosed with MS. *Id.* Dr. Chitnis's impression was clinically isolated syndrome possibly related to hepatitis B vaccination. Med. recs. at Ex. 31, p. 3. Petitioner's symptoms were stable. Her complaints of cervical muscle strain and spasm were largely unrelated to her disease. She had no evidence of MS. *Id.*

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, 956 F.2d, at 1149. Mere temporal association is not sufficient to prove causation in fact. Hasler v. US, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984).

Petitioner must show not only that but for the vaccine, she would not have had encephalomyelitis or ADEM, but also that the vaccine was a substantial factor in bringing about

her encephalomyelitis or ADEM. 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 Omnibus proceeding did not deal with ADEM. However, MS is somewhat similar being lesions developing over space and time instead of just one episode as in petitioner's case.

In the Omnibus proceeding, 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. *Id.* at *18.

In the instant action, petitioner's onset of demyelination was seven weeks after her second hepatitis B vaccination. Her history to two of her doctors that she had a flu-like or viral illness at the same time as her second hepatitis B vaccination, although occurring within one month of her first hepatitis B vaccination, is too vague a description to permit a diagnosis of a neurologic reaction to her first hepatitis B vaccination. Petitioner did not give any doctor a description of the type of symptoms she described to her doctors starting in February 2000 when she described this flu-like or viral illness occurring in November 1999. Thus, it would be a reach to say that this case involves positive rechallenge. Moreover, petitioner had no symptoms for seven weeks after her second hepatitis B vaccine and never claimed she did.

Although the Federal Circuit in Capizzano (440 F.3d at 1326) emphasized the importance of the opinions of treating physicians, the physicians in the instant action always couched their opinion of post-vaccinal encephalomyelitis as a possibility.

Petitioner is ORDERED TO SHOW CAUSE why this case should not be dismissed by **August 31, 2007.**

IT IS SO ORDERED.

June 12, 2007
DATE

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