In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 99-577V
July 30, 2007
Not to be Published

CHARLOTTE A. MANN,	*	
	*	
Petitioner,	*	
v.	*	Entitlement; hepatitis B vaccination;
	*	onset four years later of vertigo; not MS;
SECRETARY OF THE DEPARTMENT	*	no proof vaccination causes vestibular
OF HEALTH AND HUMAN SERVICES,	*	dysfunction four years later
	*	
Respondent.	*	

Clifford J. Shoemaker, Vienna, VA, for petitioner.
Linda S. Renzi, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION[1]

Petitioner filed a petition on August 4, 1999, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that hepatitis B vaccinations administered in 1991 and 1994 caused her unspecified injury.

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[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 subsequently alleged multiple sclerosis (MS). Dr. Freedman had the impression, however, that petitioner had a vestibular dysfunction and noted there were no obvious demyelinating lesions noted in her brainstem in an MRI dated July 29, 1998.

On April 10, 2007, the undersigned issued an Order to Show Cause for petitioner to show by June 1, 2007 why this case should not be dismissed. On June 1, 2007, petitioner orally moved for an extension of time to respond to the Order to Show Cause, which the undersigned granted until July 2, 2007. On July 2, 2007, petitioner filed a Status Report stating she decided to file for a Motion for Judgment on the Record. Petitioner's counsel was waiting for a signed permission from petitioner to file for judgment on the record.

On July 30, 2007, petitioner filed a Motion for Judgment on the Record, stating, "Petitioner does not feel that she can prove causation, as she cannot find an expert to support causation in her case."

FACTS

Petitioner was born on April 23, 1937.

The medical records show that petitioner received hepatitis B vaccinations on October 16, 1991, November 13, 1991, and May 13, 1991 (although that logically should be May 13, 1992). Med. recs. at Ex. 19, p. 1. Petitioner declined to take a fourth hepatitis B vaccination on June 25, 1992. Med. recs. at Ex. 19, p. 2. However, on May 3, 1994, petitioner received another hepatitis B vaccination. Med. recs. at Ex. 19, p. 3. Petitioner notes on this record that she also received hepatitis B vaccine on July 21, 1994 and November 21, 1994, although she does not have any record of these other vaccinations. *Id.*

During 1993 and 1994, petitioner was treated for depression. Med. recs. at Ex. 19, pp. 5, 7, 8. The medical records show that petitioner had two attacks of vertigo, the first in January 1998 and the second June 6, 1998. Med. recs. at Ex. 19, p. 11. She had a history of mitral valve prolapse. *Id.* Her history included hypertension, depression, early menopause at 24, hypercholesterolemia, D & C, a long history of bifrontal headaches especially in spring, and H pylori infection. Med. recs. at Ex. 19, p. 16. On June 22, 1998, her deep tendon reflexes were active (2+) and symmetric throughout, her muscle bulk and strength were normal, no pathologic reflexes were elicited, tone was normal, and pinprick, vibration, and toe position sense modalities were all normal. Med. recs. at Ex. 19, p. 17. Dr. William L. Power's impression was possible benign positional vertigo. Med. recs. at Ex. 19, p. 18.

On July 7, 1998, petitioner had an electronystagmography (ENG) evaluation which showed a mild to moderate bilateral high frequency sensorineural hearing loss. Med. recs. at Ex. 19, p. 19.

On July 29, 1998, petitioner had an MRI of her brain which showed focal areas of abnormal T2 signal within the periventricular white matter of both sides of the cerebral hemisphere. Clinical possibilities included small vessel ischemia vs. a demyelinating process. Med. recs. at Ex. 19, p. 20. A lumbar puncture done on August 20, 1998 showed positive oligoclonal bands. Med. recs. at Ex. 19, p. 23.

On August 24, 1998, Dr. Power diagnosed petitioner with MS based on the MRI which showed lesions, some of which were present in the corpus callosum, which is common in patients with MS, as well as her mild elevation of IgG synthesis rate and IgG index and the presence of oligoclonal bands in her spinal fluid. Med. recs. at Ex. 19, p. 25.

Petitioner had an episode of burning in the upper extremities and nausea but no vertigo on September 5, 1998. Med. recs. at Ex. 19, p. 28. Dr. Don F. Seelinger opined that her findings were consistent with demyelinating disease, vestibular in origin. Med. recs. at Ex. 19, p. 26.

On October 9, 1998, petitioner saw Dr. Freedman again. Med. recs. at Ex. 18, p. 8. The vestibular complaints had not returned. She complained of diffuse aches in her extremities over several years. He recommended she see Dr. Ford. *Id.*

On October 22, 1998, petitioner saw Dr. Michael Freedman. Med. recs. at Ex. 19, p. 28. She told him that she had general fatigue and an achy tired feeling for about 10 years (putting onset in 1988, or three years before her first hepatitis B vaccinations). She had been on antidepressants, most recently Prozac. *Id.* Dr. Freedman's impression was that petitioner had vestibular dysfunction which was probably a peripheral problem. There were no obvious demyelinating lesions noted in the brainstem on the MRI done on July 29, 1998. Med. recs. at Ex. 19, p. 29.

On November 9, 1998, Dr. Freedman did somatosensory evoked responses on petitioner. Med. recs. at Ex. 18, p. 9. Petitioner had normal SSEP from the upper extremities. *Id.* On that date, he also performed BAER on petitioner's ears. The result was normal. Med. recs. at Ex. 18, p. 10.

On January 11, 1999, petitioner saw Dr. Corey C. Ford, a neurologist, who concluded she possibly had MS. Med. recs. at Ex. 19, p. 32. There were no objective signs of neurological disability on examination. *Id.* Evoked potential studies by Dr. Freedman were negative. Petitioner denied any problem with balance, weakness, sensory loss, double vision, or loss of vision. Med. recs. at Ex. 19, p. 31. Her past medical history was unremarkable. *Id.* It was

difficult to date the findings on her MRI scan, and it was conceivable that they had been longstanding and static. Med. recs. at Ex. 19, p. 32.

On October 21, 1999, petitioner saw Dr. Ford again. She had a repeat MRI scan of her brain done and compared to the earlier study in July 1998. The radiologist felt there was a slight increase in the number of right high signal lesions on the most recent MRI, but there was no gadolinium enhancement suggesting any active disease process. Med. recs. at Ex. 3, p. 3. Petitioner continued to have recurrent episodes of vertigo with nausea and vomiting. She had a significant bladder frequency with recurrent urinary tract infection worsening to pyelonephritis. She denied any problems with vision, weakness, balance, numbness, or sensory disturbances. *Id.* Motor testing showed full power in all extremities. Her reflexes were normal and symmetric with flexor plantar responses. She had no incoordination or ataxia. Sensory testing showed normal light touch and vibration. Med. recs. at Ex. 3, p. 4. Dr. Ford's impression was that petitioner might have Meniere's disease. He could not relate the vertigo to petitioner's MRI and spinal fluid findings. There were no symptoms that could be linked to a definite diagnosis of MS. Dr. Ford was unsure about labeling petitioner with MS. It would be premature to begin MS therapy because petitioner's clinical picture did not fit a diagnosis of MS. The MRI scan findings could be explained on the basis of normal aging (petitioner was 62 at the time), and the spinal fluid findings were not diagnostic of MS and were occasionally found in patients with other illnesses. *Id.* He recommended petitioner see an ENT doctor to determine if she had Meniere's. *Id,*

On February 27, 2000, petitioner saw Dr. Karl L. Horn, an ENT. Med. recs. at Ex. 9, p. 2. Petitioner complained of episodic dizziness which she described as dysequilibrium. Dr. Horn

said the most like diagnosis was acute vestibular neuronitis with residual dysequilibrium. He placed her on home vestibular exercises. Med. recs. at Ex. 9, p. 3.

On April 11, 2000, Dr. Horn noted that petitioner's dizziness had resolved, her hearing was stable, and she had occasional tinnitus. Dr. Horn believed her dizziness was almost certainly related to acute vestibular neuronitis rather than a central nervous system problem. Med. recs. at Ex. 9, p. 4.

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

There are two problems in this case. The first is that, although petitioner may have had lesions in her brain consistent with MS, they are also consistent with the aging process. A subsequent interpretation was that the MRI did not show lesions. Her clinical condition has never reflected MS and her doctors, although initially positing that she might have MS, backed away from that diagnosis to decide she instead had a vestibular dysfunction, not a central nervous system condition. Thus, the findings in the Omnibus proceeding dealing with hepatitis B vaccine and demyelinating diseases appear not to apply to petitioner.

The second problem in this case is one of onset. Petitioner has never had a clinical onset of MS although her first vertiginous episode in January 1998 might putatively put onset at four years after her hepatitis B vaccination if the vertigo were diagnostic of MS which Dr. Freedman and Dr. Ford decided it was not.

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 MS and did so in that case. However, the onset interval after vaccination in Werderitsh was one month. Dr.

Roland Martin, respondent's expert, testified in Werderitsh that an appropriate temporal interval for an immune reaction would be a few days to three to four weeks.

Petitioner's onset of vestibular dysfunction four years after she received hepatitis B vaccine is beyond the appropriate temporal interval for an immune reaction, if petitioner could prove that hepatitis B vaccine causes vestibular dysfunction.

Petitioner has never filed an expert report stating that hepatitis B vaccine causes vestibular dysfunction four years later. Petitioner has never shown clinical signs of MS. Petitioner now admits that she cannot find expert medical testimony to support her allegations. Petitioner has failed to make a prima facie case of causation in fact.

CONCLUSION

Petitioner's petition is dismissed with prejudice. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment in accordance herewith.[2]

IT IS SO ORDERED.

July 30, 2007
DATE

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

[2] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party's filing a notice renouncing the right to seek review.