

OFFICE OF SPECIAL MASTERS

No. 99-435V

October 2, 2006

\*\*\*\*\*

STEPHANIE PHIPPEN,

\*

\*

Petitioner,

\*

\*

v.

\*

Hepatitis B vaccine followed  
one week later by numb feet;  
cervical myelopathy; causation?

\*

SECRETARY OF THE DEPARTMENT OF  
HEALTH AND HUMAN SERVICES,

\*

\*

\*

Respondent.

\*

\*\*\*\*\*

**ORDER TO SHOW CAUSE**<sup>1</sup>

Petitioner filed a petition on July 2, 1999, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that she received hepatitis B vaccine in March 1994 and had an adverse reaction. Petition, ¶ 2. The medical records show that petitioner's first hepatitis B vaccination was administered on February 28, 1994. Med. recs. at Ex. 2, p. 7. She

---

<sup>1</sup> 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.

received MMR vaccine on March 15, 1994. Med. recs. at Ex. 2, p. 6. She was later diagnosed with cervical myelopathy.

On March 16, 1994, petitioner saw a chiropractor for tingling in her feet and legs which began one and one-half weeks earlier (putting onset at March 5<sup>th</sup> or 6<sup>th</sup>). Med. recs. at Ex. 4, p. 5.

On March 28, 1994, petitioner phoned her employer's health department to say she had noticed progressive tingling in both feet and then in her hand. The tingling's onset had been present for about three weeks (putting onset at March 7, 1994). Med. recs. at Ex. 2, p. 8.

On April 6, 1994, petitioner saw Dr. Ronald A. Cooper, a neurologist, because of paresthesias in her lower extremities over the prior four to five weeks, putting onset at the beginning of March 1994, and a Lhermitte's<sup>2</sup> phenomena of more recent occurrence. Her neurological examination was essentially normal, except for some reflex asymmetry and a positive Lhermitte's sign. Med. recs. at Ex. 15, p. 14. About five weeks previously, petitioner noted some numbness in her feet that continued. *Id.* She inquired if she could get the second hepatitis B vaccination, and Dr. Cooper said yes on April 7, 1994. Med. recs. at Ex. 15, p. 7.

On April 7, 1994, an MRI of petitioner's brain showed multiple focal, punctate lesions of high signal intensity in the left middle cerebellar peduncle, right pons, and periventricular white matter adjacent to the frontal horns and atria of both lateral ventricles. These lesions were most consistent with demyelinating disease. Med. recs. at Ex. 15, p. 8.

---

<sup>2</sup> Lhermitte's sign is "the development of sudden, transient, electric-like shocks spreading down the body when the patient flexes the head forward; seen mainly in multiple sclerosis but also in compression and other diseases of the cervical cord." Dorland's Illustrated Medical Dictionary, 30<sup>th</sup> ed. (2003) at 1700.

Also on April 7, 1994, an MRI of petitioner's cervical spine showed focal swelling at the C2 and C3 levels. Med. recs. at Ex. 15, p. 9.

On April 9, 1994, Dr. Moore noted the results of the MRI scans suggesting a diffuse demyelinating process. This was the only attack petitioner had had and, therefore, Dr. Moore could not call it MS. Petitioner was prescribed Prednisone. Med. recs. at Ex. 15, p. 12.

On April 11, 1994, petitioner received her second hepatitis B vaccination. Med. recs. at Ex. 2, p. 7.

On May 10-12, 1994, petitioner was neurologically evaluated at the Mayo Clinic. Dr. Emre Kokmen, a neurologist, diagnosed petitioner with subacute inflammatory demyelinating central nervous system disorder. Med. recs. at Ex. 16, p. 4.

It appears that petitioner did not take the third hepatitis B vaccination because she signed a release for her employer on September 28, 1994 refusing the vaccination (although a prior medical record said she received the third hepatitis B vaccination on August 27, 1994). Cf. Med. recs. at Ex. 2, p. 7 with pp. 12 and 14.

One week is an appropriate temporal period for an adverse demyelinating reaction to occur after hepatitis B vaccine.

Respondent is ORDERED TO SHOW CAUSE by **November 3, 2006** why this case should not be in damages.

### **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 (6<sup>th</sup> Cir. 1983), *cert. denied*, 469 U.S. 817 (1984).

Petitioner must show not only that but for the vaccine, she would not have had cervical myelopathy, but also that the vaccine was a substantial factor in bringing about her cervical myelopathy. 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. February 24, 2006), the undersigned ruled that hepatitis B vaccine can cause transverse myelitis (TM), and did so in that case. The onset interval of TM after petitioner’s first and second hepatitis B vaccinations in Stevens was eight or nine days. 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, super, at \*15.

Here, petitioner's onset of numbness began five, six, or seven days after her first hepatitis B vaccination. This is an appropriate onset interval for causation.

Respondent is ORDERED TO SHOW CAUSE why this case should not be in damages by **November 3, 2006**.

**IT IS SO ORDERED.**

October 2, 2006

DATE

s/ Laura D. Millman

Laura D. Millman

Special Master