OFFICE OF SPECIAL MASTERS
No. 99-432V
September 29, 2006

JACINDA S. FISHER,	*	
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Petitioner,	*	
	*	
v.	*	Hepatitis B vaccine followed
	*	two months later by optic
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	neuritis and MS; causation?
	*	
Respondent.	*	

ORDER TO SHOW CAUSE[1]

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 on July 13, 1992, August 13, 1992, and January 23, 1993. Petition, ¶ 2. Proof of vaccination was filed as petitioner's exhibit 13. Her adverse reaction was ultimately described as multiple sclerosis (MS),

[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.

whose onset was presumably in October 1993, two months after her second hepatitis B vaccination, when she was diagnosed with optic neuritis.

Petitioner has a lengthy pre-vaccination history, including episodes of numbness beginning in 1986 (med. recs. at Ex. 14, p. 5) and continuing in 1987 (med. recs. at Ex. 7, p. 4).

On February 15, 1993, petitioner saw her doctor, complaining of pain and cramps in her left leg for about two weeks. Med. recs. at Ex. 14, p. 24. The leg cramped up at night and had been weak and gave way over the prior two weeks intermittently. Petitioner had lost sight in her left eye a few weeks previously, went to see Dr. Gillespie who gave her some drops and then went back and he gave her more drops. She went to Dr. Martin for a second opinion and he told her she had optic neuritis. However, her vision had come back gradually. Now she was beginning to get a few symptoms in the right eye as well. She continued to be weak in the left arm and left leg. *Id.*

On February 15, 1993, petitioner saw Dr. Martin, with poor vision in her left eye which could possibly be optic neuritis. Med. recs. at Ex. 5, p. 2.

On February 16, 1993, petitioner returned to her doctor. She had gotten out of the bath tub that morning and her left leg gave way. The doctor then spoke to Dr. Gerry D. Martin, an ophthalmologist, about petitioner's eye "and he said when he did check it in October [1992], her left eye had elevated disc with what he considered to be probably optic neuritis and vision was 2200." She also had a pupil that did not react (Marcus Gunn pupil), which had resolved. The doctor made an appointment for petitioner to see a neurologist (Dr. Spicuzza) on March 8, 1993 and also to have a head MRI. Med. recs. at Ex. 14, p. 25.

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On February 17, 1993, petitioner had a brain MRI after possible optic neuritis in her left eye which was transient, and left leg weakness. P. Ex. 1, p. 22. Petitioner had two or three small focal areas of increased signal on the first and second echo T2 images in the deep white matter primarily in the left hemisphere and one in the periventricular region. Dr. James E. Nathe stated that these findings were subtle and minimal at best, but could be associated with demyelinating disease, such as MS. As for the optic nerves, on the right side in one section only, there was a little increased signal intensity in the right optic nerve. Dr. Nathe suspected this was due to partial volume effect rather than a true focal enhancement of the right optic nerve, and therefore, the optic nerves were very likely within normal limits. *Id.*

Petitioner is ORDERED TO SHOW CAUSE by **November 3**, **2006** why this case should not be dismissed.

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 of MS after petitioner's second hepatitis B vaccination in Werderitsh was one month (with onset of possible optic neuritis as the beginning of her MS occurring six days after her second hepatitis B vaccination). 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 v. Secretary of HHS, No. 99-594V, 2006 WL 659525, at *15 (Fed. Cl. Spec. Mstr. Feb. 24, 2006).

Here, petitioner's onset of numbness began in 1986, six years before her hepatitis B vaccinations. However, it would be difficult at present to know if this were the onset of her MS.

The medical records petitioner filed show that she saw the ophthalmologist Dr. Green in October 1992, two months after her second hepatitis B vaccination, for optic neuritis. Assuming this was the onset of petitioner's MS, the time frame of two months exceeds the medically accepted period to ascribe causation.

Petitioner must file a medical expert report supporting that hepatitis B vaccine caused petitioner's MS two months later. Petitioner is ORDERED TO SHOW CAUSE why this case should not be dismissed by **November 3, 2006**.

IT IS SO ORDERED.

September 29, 2006
DATE

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