

OFFICE OF SPECIAL MASTERS

No. 99-466V

June 22, 2006

HARVEY GRUBER,

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Petitioner,

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v.

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Hepatitis B vaccination followed six and ½ months later by optic neuritis; MS diagnosed two years later; petitioner unlikely to prevail

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,

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Respondent.

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ORDER TO SHOW CAUSE¹

Petitioner filed a petition on July 16, 1999, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that hepatitis B vaccinations administered on February 6, 1997, March 11, 1997, and April 9, 1997 caused him unspecified injury.

Six and one-half months after his third hepatitis B vaccination, petitioner was diagnosed with optic neuritis. Two years later, petitioner was diagnosed with relapsing multiple sclerosis

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.

(MS). Petitioner is ORDERED TO SHOW CAUSE why this case should not be dismissed by July 31, 2006.

FACTS

Petitioner was born on September 3, 1967. On February 6, 1997, March 11, 1997, and April 9, 1997, he received hepatitis B vaccine, according to the allegations of the petition.

On November 4, 1997, petitioner went to see Dr. Mark J. Kupersmith, Chief of the Division of Neuro-Ophthalmology at New York Eye and Ear Infirmary, for a neuro-ophthalmic evaluation. Med. recs. at Ex. 2, p. 1. Petitioner's onset of a veil-type haze under his left eye occurred 11 days previously (or October 24, 1997, six and one-half months after his third hepatitis B vaccination). This was associated with some left temporal pain and some pain in eye movement, but only in the left eye. The pain was gone, but Mr. Gruber said his vision was still hazy. He had no preceding illness. He had no other common neurologic complaints. Mr. Gruber had an immediate MRI scan which was negative (the MRI was to check whether Mr. Gruber had demyelinating disease). On examination, the left eye was normal except for slight fullness in the disc. Neurological examination showed normal movement, strength, and reflexes. *Id.* His risk of developing MS within five years was 18%. Med. recs. at Ex. 2, p. 2.

On August 16, 1999, petitioner reported occasional paresthesias. His brain MRI was now diagnostic and he had probable relapsing MS. Med. recs. at Ex. 6, pp. 16, 17.

DISCUSSION

This is a causation in fact case. To satisfy his 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, he would not have had optic neuritis and MS, but also that the vaccine was a substantial factor in bringing about his optic neuritis and MS. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

In Werderitsh v. Secretary of HHS, No. 99-319V, 2006 WL _____ (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. Here, the onset interval between Mr. Gruber’s third hepatitis B vaccination and optic neuritis was six and

one-half months (followed two years later with a diagnosis of relapsing MS). Respondent's expert Dr. Martin 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 optic neuritis six and one-half months after his third hepatitis B vaccination is beyond the appropriate temporal interval for an immune reaction.

The undersigned doubts that petitioner will find an expert to provide a report stating that petitioner's third hepatitis B vaccination six and one-half months before the onset of his optic neuritis was the cause of his optic neuritis or of his MS two years later.

Petitioner is ORDERED TO SHOW CAUSE why this case should not be dismissed by **July 31, 2006.**

IT IS SO ORDERED.

DATE

Laura D. Millman
Special Master