

OFFICE OF SPECIAL MASTERS

No. 99-611V

July 7, 2006

WALTER AUGUSTYNSKI,

*

*

Petitioner,

*

*

v.

*

Hepatitis B vaccination with numbness and tingling the next day; is one day too short for causation of MS from vaccine?

*

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,

*

*

*

Respondent.

*

ORDER¹

Petitioner filed a petition dated August 4, 1999, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that hepatitis B vaccine administered on July 29, 1996 caused him unspecified injury (ultimately, petitioner was diagnosed with multiple sclerosis). He had numbness and tingling the day after vaccination, which eventually spread up

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.

his legs. Over two months later, he experienced vision loss in his right eye which was diagnosed as optic neuritis. A brain MRI confirmed he has multiple sclerosis (MS).

FACTS

Petitioner was born on April 14, 1957. On June 24, 1996, he received his first hepatitis B vaccine. Med. recs. at Ex. 6, p. 3. On July 29, 1996, petitioner received his second hepatitis B vaccine. Med. recs. at Ex. 6, p. 8. This record is not a vaccination record, but a “Resurrection Health Care Report of Employee Incident.” In it, petitioner states he had, on the day after he received his second hepatitis B vaccination, tingling, numbness in his feet, and stomach pains. On July 31, 1996, the tingling and numbness spread to his knees and his stomach pain continued. On August 1, 1996, this spread to his thighs. By the end of that week, tingling and numbness spread to his hips and his stomach pain continued. *Id.*

Petitioner went to the Emergency Department of Our Lady of the Resurrection Medical Center on August 7, 1996. He stated he had hepatitis B vaccine on July 29, 1996, and had the onset of a tingling sensation and numbness on July 30, 2006 of both feet gradually involving his upper legs with an episode of abdominal pain. He saw his primary care physician last Saturday (August 3, 1996). Med. recs. at Ex. 1, p. 9. He was told he had no problems, but since August 3rd, he has continued to have intermittent tingling and numbness bilaterally of the lower extremities extending to include his abdomen. Med. recs. at Ex. 1, p. 11.

On August 20, 1996, petitioner saw Dr. Ralph Cabin, who diagnosed him with post-immunization neuropathy. Med. recs. at Ex. 7, p. 2.

On October 23, 1996, petitioner saw Dr. Andrew A. Berman, a neuro-ophthalmologist. Med. recs. at Ex. 2, p. 1. Petitioner stated he had perfect vision until October 9, 1996, when he

could not see well out of his right eye. Petitioner stated he had no antecedent trauma or illness, but had received the first two hepatitis B vaccinations in June and July 1996. The day after his second hepatitis B vaccination on July 29, 1996, he developed lower extremity weakness and paresthesias which a neurologist diagnosed as Guillain-Barre Syndrome. *Id.* Dr. Berman's impression was that petitioner had retrobulbar optic neuritis in his right eye. Med. recs. at Ex. 2, p. 2.

On October 25, 1996, petitioner had a brain MRI done whose result was abnormal, showing multiple tiny high signal lesions in the periventricular white matter, a pattern most likely due to multiple sclerosis. Med. recs. at Ex. 1, pp. 14, 15.

On August 25, 1997, petitioner saw Dr. John A. Vottero. Med. recs. at Ex. 4, p. 1. He stated that he received the second hepatitis B vaccination on July 29, 1996, and the next day, he developed bilateral foot numbness progressing in severity and extending to his knees on the second day, and to his thighs on the third day. Although his initial diagnosis was GBS, that changed to MS after he developed optic neuritis. Dr. Vottero agreed with the MS diagnosis. *Id.*

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 MS, but also that the vaccine was a substantial factor in bringing about his 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 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 after vaccination in Werderitsh was one month. 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 symptoms was one day, consisting of numbness and tingling in his feet, which eventually spread upwards. Over two months later, petitioner

herein experienced optic neuritis. The issue concerning the undersigned is whether petitioner's onset of symptoms of one day is too short for there to be causation of a demyelinating illness such as MS. Petitioner must submit an expert report stating that one day is a medically appropriate temporal period to have causation from a vaccination in order to satisfy the third prong of the Althen criteria. 418 F.3d at 1278.

Petitioner is ORDERED to file an expert opinion in support of one-day causation of MS by **September 1, 2006**.

IT IS SO ORDERED.

DATE

Laura D. Millman
Special Master