

OFFICE OF SPECIAL MASTERS

No. 99-307V

June 22, 2006

PATRICIA RODRIGUEZ, *

*

Petitioner, *

v. *

SECRETARY OF THE DEPARTMENT *

OF HEALTH AND HUMAN SERVICES, *

*

Respondent. *

Hepatitis B vaccination followed two years later by relapsing/remitting MS (a week after a cold); petitioner unlikely to prevail

ORDER TO SHOW CAUSE¹

Petitioner filed a petition on May 14, 1999, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that hepatitis B vaccinations administered on September 17, 1993, November 4, 1993, and May 31, 1994 caused her unspecified injury. Two years after her third hepatitis B vaccination, petitioner was diagnosed with relapsing/remitting

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.

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

FACTS

Petitioner was born on December 6, 1961. On September 17, 1993, November 4, 1993, and May 31, 1994, she received hepatitis B vaccine. Med. recs. at Ex. 1.

On March 25, 1996, she had an upper respiratory infection. Med. recs. at Ex. 5, p. 20. On May 7, 1996, she saw Dr. Anna Fernandez-Maitlin, complaining of numbness in her cheek and tongue, heartburn, and stress. Med. recs. at Ex. 5, p. 13. On May 28, 1996, she complained of a visual problem. Ex. 4, p. 1; Ex. 11, p. 2.

On September 9, 1996, petitioner saw Dr. Enrique J. Carrazana, stating she began to experience numbness in her feet two weeks previously. She may have had a viral infection or a cold a week prior to the onset of her symptoms. Her past medical history was unremarkable. Med. recs. at Ex. 2, p. 36; Ex. 17, p. 96.

On October 17, 1996, Dr. Howard L. Zwibel diagnosed petitioner with relapsing/remitting MS, with onset of sensory and motor complaints in August 1996, preceded by a minor upper respiratory infection. Prior to this, she had no known history of neurologic dysfunction although she had a possible transient blurring in one eye earlier in 1996. Clearly, she had not had any other episodes of neurologic dysfunction. Her past history was negative for serious medical or neurologic illness. Med. recs. at Ex 2, p. 12.

Petitioner's paternal first cousin has MS. Med. recs. at Ex. 7, p. 3.

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. 99-319V, 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 is two years. 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. In petitioner's case, herein, she had an upper respiratory infection one week before onset of her lower extremity numbness. This is an appropriate temporal relationship for causality.

Even if petitioner's onset of MS herein were earlier than her August 1996 upper respiratory infection, it is no earlier than her May 1996 complaints of visual disturbance and tongue and cheek numbness. Whether an earlier upper respiratory infection in March 1996 played a role in causing these complaints is speculative at this point. Her onset of MS is two years after her third hepatitis B vaccination, and two and one-half years after her first two hepatitis B vaccinations.

The undersigned doubts that petitioner will find an expert to provide a report that petitioner's hepatitis B vaccinations, occurring two or more years before her onset of MS, were the cause of her MS, particularly in light of the upper respiratory infection occurring one week before the onset of her MS.

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