

OFFICE OF SPECIAL MASTERS

No. 99-308V

June 22, 2006

\*\*\*\*\*

NICOLE HAMELIN-GARCIA, \*

\*

Petitioner, \*

\*

v. \* Hepatitis B vaccinations

\*

followed by back pain and

SECRETARY OF THE DEPARTMENT OF \* leg numbness; ultimately MS;

\*

perhaps litigative risk

HEALTH AND HUMAN SERVICES, \*

\*

settlement

Respondent. \*

\*

\*\*\*\*\*

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

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 in August and October 1992 caused her unspecified injury, later diagnosed as multiple sclerosis (MS). The undersigned could not find documentation of petitioner's alleged hepatitis B vaccinations, but the medical records indicate onset was within a month of her August 1992 hepatitis B vaccination

---

<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.

and she had leg numbness in October 1992, medically appropriate temporal relationships to indicate causality.

Respondent is ORDERED TO SHOW CAUSE why this case should not proceed to damages by July 31, 2006.

### **FACTS**

Petitioner was born on February 19, 1965. In August and October 1992, she received hepatitis B vaccine, according to the allegations of the petition.

According to a discharge summary from a hospital, dated March 22, 1993, petitioner had lower back pain in August 1992. Med. recs. at Ex. 2, p. 17. According to a record dated July 15, 1994, she began to notice numbness of her left leg in October 1992. Med. recs. at Ex. 4, p. 24. According to a record dated October 27, 1998, petitioner had hepatitis B vaccine and the symptoms started within a month. She had initial numbness from the waist down to the toes and also weakness. (This differs from her prior report in 1994 that she had numbness in her left leg.) Med. recs. at Ex. 11, p. 22.

These are the total records that the undersigned could find to link onset of petitioner's neurologic symptoms to her purported two hepatitis B vaccinations. Petitioner has not submitted her affidavit or proof of vaccinations. The undersigned could not find any records that are contemporaneous to the onset of back pain in August 1992 and of numbness in her left leg in October 1992.

### **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 (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 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. The onset interval after vaccination in Werderitsh was one month. Here, petitioner has

three records that indicate onset was within a month of each alleged vaccination. In August 1992, when she allegedly received her first vaccination, she had back pain. This may or may not be of medical significance to her ultimate MS diagnosis. In October 1992, when she allegedly received the second vaccination, she had numbness in her left leg. 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.

Although these are slim reeds upon which to prove causation, respondent may be amenable to engaging in a litigative risk settlement.

Respondent is ORDERED TO SHOW CAUSE why this case should not go into damages by **July 31, 2006**.

**IT IS SO ORDERED.**

\_\_\_\_\_  
DATE

\_\_\_\_\_  
Laura D. Millman  
Special Master