

OFFICE OF SPECIAL MASTERS

No. 99-645V

July 11, 2006

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CAREN RUBIN,

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Petitioner,

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v.

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Hepatitis B vaccination with  
optic neuritis within 24 hours;  
is that onset too short for  
causation of MS from vaccine?

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SECRETARY OF THE DEPARTMENT OF  
HEALTH AND HUMAN SERVICES,

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Respondent.

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

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 January 24, 1990 caused her unspecified injury (ultimately, petitioner was diagnosed with multiple sclerosis or MS). She had optic neuritis within 24 hours of her third vaccination. This was the first symptom of her MS which was diagnosed two days later.

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<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.

Petitioner is ORDERED TO SHOW CAUSE why this case should not be dismissed by September 1, 2006 unless petitioner files an expert affidavit that hepatitis B vaccine can cause MS within 24 hours of vaccination.

### **FACTS**

Petitioner was born on June 12, 1952. She received hepatitis B vaccine on July 24, 1989, August 21, 1989, and January 24, 1990. Med. recs. at Ex. 2, p. 31. On January 25, 1990, she saw Dr. Bruce J. Gillers with a one-day history of decreased vision in her right eye and an afferent pupillary defect in her left eye. Dr. Gillers diagnosed petitioner with optic neuritis. Med. recs. at Ex. 4, p. 6. Subsequent medical histories state the onset was the day after the third vaccination, but Dr. Gillers was the physician she saw for her optic neuritis and he records that her visual difficulties when he saw her January 25, 1990 were of one day's duration, putting onset on the day of the vaccination. Petitioner states in her affidavit that the onset of her optic neuritis was less than 24 hours after her third hepatitis B vaccination. Med. recs. at Ex. 13, p. 1.

On January 27, 1990, she had an MRI which confirmed inflammation or demyelination of the brain compatible with a diagnosis of MS. Med. recs. at Ex. 4, p. 2.

### **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 (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 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 within 24 hours of vaccination, consisting of optic neuritis. The issue concerning the undersigned is whether petitioner’s onset

of optic neuritis, which was the first clinical sign of her MS, is too short for there to be causation.

Petitioner must submit an expert report stating that onset within 24 hours of vaccination is a medically appropriate temporal period for causation from a vaccination in order to satisfy the third prong of the Althen criteria. 418 F.3d at 1278.

Petitioner is ORDERED TO SHOW CAUSE why this case should not be dismissed by filing an expert opinion in support of causation of MS within 24 hours by **September 1, 2006**.

**IT IS SO ORDERED.**

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DATE

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Laura D. Millman  
Special Master