

OFFICE OF SPECIAL MASTERS

No. 99-592V

June 7, 2006

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EILEEN SCHWANKL, \*

Petitioner, \*

v. \*

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, \*

Respondent. \*

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Time interval between vaccination and injury five months or even a year; P must show cause why case should not be dismissed

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

Petitioner filed a petition on August 4, 1999 under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10 et seq., on her own behalf, ultimately alleging that her third hepatitis B vaccination administered on April 24, 1996 caused her fatigue, dizziness, and decreased and blurred vision five months later, in September 1996, although the medical records establish an

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<sup>1</sup> Because this order to show cause contains a reasoned explanation for the special master's action in this case, the special master intends to post this order to show cause 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.

onset one year later in April or May 1997. This case was suspended with over 60 others cases while the hepatitis B vaccine-demyelinating diseases Omnibus proceeding was concluded. The undersigned has recently concluded those proceedings, ruling that hepatitis B vaccine can cause TM, GBS, CIDP, and MS. Petitioner has never been diagnosed with MS. She does not have TM, GBS, or CIDP.

The undersigned does not believe that petitioner will find an expert witness to support her allegation that hepatitis B vaccine caused her right retrobulbar neuritis or optic neuritis one year or even five months after vaccination. The undersigned ORDERS petitioner to SHOW CAUSE why this case should not be dismissed by July 19, 2006.

#### **FACTS**

Petitioner was born on February 7, 1954. She received her first hepatitis B vaccination on August 29, 1995 and her second hepatitis B vaccination on October 25, 1995. Neither caused her any problem, according to her affidavit. P. Ex. 1. She received her third hepatitis B vaccination on April 24, 1996. According to petitioner's affidavit, five months later in September 1996, she experienced fatigue, dizziness, and loss and blurring of vision. P. Ex. 1. The medical records petitioner submitted do not support petitioner's affidavit that petitioner had fatigue, dizziness, and loss and blurring of vision in September 1996. (Section 13(a)(1) of the Act states that the undersigned may not rule for petitioner based on petitioner's claims alone, unsubstantiated by medical records or medical opinion.)

On May 17, 1997, petitioner went to Itasca Medical Center Emergency Room where she saw Dr. Thomas R. Edwards. She told him that she had vision loss in her right eye that began one week previously (which would put onset at May 10, 1997). Med. recs. at Ex. 5, p. 11. Dr.

Edwards recommended that she see Dr. Chris T. Buntrock, which she did on May 19, 1997. Med. recs. at Ex. 5, p. 14. She told Dr. Buntrock that she had been experiencing decreasing vision in her right eye over the last several weeks which became especially acute on May 17, 1997. (The “last several weeks” would put onset in April 1997.) Thirteen years previously, petitioner developed weakness in one leg which resolved. She experienced some paresthesias recently on the back surface of one of her hands. Dr. Buntrock diagnosed right retrobulbar neuritis and prescribed steroids. *Id.*

Also on May 19, 1997, Dr. Roger A. Ralston, an internist with Grand Rapids Medical Associates, wrote that petitioner had called the office on Saturday, May 17, 1997 to report visual loss in her right eye and she described a week’s worth of intermittent visual symptoms followed by decreasing vision rapidly over hours. Med. recs. at Ex. 7, p. 4. (A “week’s worth” would put onset at May 10, 1997.) The personnel asked her to go to the Itasca Medical Center ER where Dr. T.R. Edwards saw her. Thirteen years previously, she had an episode of left-sided paresthesias including her arm, trunk, and leg. She also had brief difficulty writing with her right hand and noticed right foot drag. Dr. Ralston’s diagnosis was acute right-sided optic neuritis. Med. recs. at Ex. 7, p. 5.

## **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 retrobulbar neuritis or optic neuritis, but also that the vaccine was a substantial factor in bringing about her retrobulbar neuritis or optic neuritis. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

One of the three Althen criteria petitioner must satisfy is a that there was a medically-appropriate temporal relationship between her vaccination and illness. The undersigned doubts

that five months, much less one year, is a medically-appropriate temporal relationship between hepatitis B vaccination and retrobulbar neuritis or optic neuritis.

Petitioner is ORDERED TO SHOW CAUSE why this case should not be dismissed by July 19, 2006.

**IT IS SO ORDERED.**

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DATE

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Laura D. Millman  
Special Master