

OFFICE OF SPECIAL MASTERS

No. 99-618V

July 11, 2006

DAVID EKLUND,

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Petitioner,

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v.

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Hepatitis B vaccination followed by TM 19 days later; why should this case not be in damages?

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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 CAUSE¹

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 30, 1997 caused him unspecified injury (ultimately, petitioner was diagnosed with transverse myelitis or TM). Onset was 19 days.

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.

Respondent is ORDERED TO SHOW CAUSE by August 10, 2006 why this case should not proceed to damages.

FACTS

Petitioner was born on January 26, 1930. He received his first hepatitis B vaccination on May 28, 1997. Med. recs. at Ex. 2, p. 18. He received his second hepatitis B vaccination on June 30, 1997. Med. recs. at Ex. 2, p. 19. Nineteen days later, on July 19, 1997, petitioner had a tingling sensation starting in his toes and extending to his waist. In 90 minutes, he was paralyzed below the waist. Med. recs. at Ex. 2, p. 20; Ex. 1, p. 1.

On July 19, 1997, petitioner went to University Hospitals of Cleveland from which he was discharged on July 26, 1997. Med. recs. at Ex. 8, p. 2. Petitioner was well until the day of admission when he felt the sudden onset of tingling and numbness over both feet. Over the next two hours, he had increased numbness over both legs associated with progressive weakness and ultimately could not walk. He could not use his bladder or bowel. He had a hepatitis B vaccination two weeks earlier. *Id.*; med. recs. at Ex. 8, pp. 8, 13.

From July 26, 1997 to August 29, 1997, petitioner was in a rehabilitation center. Med. recs. at Ex. 8, p. 151.

On November 3, 1997, Dr. Donald R. Bodner, a urologist, wrote a letter to Dr. Donald Junglas, in which he states that petitioner was recuperating from TM secondary to hepatitis B. Med. recs. at Ex. 2, p. 31.

On November 17, 1997, Dr. Tim J. Flenner wrote that petitioner's TM was thought to have been related to his having received hepatitis vaccine. Med. recs. at Ex. 4, p. 5.

On November 3, 1999, Dr. Mark A. Snyder, an orthopedist, wrote Dr. Douglas Moody that petitioner's TM was a complication of hepatitis B vaccination. Med. recs. at Ex. 7, p. 10.

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 TM, but also that the vaccine was a substantial factor in bringing about his TM. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

In Stevens v. Secretary of HHS, No. 99-594V, 2006 WL 659525 (Fed. Cl. Spec. Mstr. Feb. 24, 2006), the undersigned ruled that hepatitis B vaccine can cause TM and did so in that case. 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 TM was 19 days, which fits well within the appropriate temporal time frame for a vaccine reaction.

The Federal Circuit in Capizzano emphasized the importance of the opinions of treating physicians. In Capizzano, four of Mrs. Capizzano's treating physicians viewed her rheumatoid arthritis as caused by hepatitis B vaccine. 440 F.3d at 1326. In the instant action, three of petitioner's treating physicians opined that his TM was caused by hepatitis B vaccine.

Respondent is ORDERED TO SHOW CAUSE why this case should not proceed to damages by **August 10, 2006**.

IT IS SO ORDERED.

DATE

Laura D. Millman
Special Master