

OFFICE OF SPECIAL MASTERS

No. 01-187V

August 1, 2006

JESSICA ZLOTNICK, *

Petitioner, *

v. *

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, *

Respondent. *

TM two weeks after upper respiratory infection and two months after hepatitis B vaccination; causation from vaccination unlikely

ORDER TO SHOW CAUSE¹

Petitioner filed a petition dated April 2, 2001, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that her third hepatitis B vaccine administered on January 4, 1999 caused her to have transverse myelitis (TM) two months (54 days) later, but only two weeks after an upper respiratory infection (URI). Petitioner is ORDERED TO SHOW CAUSE by September 22, 2006 why this case should not be dismissed.

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.

FACTS

Petitioner was born on October 6, 1980. She received Her first hepatitis B vaccination on May 14, 1998, her second hepatitis B vaccination on June 23, 1998, and her third hepatitis B vaccination on January 4, 1999. Med. recs. at Ex. 1, p. 2.

On February 27, 1999, petitioner went to the Emergency Room at Shands Hospital at the University of Florida and gave a history that she had been generally healthy, but that day, while taking a shower, she started having back pain, and numbness in her legs which was worse in her feet. She could not walk secondary to unsteadiness on her feet. She had a URI two weeks previously with laryngitis, and no fever, which lasted five days and then resolved without treatment. She had radiating pain down her legs. Med. recs at Ex. 2, p. 11.

An Emergency Room Neurology Consultation was performed to evaluate petitioner's lower extremity numbness. Two weeks ago, she had laryngitis, cough, and a URI. At 5:30 p.m. February 27, 1999, petitioner felt her left leg falling asleep, her whole right leg went numb, she had pins and needles sensation, and she was numb below the umbilicus. She felt as if she were off-balance. Her appetite was good and she slept well. The neurologist's impression was TM. Med. recs. at Ex. 2, p. 12.

On February 27 to March 3, 1999, petitioner was hospitalized at Shands at the University of Florida. Med. recs. at 2, p. 3. Dr. Robert T. Watson, a neurologist, wrote the history and physical on February 27, 1999. Two weeks ago, she had laryngitis, a cough, and a URI. These symptoms resolved spontaneously. At 5:30 p.m. that day, February 27, 1999, she felt as if her left leg was falling asleep. Her whole right leg went numb. She described this as a pins and needles sensation in both her extremities. Her right leg was worse than her left. She felt as if her

bottom were numb and she was numb below the umbilicus. Her flanks up to her mid-thoracic region felt a sandpaper sensation to touch. She was off-balance and had to look at her feet to walk. She had no previous episodes of weakness or numbness. Med. recs. at Ex. 2, p. 13. On physical examination, she had normal strength. Dr. Watson's impression was TM. Med. recs. at Ex. 2, p. 14.

Dr. Watson saw petitioner on February 28, 1999 with Dr. Michael Okun. She denied any previous neurological symptoms including diplopia, visual loss, unsteadiness, weakness, or sensory change. Med. recs. at Ex. 2, p. 15. On physical examination, she was clearly weaker than she was the prior night when Dr. Okun examined her. She probably had a spinal cord process. *Id.*

On March 3, 1999, Dr. Melvin Greer, Chairman of the Department of Neurology, wrote the discharge summary, stating that petitioner had an acute onset of lower extremity numbness and weakness about two weeks after an upper respiratory infection. On the day following admission to the hospital, petitioner's neurologic examination worsened with greater weakness on the right, decreased proprioception more so on the right than on the left, and decreased pin prick once again more on the right than on the left. *Id.*

On March 10, 1999, petitioner was at Boca Raton Community Hospital, Inc. rehabilitative services and related that she had been well until February 27, 1999. Med. recs. at Ex. 4, p. 9.

On August 11, 2000, petitioner told Dr. Richard S. Bailyn, a neurologist, that her TM occurred six weeks (not almost eight weeks) after she received hepatitis B vaccine, and she

omitted mentioning that she had had a URI two weeks before onset of her TM. Med. recs. at Ex. 6, p. 1.

Petitioner's affidavit, dated March 16, 2001, omits mention of her preceding URI. Med. recs. at Ex. 7.

On January 3, 2002, petitioner gave a history to Dr. Harish D. Thaker, a neurologist, that her TM began two weeks after she received hepatitis B vaccine. Med. recs. at Ex. 9, p. 1.

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 TM, but also that the vaccine was a substantial factor in bringing about her 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. The onset intervals after Ms. Stevens' two hepatitis B vaccinations were eight and nine days, appropriate temporal periods for an immune reaction. 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.

Here, the vaccination occurred two months (54 days) before the onset of petitioner's TM. However, petitioner had a URI just two weeks before her TM, which reflects the proper medical time frame for a vaccine reaction. When asked to pick between a preceding infection that is the appropriate time interval of two weeks versus a vaccination that is nearly eight weeks earlier, the undersigned suspects an expert medical witness would pick the preceding URI as the cause of petitioner's TM. The undersigned notes that, over time, petitioner omits the existence of the URI and finally tells a neurologist that her TM occurred two weeks after she received hepatitis B vaccine, which is untrue. Repeatedly, in her contemporaneous medical records, petitioner gave a

history that she had been well until February 27, 1999 and that she had had a URI two weeks before the onset of her neurologic symptoms.

The undersigned doubts that petitioner will find an expert to provide a report that her third hepatitis B vaccination, occurring two months before her TM, was the cause of her TM, especially in light of the fact that her URI occurred just two weeks before her TM.

Petitioner is ORDERED TO SHOW CAUSE why this case should not be dismissed by **September 22, 2006.**

IT IS SO ORDERED.

DATE

Laura D. Millman
Special Master