

OFFICE OF SPECIAL MASTERS

No. 99-410V

September 21, 2006

SUE CRUZ,

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Petitioner,

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v.

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Hepatitis B vaccine followed five years later by MS; P alleges one-day onset; causation?

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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 on June 28, 1999, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that she received hepatitis B vaccine on October 5, 1992 and experienced an adverse reaction. She was diagnosed with multiple sclerosis (MS) in 1997. Petitioner’s first and second hepatitis B vaccinations were administered on April 6 and May 6, 1992.

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.

Petitioner filed affidavits from friends, including Francis X. Reilly (Ex. 9) who states that a day or two after petitioner received her third hepatitis B vaccination, she began developing unusual symptoms such as nearly passing out when taking a hot shower or when washing dishes that were in water that was too hot. She started to have frequent dizzy spells. Then she had frequent urinary tract infections and constipation.

Petitioner filed her own affidavit, dated June 9, 2003, stating that the day after her third hepatitis B vaccination, she stepped into a hot shower and everything went black. P. Ex. 14, p. 1. The same thing happened a short while later and petitioner learned to take cooler showers. She began to have bowel trouble and frequent urinary infections, as well as intermittent dizzy spells. In May 1997, she became very ill and was diagnosed with labyrinthitis and she was subsequently diagnosed with MS.

Petitioner is ORDERED TO SHOW CAUSE by **October 27, 2006** why this case should not be dismissed.

FACTS

Petitioner was born on September 27, 1952.

She received hepatitis B vaccine on April 6, 1992 and May 6, 1992. Med. recs. at Ex. 2, p. 9.

On August 3, 1992, petitioner saw her doctor for vaginal itching, yellow discharge, and burning for one week. Med. recs. at Ex. 2, p. 49.

On September 29, 1992, petitioner saw her doctor, feeling well but complaining of chronic back pain occurring only at night and located in the mid to low back area. Med. recs. at Ex. 2, p. 48.

On October 2, 1992, petitioner returned to her doctor, complaining that her back pain had worsened. Med. recs. at Ex. 2, p. 48.

On October 5, 1992, petitioner received her third hepatitis B vaccination. Med. recs. at Ex. 2, p. 9.

On May 5, 1993, petitioner saw her doctor with a vaginal yeast infection. She had itching, burning, and yellow discharge. The last three years (onset 1990), she had had yeast infections and trichomonias (vaginitis) once a year. Med. recs. at Ex. 2, p. 48.

On November 5, 1993, petitioner saw her doctor with an upper respiratory infection, with congestion, cough, and aching all over. Med. recs. at Ex. 2, p. 47.

On November 20, 1993, petitioner saw her doctor with a vaginal infection, which was itchy but had no discharge. It occurred before her period. She has had trichomonias in the past. *Id.*

On February 8, 1994, petitioner saw her doctor with a very painful cystic lesion in the right ear area. Her temperature was 99.6 degrees. Med. recs. at Ex. 2, p. 46.

On February 12, 1994, petitioner returned to her doctor much improved. *Id.*

On October 12, 1994, petitioner underwent a physical examination to work at Med Tech. The doctor found her fit for employment. She had no dysuria (burning urine), constipation, dizziness, or fainting. Med. recs. at Ex. 2, p. 36.

On January 20, 1995, petitioner went to North Penn Hospital, having tripped over a phone cord at work, falling on both knees. She had an increase in left knee pain as the day went on. The pain was more in the back of her leg. She was x-rayed and given medication and discharged. Med. recs. at Ex. 2, p. 37.

On April 26, 1995, petitioner underwent a physician's examination in order to qualify as a nurse's aide at Saint Mary's Manor. Dr. Ronald B. Frank examined her and found her normal, without restrictions, and that she could lift a maximum of 50 pounds. Med. recs. at Ex. 16, p. 6.

On May 6, 1995, petitioner saw the doctor for abdominal pain off and on. She had no difficulty voiding, but had vaginal discharge. She had a history of severe middleshmertz (ovulation pain). Med. recs. at Ex. 2, p. 45.

On May 10, 1995, petitioner went to Sullivan County Medical Center, complaining of dizziness with nausea. Med. recs. at Ex. 3, p. 3. She stated that she had pain in her left ear about five days previously. About two days previously, she stated she began to be dizzy which caused her nausea. She had a sore throat and rhinorrhea that subsided. She stated the room spun mostly while she was standing erect. She lost her balances. She did not have fever or chills. She was diagnosed with labyrinthitis of the left ear. *Id.*

On May 16, 1995, petitioner returned to the doctor with the symptoms of abdominal pain having resolved. Med. recs. at Ex. 2, p. 45.

On July 5, 1995, petitioner had a physical examination which was normal, according to Dr. Peter Cartaginness, an internist. Med. recs. at Ex. 16, p. 4.

On July 29, 1996, petitioner came to the Dushore Clinic, complaining of upper respiratory symptoms and stuffy head, accompanied by low back pain, body aches, urgency, and frequency. On physical examination, she was awake, alert, and oriented. Her nasal mucosa was erythematous with a white discharge. Her facial bones were tender to percussion. Her pharynx was slightly erythematous with exudate. PA Bruce W. Body's assessment was sinusitis. He placed her on Augmentin. *Id.*

On October 12, 1996, petitioner came in for a physical for employment at Victoria Manor. She stated she felt fine. Med. recs. at Ex. 2, p. 42.

On November 5, 1996, petitioner went to Dr. Cartaginess, complaining of middle ear infection. On examination, she had tympanic bulging. His opinion was that petitioner had otitis media which had been causing vertigo. He prescribed spray and Amoxicillin. Med. recs. at Ex. 16, p. 3.

On May 10, 1997, petitioner went to the Sullivan County Medical Center Emergency Room, complaining of dizziness with nausea, and pain in her left ear, which began two days previously. She was diagnosed with sore throat and rhinorrhea. Med. recs. at Ex. 2, p. 1.

On May 16, 1997, petitioner went to the Emergency Room of Geisinger Medical Center where she told Dr. John Skiendzielewski and Dr. John D'Angelo that she began having vertigo approximately nine days previously associated with nausea and vomiting. She was seen by her primary doctor on May 10, 1997 with a diagnosis of labyrinthitis and started on Antivert. She claimed the Antivert initially helped with nausea and vomiting, but she did not have relief of her vertigo. For the past three days, she had left-sided weakness, and incoordination of gait, as well as weakness of her left upper extremity. She denied visual changes, headache (although she had occasional jaw pain on the right), fevers, chills, chest pain, palpitation, shortness of breath, abdominal pain, syncope (fainting), or tinnitus. Med. recs. at Ex. 1, p. 67.

On examination, petitioner had positive vertigo and horizontal nystagmus which was slow and nonfatigable. The doctors did not think that benign positional labyrinthitis was the most likely etiology and petitioner needed further work-up. They suspected a central nervous

system cause. Med. recs. at Ex. 1, pp. 67-68. Petitioner was well prior to onset of vertigo and nausea one week previously. Med. recs. at Ex. 1, p. 69.

On May 16, 1997, petitioner saw Dr. P.R. Spilsbury, a neurologist, at the Geisinger Medical Center, having been admitted by the Emergency Room. Eight days previously (May 8, 1997), she felt well when, on first getting up, she noted a spinning dizziness and nausea. She had left-sided weakness. She denied any preceding illness except for a scratchy throat a few days prior. Her ears felt a little full. Med. recs. at Ex. 1, p. 71.

On May 19, 1997, petitioner had an MRI of her brain which showed multiple lesions, one and possibly two of which might be mildly enhancing. Many were periventricular and were seen in the corpus callosum, probably representing MS. Med. recs. at Ex. 1, p. 20.

On May 30, 1997, petitioner saw speech and language pathologist Judith F. Williams for mild speech dysarthria. Med. recs. at Ex. 6, p. 123. She had left facial weakness. Intelligibility at the conversational level was 90%. *Id.* She was initially admitted on May 16, 1997 with a one-week history of vertigo associated with unsteadiness and left-sided weakness and incoordination. She developed some numbness in the left perioral region, her speech was slurred, and she had some urinary urgency. A principal diagnosis of acute multiple sclerosis was made. *Id.*

On an Employment Assessment Form petitioner filled out on August 7, 1997, petitioner's doctor Anthony Turel stated petitioner became temporarily disabled on May 1, 1997. Med. recs. at Ex. 6, pp. 54-55.

On August 17, 1998, petitioner saw Dr. Amy Pruitt. Her neurologic history began in March 1997 with vertigo, initially thought to be due to an inner ear infection, which recurred in May 1997. Urinary urgency and dysarthria occurred as well. For the last five years (putting

onset in 1993), she had three episodes per month of minor symptoms such as everything turning black when she was in hot showers. Dr. Pruitt did not know if these were related to the evolving illness. She had sinus trouble off and on. Med. recs. at Ex. 1, p. 4. MRI showed multiple periventricular plaques and a plaque in the corpus callosum and left medulla. Petitioner was diagnosed with demyelinating disease. Med. recs. at Ex. 1, p. 5.

An August 27, 1998 MRI was diagnostic of MS. Med. recs. at Ex. 1, p. 7.

On October 11, 1999, petitioner saw Dr. Pruitt with a great deal of information about the relationship of hepatitis B vaccine and her current neurologic condition. Med. recs. at Ex. 4, p. 19. Petitioner stated that she completed her series in May, June, and October 1992, and “soon thereafter noted heat sensitivity. She said when she got into a hot shower she would nearly pass out or at times when she was washing the dishes in hot water she would feel that she was dizzy and would have a near syncopal episode. This is what occasioned her diagnosis in 1997 as well.” *Id.* (The medical histories petitioner gave in 1997 do not reflect any sensitivity to hot water.) Dr. Pruitt said she would look into this and speak about it with other doctors in her group. *Id.*

On March 13, 2000, petitioner told Dr. Pruitt that she had been quite confused about whether some of her symptoms related to estrogen depletion or to multiple sclerosis. She still had insomnia and what sounded like hot flashes. Dr. Pruitt stated petitioner was clearly perimenopausal and she suggested hormones to her, but petitioner was taking calcium supplements, black cohosh, and Healthy Woman vitamin preparation, which she stated had toned down some of her symptoms. She had not had any new urinary tract infections. She used decongestants twice a day and petitioner noted other people who had neurologic symptoms after hepatitis B vaccination had nasal congestion as well. Med. recs. at Ex. 5, p. 8.

On December 3, 2001, petitioner told Dr. Pruitt that after hepatitis B vaccination, she had a period of urinary tract infection. Med. recs. at Ex. 5, p. 3.

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 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. 99-310V, 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 hepatitis B vaccination was four weeks in that case.

Respondent's expert, Dr. Roland Martin, testified in the Omnibus hepatitis B-demyelinating diseases proceeding that the appropriate onset interval, if a vaccination were to cause an acute demyelinating reaction, would be a few days to three to four weeks. Stevens v. Secretary of HHS, No. 99-594V, 2006 WL 659525, at *15 (Fed. Cl. Spec. Mstr. Feb. 24, 2006).

Here, petitioner's onset of MS symptoms was five years after her hepatitis B vaccinations, although petitioner alleges one day-onset. She alleges that her numerous episodes of dizziness associated with hot water began the day after her third hepatitis B vaccination, and her long-time friend Francis Reilly asserts the onset was one or two days after this vaccination. Petitioner has not filed an expert medical report that this hot-water episode, if it occurred, was the onset of her MS. Moreover, according to the testimony of Dr. Martin, the earliest that a demyelinating reaction could be attributed to vaccination would be three days. Petitioner asserts a one-day onset. Her friend Mr. Reilly asserts one or two days. Petitioner has not filed an expert medical report that hepatitis B vaccine may cause MS, a demyelinating disease, the next day or two days later.

The undersigned notes that petitioner saw physicians frequently during the five years between vaccination and onset of her MS and there are no complaints of dizziness until May 10,

1995. On October 12, 1994, she denied dizziness. As for urinary difficulties, petitioner gave a history in 1993 that she had had urinary difficulties since 1990, and she was also noted to have a long history of ovulation pain.

Petitioner is ORDERED TO SHOW CAUSE why this case should not be dismissed by **October 27, 2006**.

IT IS SO ORDERED.

September 21, 2006

DATE

s/ Laura D. Millman

Laura D. Millman
Special Master