

OFFICE OF SPECIAL MASTERS

No. 02-968V

August 8, 2006

SHARON LANG,

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Petitioner,

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v.

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Hepatitis B vaccine given while petitioner feverish with either URI or pneumonia; onset of TM either two or three days or two weeks later; cause?

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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 12, 2002, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., and an amended petition dated July 19, 2005, alleging that hepatitis B vaccine administered on August 16, 1999, while petitioner was still febrile from upper respiratory symptoms, caused her transverse myelitis (TM) four hours after vaccination (¶

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.

3 of original petition, although omitted from amended petition where, according to ¶ 4, onset of TM was within two weeks).

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

FACTS

Petitioner was born on August 19, 1954.

On August 16, 1999, petitioner filled out an employee health form and listed as her current health problem: Flu! Med. recs. at Ex. 1, p. 9; refiled as Ex. 1, p. 8. Also on August 16, 1999, petitioner received hepatitis B vaccine. Med. recs. at Ex. 1, p. 2.

On August 31, 1999, petitioner saw Michael J. Anderson, a chiropractor. She filled out a form saying she had pneumonia two weeks earlier. Med. recs. at Ex. 2, p. 22; refiled as Ex. 2, pp. 2, 9. The reason she was seeing the chiropractor was for neck pain whose onset was that day. *Id.* at 22 and 2. Petitioner had pain in both sides of her neck, tingling in her hand, ankle, foot, and toes bilaterally, and spasms in her neck, the area between her shoulders, and the top of her shoulders bilaterally. The onset was August 31, 1999. Med. recs. at Ex. 2, p. 18. She had diminished right knee reflex. *Id.*

On September 1, 1999, petitioner saw the chiropractor and her pain was improved. Med. recs. at Ex. 2, p. 19; refiled as Ex. 2, p. 6. On September 2, 1999, petitioner saw the chiropractor and her pain was again improved. *Id.* The same occurred on September 3, 1999 and September 8, 1999. Med. recs. at Ex. 2, p. 20; refiled as Ex. 2, p. 7. She paid him another visit on September 30, 1999. Med. recs. at Ex. 2, p. 21; refiled as Ex. 2, p. 8.

On September 8, 1999, petitioner saw Dr. Michael Stewart, complaining of numbness in her upper and lower extremities and a burn on her right hip. Med. recs. at Ex. 7, p. 14. She had been treated as an outpatient for possible pneumonia with Augmentin. She said she improved but, on day ten of Augmentin, she developed hives. She took Benadryl at night and awoke the next morning numb from her midchest down. She stayed in bed for four days without seeking medical care. She developed a small burn on her right hip due to a heating pad and numbness. Her numbness has steadily improved since then and she now reported normal sensation had returned. She complained of tremor of her right hand. *Id.* Dr. Stewart's assessment was possible TM resolving. *Id.*

On September 10, 1999, petitioner sent a letter of resignation to the Department of RUSH Pathology where she worked. She stated that on the day of her employee physical, she had pneumonia and was put on antibiotics. She told the physician she had a fever and her current condition, yet he vaccinated her anyway and she contracted TM. Med. recs. at Ex. 5, p. 31; refiled as Ex. 5, p. 1.

On September 14, 1999, petitioner had an MRI of her cervical spine which was abnormal, with increased signal within the spinal cord between C2 and C5, most prominent at C3. There was also increased signal at C6. This was consistent with myelitis. Med. recs. at new Ex. 3, p. 5.

Also on September 14, 1999, petitioner had an MRI of her thoracic spine which was normal. There was no evidence of TM. Med. recs. at new Ex. 3, p. 6.

Also on September 14, 1999, petitioner had an MRI of her brain, which was normal. Med. recs. at new Ex. 3, p. 7.

On September 17, 1999, petitioner saw Dr. Michael M. Minioka. He recounted that petitioner had fever and upper respiratory symptoms in the middle of August. While she was still febrile, she received hepatitis B vaccine and, a few days later, noticed numbness from the middle of her chest down. She had trouble urinating and had to use a catheter. Her symptoms slowly resolved and, at the September 17th examination, she noticed only a “funny” sensation when she bent her neck forward, and some tightness in the ulnar distributions of both hands. She was not weak, had no sensory loss, and had no bladder dysfunction. Med. recs. at Ex. 3, p. 27; refiled as Ex. 3, p. 1. On examination, she had normal strength and reflexes. Her neurologic examination was unremarkable except for a subjective slight decrease of sensation in the right leg compared to the left. *Id.*

In Dr. Minioka’s handwritten notes of September 17, 1999, petitioner told him that on August 14, 1999, she had fever and a cough and started Augmentin. She states she received hepatitis B vaccine on August 16 (although it was the 19th). On August 18, 1999, she was unable to get out of bed and had no sensation from the chest down. She said she was still feverish. She had bladder and bowel difficulty and catheterized herself. Her feeling was slowly returning and her bladder and bowel function returned. Med. recs. at new Ex. 3, p. 8.

On December 5, 2000, petitioner returned to the chiropractor. She had woken that morning with severe neck pain and tingling in the upper and lower extremities, and was unable to get out of bed due to pain. Med. recs. at Ex. 2, p. 15; refiled as Ex. 2, p. 2. She had never had a problem like this before and had just completed a two-week course of Augmentin for a respiratory infection. *Id.* (The undersigned believes this record actually reflects December 5, 1999.)

Petitioner asserts in her affidavit that she still has tremors in both hands and a general loss of sensation in the right side as well as some loss of urinary sensation. Med. recs. at Ex. 10, p. 2, ¶ 4. Petitioner has not submitted any medical records to prove that her residua of TM lasted more than six months.

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 *15.

In the instant action, petitioner initially alleged that onset was four hours after vaccination, but in her amended petition, alleged onset was within two weeks. If onset were only hours after vaccination, that would be too short for causation from the vaccination.

One of the histories petitioner gave was onset of TM within two days of vaccination. Another history she gave was onset three days after vaccination, She also gave a history of two weeks' onset in other medical records. If onset were from three days to two weeks, petitioner would fall within the range Dr. Roland described in the Omnibus proceedings. If onset were two days, it would be too short.

There are two other problems here. The first is that petitioner had either a URI or pneumonia and was feverish at the time she received her hepatitis B vaccination. Viruses may cause TM. Petitioner must file an expert report stating that hepatitis B vaccine was a substantial

factor in causing her TM, not the viral condition that caused her fever and necessitated her taking Augmentin (or both were substantial factors), and the basis for the expert's opinion. The undersigned notes that petitioner herself thought Benadryl played a factor in her TM because she had onset the next morning after taking Benadryl after breaking out in hives on day ten of Augmentin.

The second problem is that petitioner has not filed any medical records proving that the sequelae of her TM lasted more than six months, as the Vaccine Act requires. 42 U.S.C. §300aa-11(c)(1)(D)(i). The undersigned cannot rely upon petitioner's claim of sequelae unsubstantiated by medical confirmation. 42 U.S.C. §300aa-13(a)(1).

Petitioner must file an expert report by **September 22, 2006** or this case will be dismissed. 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