

OFFICE OF SPECIAL MASTERS

No. 01-537V

August 7, 2006

PAUL SHIRLEY,

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Petitioner,

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v.

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GBS onset either within hours of second hepatitis B vaccine or seven weeks later; is onset too soon or too late for causation from vaccine?

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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 September 24, 2001, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., and an amended petition dated January 3, 2002, alleging that his second hepatitis B vaccine administered on September 27, 2000 caused his Guillain-Barre Syndrome (GBS) whose onset was within hours of vaccination. Petitioner affidavit states at page 2 that within a couple of hours of receiving his second hepatitis B

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.

vaccination, he had some dizziness, slight nausea, and achiness. He was diagnosed with GBS on December 6, 2000, more than ten weeks after receiving hepatitis vaccine. Med. recs. at Ex. 11. According to histories he gave to medical providers, the onset of his neurologic symptoms was seven weeks after vaccination.

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

FACTS

Petitioner was born on December 24, 1942.

On December 6, 2000, petitioner saw Dr. Amy K. Dorn with a two-week history (which would put onset on November 22, 2000, 56 days or seven weeks post-vaccination) of progressive numbness in both feet and hands, progressive weakness, inability to climb stairs, inability to tie his shoes, sharp pains in his upper and lower back, stress, and losing weight. Med. recs. at Ex. 1, p. 6.

On December 6, 2000, petitioner saw Dr. Daniel H. Jacobs, a neurologist. Med. recs. at Ex. 4, p. 6. Petitioner described a rapid onset of numbness and tingling, loss of balance and instability. He stated its onset was one and one-half weeks earlier when his right foot tingled and he felt gravel in his shoes that tingled. He noticed trouble with his writing. He had hepatitis in the second grade. He had a major flu infection about six months previously. *Id.* Dr. Jacobs diagnosed likely GBS. Med. recs. at Ex. 4, p. 7.

On December 6, 2000, petitioner was admitted to Orlando Regional Healthcare System. P. Ex. 1, pp. 54-55; the third page is at P. Ex. 9, p. 27. Dr. Dorn states petitioner had been in her office that day with the chief complaint of numbness in his hands and feet, difficulty walking up

stairs and inability to tie his shoes. It had started in his lower extremities and progressed to his hands. He had multiple trauma in his hips and back doing significant physical work and falling while training at the police academy for the past several months. He had at some times significant pain in his lower back and in his thoracic back. He also had over the prior several months severe anxiety, depression, and weight loss over loss of a previous job and training for this new job. Past hospitalizations had been for a L4-L5 disc. Med. recs. at Ex. 1, p. 54.

Dr. Dorn's impression was acute ascending paralysis, weight loss over the past several months of 25 pounds, severe anxiety, and depression. Med. recs. at Ex. 1, p. 55. On December 9, 2000, no campylobacter was isolated. Med. recs. at Ex. 9, p. 95.

On December 15, 2000, Dr. Jacobs did a nerve conduction study on petitioner, the result of which was polyneuropathy principally affecting the motor nerves than the sensory nerves. Clinically, this was consistent with GBS. Med. recs. at Ex. 1, p. 57.

On December 20, 2000, Dr. Jacobs wrote a response to petitioner's note to him, stating that he had treated him for GBS whose onset was probably one and one-half weeks before that. Med. recs. at Ex. 4, p. 9. There was some literature suggesting vaccinations can act as a trigger on a subacute or delayed basis and his vaccination in September was potentially culpable. Med. recs. at Ex. 4, p. 9.

On January 18, 2001, petitioner saw Dr. Michael A. Gebel. Med. recs. at Ex. 3, p. 1. Petitioner received his second hepatitis B vaccine and started to have symptoms almost immediately. Over the next ensuing days, he started to have tingling in his legs and weakness.

Id.

Curiously, petitioner's workmen's compensation papers mostly reflect that the "date of accident" was August 29, 2000, the date of his first hepatitis B vaccination. Med. recs. at Ex. 6. Other records reflect the date of the accident as November 7, 2000 at 9:00 a.m. Med. recs. at Ex. 7.

From January 23, 2001 to January 26, 2001, petitioner was at Florida Hospital Medical Center. Dr. David Nels Westerdahl wrote that petitioner's EMG showed demyelinating sensory motor neuropathy with worsening compared to the EMG done December 22, 2000 at Orlando Regional Medical Center. Med. recs. at Ex. 10, p. 536. However, the EMG did not show evidence of axonal injury which was a positive prognostic factor. *Id.*; Ex. 10, pp. 552-53. Cerebrospinal fluid (CSF) protein was high at 54 mg/dl on January 23, 2001. Med. recs. at Ex. 10, p. 583.

From February 23, 2001 to April 5, 2001, petitioner was at Florida Hospital Medical Center. Med. recs. at Ex. 10, p. 10. Dr. Michael J. Creamer wrote that petitioner had a second hepatitis B vaccine in September 2000 and then, around Thanksgiving, began to have weakness. He had a course of gradually worsening weakness and numbness in his extremities beginning distally in his feet. He had very prominent demyelination on nerve conduction study. *Id.*

On March 8, 2001, petitioner saw Dr. Todd C. Hartley. Med. recs. at Ex. 2, p. 5. Petitioner had a second hepatitis B vaccination in September and then, in November around Thanksgiving, he began having the symptoms for which he was seeing Dr. Hartley. *Id.* Because petitioner's illness had extended four weeks and was continuing to worsen, Dr. Hartley opined petitioner had chronic inflammatory demyelinating polyneuropathy (CIDP). Med. recs. at Ex. 2, p. 6.

On March 9, 2001, petitioner saw Dr. Dennis R. Stevenson. Med. recs. at Ex. 2, p. 8. Petitioner had a second hepatitis B vaccination in September and then progressive neurological ascending paralysis since November. *Id.*

On March 9, 2001, petitioner saw Dr. John A. Coleman, Jr. Med. recs. at Ex. 2, p. 11. Petitioner stated he had his first hepatitis B vaccination in late August and his second hepatitis B vaccination in late September and, on November 18, 2000, he began to have significant back pain. On November 23, 2000, he had tingling in his extremities and progression of symptoms of GBS. Petitioner had flu-like symptoms immediately after his second hepatitis B vaccination. *Id.*

On March 21, 2002, petitioner saw Dr. Vincent M. Spoto. Med. recs. at Ex. 5, p. 4. Petitioner started a new job with the corrections system in May 2000. He had been undergoing training at the academy since that time. He received his first hepatitis B vaccination on August 29, 2000 and his second hepatitis B vaccination on September 27, 2000. He recalled having a flu-like illness occurring within about 24 hours of the second vaccination with some mild body aches and nausea. These symptoms ultimately improved. However, beginning about November, he began experiencing neurologic symptoms including tingling involving his feet and then subsequently numbness in an ascending fashion. Med. recs. at Ex. 5, p. 5.

On May 1, 2003, petitioner had a CT of his lumbar spine which Dr. Michael P. O'Neill interpreted as showing moderate diffuse degenerative disc disease throughout the mid and inferior lumbar spine. There was more advanced disc degeneration at the L4-L5 level with prominent disc narrowing. Med. recs. at Ex. 18, p. 22. Petitioner had mild circumferential spondylitic bulge at the L3-L4 level with ligamentum flavum hypertrophy and suspected

congenitally short pedicles. Dr. O'Neill noted moderate central canal stenosis at the L4-L5 levels. Med. recs. at Ex. 18, p. 23.

Also on May 1, 2003, petitioner had an MRI of his lumbar spine which Dr. Charles L. Domson interpreted. Med. recs. at Ex. 22, p. 16. He had degenerative dessicated discs at L4-L5. He had right central disc protrusion, causing moderate canal stenosis and moderate to severe foraminal narrowing and lateral recess narrowing on the right. He had disc bulge at L5-S1 effacing the ventral epidural fat. Bilateral facet hypertrophy was seen, right greater than left, with mild to moderate foraminal narrowing on the right. He had small right central disc protrusion at L3-L4, with osteophytes and facet hypertrophy causing mild canal stenosis and mild to moderate foraminal narrowing on the right. Med. recs. at Ex. 22, p. 17.

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

In Gilbert v. Secretary of HHS, No. 04-455V, 2006 WL 1006612 (Fed. Cl. Spec. Mstr. Mar. 30, 2006), the undersigned ruled that hepatitis B vaccine can cause GBS and CIDP, and did so in that case. Respondent's expert in the Omnibus proceedings, 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.

In the instant action, the onset of petitioner's GBS is either hours after his second vaccination when he claimed a flu-like illness or seven weeks later when, in numerous histories he gave to medical personnel, he began to experience numbness and weakness. If the onset of his GBS was within hours of his second hepatitis B vaccination, that is too short for GBS/CIDP to be causally related. Demyelination takes more than a few hours. If the onset of his GBS/CIDP is seven weeks, that is too late for causation from the second vaccination.

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