

OFFICE OF SPECIAL MASTERS

No. 02-156V

March 14, 2007

Not to be Published

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GINA RUIZ,

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Petitioner,

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v.

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Entitlement; failure to prove  
a prima facie case; no expert

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SECRETARY OF THE DEPARTMENT OF  
HEALTH AND HUMAN SERVICES,

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Respondent.

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Richard Gage, Cheyenne, WY, for petitioner.

Alexis B. Babcock, Washington, DC, for respondent.

**MILLMAN, Special Master**

**DECISION<sup>1</sup>**

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<sup>1</sup> Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this unpublished decision on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub.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 a petition on March 1, 2002, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., under the name Gina Manderfeld,<sup>2</sup> alleging that a second hepatitis B vaccination she received on June 8, 2001 caused her anaphylactic shock and neurologic symptoms (tremor, severe headaches, loss of appetite and energy, twitching, and numbness and weakness in her extremities).

The medical records, particularly those of Dr. Kumar, Dr. Shannon, and Dr. Friedman, suggest petitioner's condition is psychogenic in origin.

This case was associated with the cases pending the Omnibus proceeding concerning whether hepatitis B vaccine can cause four types of demyelinating neurologic illnesses: Guillain-Barré Syndrome (GBS), chronic inflammatory demyelinating polyneuropathy (CIDP), transverse myelitis (TM), and multiple sclerosis (MS). The hepatitis B vaccine-demyelinating diseases Omnibus proceeding was completed in 2006, the undersigned having ruled in the paradigm cases that hepatitis B vaccine can cause GBS, CIDP, TM, and MS. The undersigned, having read Ms. Ruiz's medical records, does not see anything resembling GBS, CIDP, TM, or MS in this case. Therefore, the results of the Omnibus proceeding are irrelevant to petitioner's case.

On February 2, 2007, the undersigned issued an Order to Show Cause to petitioner to show why this case should not be dismissed.

On March 8, 2007, petitioner filed a letter dated February 20, 2007, addressed to petitioner's counsel, from Chuck Denison, a psychologist, who is a Ph.D., but not an M.D. P. Ex. 15. He states on page 2 of his letter that he is without any training in neurology and

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<sup>2</sup> On February 27, 2007, petitioner moved to amend the caption to reflect her new last name. On March 5, 2007, the undersigned granted petitioner's motion.

“obviously could not speculate as to differential diagnosis.” *Id.* at 2. However, he concludes that, based on the “fact pattern” of the case, hepatitis B caused petitioner’s “ongoing physical and psychological condition....” *Id.*

On March 9, 2007, the undersigned issued an Order striking page 2 of Chuck Denison’s opinion on causation since he is not a medical doctor, citing Domeny v. Secretary of HHS, No. 94-1086V, 1999 WL 199050 (Fed. Cl. Spec. Mstr. March 15, 1999), aff’d, (Fed. Cl. May 25, 1999) (unpublished), aff’d, 232 F.3d 912 (Fed. Cir. 2000) (per curiam) (proffer of dentist’s testimony for diagnosis of a neuropathy rejected). Mr. Denison is not competent to opine on medical causation.

Also, on March 9, 2007, petitioner filed a Motion for Decision on the Record, stating that none of petitioner’s doctors had “provided a specific name” for her symptoms, but merely described the symptoms. Motion, at 3. The inability to come up with a diagnosis “has made it difficult to retain an expert that will give admissible testimony in relation to the movement disorder aspect of her vaccine injury. Petitioner, therefore, at this time does not anticipate providing such testimony.” *Id.* Petitioner states the undersigned has discretion to rule on behalf of petitioner based on the treating doctors’ diagnoses that hepatitis B vaccine caused petitioner’s involuntary movement disorder. *Id.* Petitioner also posits that hepatitis B vaccine caused her emotional disorder. *Id.* at 3-4.

## FACTS

Petitioner was born on August 29, 1977.

On January 28, 2000, petitioner was tossed from an inner tube. She is left hand dominant. She struck her head and had a possible concussion. She broke her nose and injured

her left shoulder which occasionally popped. The diagnosis was capsular strain. Med. recs. at Ex. 3, p. 6.

On February 11, 2000, petitioner had persistent pain of her left shoulder and a popping sensation. Med. recs. at Ex. 3, pp. 6, 7. The diagnosis was post-traumatic anterior subluxation with strain of the anteriolateral humeral ligament. Med. recs. at Ex. 3, p. 7.

On March 24, 2000, petitioner was still markedly symptomatic with left shoulder pain. Med. recs. at Ex. 3, p. 7.

On April 11, 2000, petitioner had shoulder surgery. Med. recs. at Ex. 3, p. 8.

On May 7, 2001, petitioner received her first hepatitis B vaccination.

On May 29, 2001, petitioner saw Dr. Brendan Fitzsimmons, complaining of nausea over the prior four weeks, which was worse after eating. The diagnosis was gastritis/peptic ulcer disease. Med. recs. at Ex. 8, p. 4.

On June 8, 2001, she received her second hepatitis B vaccination. Med. recs. at Ex. 1. The injection was administered in the right shoulder, according to the nurse. That same day, Nurse Lorie J. Christy of Albany County Public Health wrote that petitioner had a small bump that immediately appeared after her second hepatitis B vaccination and her right shoulder flushed bright red. She had bruised at the injection site. There was a hive-like area. Petitioner complained of not feeling well and of being hot. Med. recs. at Ex. 6, p. 1.

On June 8, 2001, petitioner saw her doctor with a reaction to hepatitis vaccine. She was injected in the right shoulder, which flushed afterwards. She had bruising in the area. She had hives. Ice was applied. She was not feeling well but walked without assistance. She was not lightheaded. She had a little nausea. She was somewhat pale, but not in any distress. She was

breathing easily. Her blood pressure was 108 over 68. Her temperature was 96.8°. Her right shoulder had a small area of erythema that was already abating. She was prescribed epinephrine and Benadryl. Med. recs. at Ex. 8, p. 6.

On June 12, 2001, petitioner continued to feel hot and achy. She had some twitching and spasms in her shoulders and neck. Her appetite was off. Her energy was low. She had severe headache. Med. recs. at Ex. 8, p. 7.

On June 14, 2001, petitioner had a muscle spasm in her left arm. Med. recs. at Ex. 8, p. 8.

On June 18, 2001, petitioner had a bruise on her right shoulder which looked a little worse. Med. recs. at Ex. 8, p. 10.

On June 20, 2001, petitioner saw Dr. Kurt J. Hopfensperger, a neurologist, complaining of an acute onset of a markedly abnormal movement disorder involving the left upper extremity and left shoulder girdle musculature and the left neck musculature for the last 9-10 days. She had an injection in the right shoulder. Med. recs. at Ex. 7, pp. 1, 3. The movement disorder consisted of tremor, rough choreoathetotic movements and myoclonic-type jerking of the left upper extremity. She had episodic and sudden clonic head jerking to the left. This lessened when she was drowsy. It went away when she was asleep. She woke up with it. It went away when she was gripping a tennis racket. There were no similar movement on the right upper or lower extremities. She had a reaction to anesthesia in surgery in April 2000 and a history of headaches. Med. recs. at Ex. 7, p. 2. A CT scan of her head when she was nine years old was normal. On physical examination, she had frequent, sudden lateral flexion of the neck with the left shoulder rising. She had normal strength and no sensory loss. She had minor clumsiness.

She had marked postural tremor of the left upper extremity. At times it was myoclonic, and at other times it was choreoathetotic. She had absent Babinskis. Med. recs. at Ex. 7, p. 3.

On June 20, 2001, petitioner's ANA (antinuclear antibodies) were negative. Med. recs. at Ex. 7, p. 4.

On June 22, 2001, petitioner had a brain MRI which was normal. Med. recs. at Ex. 4, p. 20.

On June 28, 2001, petitioner returned to Dr. Hopfensperger with the same symptoms (continued tremor and rough choreoathetotic movements and jerking of the left upper extremity; sudden head jerking to the left which had abated somewhat) but with new onset sensory loss. Med. recs. at Ex. 7, p. 14. On physical examination, petitioner had patchy sensory loss in the forearm and in the hand not corresponding to a peripheral nerve or a radicular distribution. *Id.*

On July 6, 2001, petitioner had an MRI of her thoracic spine which showed a normal right brachial plexus. Med. recs. at Ex. 4, p. 23. On that date, she also had an MRI of her cervical spine which was normal. Med. recs. at Ex. 4, p. 24.

On July 13, 2001, petitioner had an MRI of her left brachial plexus which was normal. Med. recs. at Ex. 4, p. 25.

On July 25, 2001, petitioner returned to Dr. Hopfensperger, complaining that she was worse and had numbness and weakness in her left lower extremity. Med. recs. at Ex. 7, p. 15.

On August 2, 2001, petitioner saw a doctor with a several-week history of frequent epigastric pain. Med. recs. at Ex. 3, p. 11. Earlier that summer, she had received her second hepatitis B vaccination and, almost immediately, developed anaphylactic shock. She was prescribed adrenaline and Benadryl. Since then, she had a tremor in her left upper and lower

extremities. No diagnosis was made except for an adverse reaction to hepatitis B vaccine. She will have a lumbar puncture to rule out multiple sclerosis. Many MRIs were unrevealing. She had ongoing nausea but no vomiting or change in her bowel habits. She lost 10 pounds in four months. She took Valium to control the spasm in her left neck. On physical examination, she had a resting tremor in her left upper extremity. She was tender to palpation of the epigastrium. The diagnosis was suspected gastritis.

On August 7, 2001, petitioner had an MRI of her cervical spine which was normal. Med. recs. at Ex. 4, p. 27. On the same date, she had an MRI of her brain because she had a loss of sensation in her left leg since her last MRI. The MRI was normal. Med. recs. at Ex. 4, p. 28.

On August 16, 2001, petitioner returned to Dr. Hopfensperger. Over the last several weeks, her left arm tremor and choreoathetotic movements had become less. Now, she had developed pain, weakness, and abnormal movements in her left lower extremity and fallen three times. She had sensory loss in her left leg. On physical examination of the left leg, she had sensory loss, but normal strength, no atrophy, normal reflexes, and no fasciculations. Med. recs. at Ex. 7, p. 18.

On September 12, 2001, petitioner saw Dr. Sheri J. Friedman. According to petitioner's mother, petitioner did not have any movements during sleep. Med. recs. at Ex. 14, p. 1. Her stomach problems began last March. Her ability to suppress the movements made the disorder unusual. There appeared to be some distractibility. Med. recs. at Ex. 14, p. 2.

On September 14, 2001, petitioner's cerebrospinal fluid was tested. Med. recs. at Ex. 9, p. 4. The hepatitis B surface antigen was negative. Med. recs. at Ex. 9, p. 5. Her protein count was normal. Med. recs. at Ex. 9, p. 10.

On September 20, 2001, petitioner saw Dr. Rajeev Kumar. Med. recs. at Ex. 10, p. 1. He stated there was no evidence of an organic tremor disorder. Petitioner fulfilled all the diagnostic criteria for psychogenic tremor. All of her tremor was extremely distractible and disappeared entirely when he had her perform different physical and mental maneuvers. Med. recs. at Ex. 10, p. 3. Her lumbar puncture was completely normal. All her movements increased with anxiety, cold, and excitement, but decreased when she was relaxed. Med. recs. at Ex. 10, p. 1. On physical examination, her strength was 5/5 in the upper and lower extremities. Her muscle tone and bulk were normal. Her reflexes were normal. Her plantar reflexes were negative. Dr. Kumar stated that petitioner's pattern of sensory abnormalities did not follow any well-described dermatome, length dependent or peripheral nerve distribution whatsoever. Her description of sensory impairment was rather variable. *Id.* She had typical distractibility, variability, entrainment of tremor, and response to placebo and suggestion. Petitioner had a conversion disorder. Med. recs. at Ex. 10, p. 4. Many of her gastrointestinal symptoms may also be psychogenic in nature. *Id.*

On September 24, 2001, petitioner went to The Psychology Clinic where she admitted that she had some nausea from stress the prior spring when she lost her faith from February to March 2001. Med. recs. at Ex. 13, pp. 1, 2.

On October 1, 2001, petitioner saw Dr. Friedman again. Med. recs. at Ex. 9, p. 13. She had recently seen Dr. Kumar who felt that she had a psychosomatic disorder. Dr. Friedman diagnosed a real movement disorder at least to some extent. *Id.*

On October 18, 2001, petitioner saw Dr. Scott Shannon, a psychiatrist, who diagnosed her with post-traumatic stress disorder. Med. recs. at Ex. 11, pp. 1, 2.

On October 20, 2001, petitioner had very obvious intentional tremor in her left hand. Med. recs. at Ex. 3, p. 16.

On October 29, 2001, petitioner returned to Dr. Friedman. Med. recs. at Ex. 9, p. 14. The symptoms might be moving to the right lower extremity. Dr. Friedman stated, “I did not see any jerking movements or contractions of her left leg except when I began discussing the symptoms in her right leg with her. Her left leg, when I call attention to it, then begins having some jerking movements.” *Id.*

On November 1, 2001, petitioner had an upper gastrointestinal series because of constant nausea. The upper GI series was normal. Med. recs. at Ex. 4, p. 30.

## DISCUSSION

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 1317, 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...”

Close calls are to be resolved in favor of petitioners. Capizzano, supra, at 1327; Althen, supra, at 1280. *See generally, Knudsen v. Secretary of HHS*, 35 F.3d 543, 551 (Fed. Cir. 1994).

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 (6<sup>th</sup> Cir. 1983), cert. denied, 469 U.S. 817 (1984).

Petitioner must show not only that but for the vaccine, she would not have had whatever is wrong with her, but also that the vaccine was a substantial factor in bringing about whatever is wrong with her. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

The Federal Circuit in Capizzano emphasized the opinions of petitioner's four treating doctors in that case. 440 F.3d at 1326.

Here, petitioner cannot provide expert medical testimony at all. The medical records are replete with examinations that proved normal, although petitioner complained about various symptoms. Her history to a doctor that she had anaphylactic shock after receiving the second hepatitis B vaccination is not what the contemporaneous medical records state. No one diagnosed petitioner with anaphylactic shock. It would be difficult to be in shock with normal breathing and normal blood pressure.

Beyond her initial and transitory red and bruised right shoulder and feeling of weakness, petitioner has not proved that she had a lasting injury, whether neurological or gastric, due to hepatitis B vaccine. The only record petitioner provided that surmises more than a transient

reaction to the vaccine occurred is from the psychologist Chuck Denison who admits he is not trained to diagnose neurologic illnesses. He offered an opinion on causation which the undersigned struck based on her decision not to admit the testimony of a dentist on diagnosing a neurologic condition in Domeny v. Secretary of HHS, No. 94-1086V, 1999 WL 199059 (Fed. Cl. Spec. Mstr. March 15, 1999), aff'd, (Fed. Cl. May 25, 1999) (unpublished), aff'd, 232 F.3d 912 (Fed. Cir. 2000) (per curiam) (unpublished) (proffer of dentist's testimony for diagnosis of a neuropathy rejected). Petitioner's counsel herein is the same counsel that represented Ms. Domeny.

The neurologists who examined petitioner found nothing organically wrong with her. Her gastric problems came before vaccination and are due to stress. Petitioner's vaccine injury of a red and bruised arm was disappearing on the day of the vaccination. No one diagnosed her with anaphylactic shock.

The Vaccine Act requires that petitioner's vaccine injury and its sequelae last more than six months. 42 U.S.C. §300aa-11(c)(1)(D)(i). Petitioner has not proved that she had a vaccine injury lasting more than six months. She has not proved that she had a neurological reaction to the vaccination. Her gastric problems and headaches preceded the vaccination. No medical doctor diagnosed her psychological problems were caused by vaccination.

The doctors found that petitioner's complaints do not match any neurologic or physiologic distribution and that if she were distracted, her tremors stopped. Her tremors also stopped when she was sleeping. The only reasonable conclusion of the doctors was that petitioner did not have an organic basis for her symptoms. Dr. Kumar diagnosed her with conversion disorder.

Petitioner has failed to prove a prima facie case on the record that would justify compensation in this case. Therefore, her petition must be dismissed.

The telephonic status conference set for March 20, 2007 at 2:30 p.m. (EDT) is hereby cancelled.

### **CONCLUSION**

Petitioner's petition is dismissed with prejudice. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment in accordance herewith.<sup>3</sup>

**IT IS SO ORDERED.**

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DATE

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Laura D. Millman  
Special Master

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<sup>3</sup> Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party's filing a notice renouncing the right to seek review.