OFFICE OF SPECIAL MASTERS
No. 05-1080V
July 31, 2006
To Be Published

MARY A. SCHOEPPNER,	*	
	*	
Petitioner,	*	
	*	
v.	*	Entitlement. GBS does not
	*	have vegetative symptoms
SECRETARY OF THE DEPARTMENT OF	*	for six months pre-manifestation;
HEALTH AND HUMAN SERVICES,	*	flu vaccine not the cause
	*	
Respondent.	*	

Nicole V. Gurkin, New York, NY, for petitioner.
Mark C. Raby, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION[1]

Petitioners Michael A. and Mary A. Schoeppner filed a petition on October 12, 2005, under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10 et seq., alleging that Mary A. Schoeppner (hereinafter, "Ms. Schoeppner") developed Guillain-Barre Syndrome (GBS) as a consequence of taking influenza virus vaccine on September 26, 2003. Since Ms.

[1] 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.

Schoeppner is an adult, her husband Michael has no representative capacity under the Vaccine Act, §300aa-11(b)(1)(A). He was struck as a petitioner on November 8, 2005.

On July 28, 2006, petitioner's counsel requested the undersigned to rule on the record although petitioner was given the option of having a hearing.

FACTS

Petitioner was born on July 8, 1957.

On May 21, 1998, she saw Dr. Martha Price with an elevated thyroid stimulating hormone of 9.1 (normal range being between 0.4 and 5.5). Med. recs. at Ex. 9, p. 2.

On July 9, 1998, she was at St. Joseph's Diagnostic Center. She was hypothyroid by laboratory tests and symptoms. She had essentially normal thyroid uptake. Med. recs. at Ex. 10, p. 1.

On July 13, 2001, petitioner saw her physician, Dr. Wendy Weiss, because of her hypertension. She was on Synthroid. Med. recs. at Ex. 11, p. 2.

On September 25, 2003, petitioner had her annual physical with Dr. Weiss. She had a psychiatric history of depression. She had a cardiovascular history of hypertension. She reported alcohol use. She smoked and she was hypothyroid. Med. recs. at Ex. 1, p. 1.

One day later, on September 25, 2003, petitioner received influenza vaccine. Med. res. at Ex. 2, p. 1.

On October 23, 2003, petitioner saw Dr. Weiss, complaining of depression. She was not in acute distress. Med. recs. at Ex. 1, p. 3.

On October 28, 2003, petitioner saw Dr. Weiss, complaining of swelling around her eyes for the prior two days. She was unable to open them the morning before. Benadryl helped. The

swelling started with her use of a vitamin E and aloe cream. On physical examination, she was not in acute distress. Dr. Weiss diagnosed petitioner with an allergic reaction. Med. recs. at Ex. 1, p. 4.

On January 21, 2004, petitioner saw Dr. Weiss, complaining of depression and hypertension. On physical examination, she was not in acute distress. Dr. Weiss diagnosed petitioner with depression, hypertension, and eczema. Med. recs. at Ex. 1, p. 5.

On April 4, 2004, petitioner saw Dr. Weiss, complaining of low back pain, and some tingling in her feet for the past month which had become more constant and extended to her upper thigh. Petitioner denied numbness. She had no previous history of back injury or problems. Petitioner stated she had moved about one month previously and did a lot of heavy lifting. She felt her back pop a couple of times in the middle of the move, but did not have any pain. On physical examination, she was not in acute distress. Her deep tendon reflexes (DTRs) were normal. Dr. Weiss's impression was low back pain. Med. recs. at Ex. 1, pp. 7, 8.

Five days later, on April 9, 2004, petitioner saw Dr. Weiss, complaining of worsening pain in her back, and numbness in her hands and legs. On physical examination, petitioner had decreased reflexes in her patella and brachial area, and tenderness in her lumbar spine. Med. recs. at Ex. 1, p. 9.

Three days later, on April 12, 2004, petitioner saw Dr. Weiss, complaining of worsening weakness in her legs, and numbness. She had deteriorated significantly since her visit three days prior. She was unable to ambulate independently. Med. recs. at Ex. 1, p. 10.

That same day, April 12, 2004, petitioner went to St. Joseph's Hospital where Dr. Susan Steen, a neurologist, took a history that petitioner had low back pain for six weeks. Over the

prior two weeks, she had tingling in her feet, paresthesia, and some dysesthesia. In the past day or two, she noticed this in her hands. She was markedly unsteady and unable to walk over the prior few days. She had had four migraines in her life. Otherwise, she had no history of headaches or visual disturbance. Med. recs. at Ex. 3, p. 3.

On April 12, 2004, a brain MRI was done which was normal. Med. recs. at Ex. 3, p. 9.

On April 14, 2004, an EMG and nerve conduction study were done. Dr. Jo Parada found the results to be normal. Med. recs. at Ex. 3, pp. 14, 16.

On April 20, 2004, a consultation report by Dr. Kantilal Bhadja at Tampa General Hospital states that petitioner received physical therapy, occupational therapy, and rehabilitation for generalized weakness and ataxic gait secondary to GBS. She complained of some tingling and numbness in her extremities. The GBS started about a week previously. Med. recs. at Ex. 4, p. 1.

On April 21, 2004, Dr. Venerando Batas at Tampa General Rehabilitation Center stated that petitioner was in a state of good health until about six weeks prior to admission when she developed back pain. She had no history of back pain. Over the prior two weeks, she developed paresthesias in her hands and feet. Within a couple of days, she developed weakness in her legs. Med. recs. at Ex. 4, p. 3.

Petitioner filed a VAERS[2] report dated December 24, 2004. Ms. Schoeppner filled out this form herself. Under the onset for the vaccine reaction, she listed March 2004. Med. recs. at Ex. 15, p. 3.

Other Submitted Material

[2] Vaccine Adverse Event Reporting System.

Petitioner's affidavit, attached to the petition and dated September 28, 2005, states that by mid-October 2003, she had headaches, depression, anxiety, and trembling. She saw Dr. Weiss on October 23, 2003, and the depression continued. In late February or early March 2004, she had pronounced back pain, and her extremities were tingling.

Petitioner's husband's affidavit, attached to the petition and dated September 28, 2005, states that shortly after she received her flu vaccination, she became depressed, had no energy, started missing work, and lost all desire to go out. Gradually, she started to feel tingling in her fingers and feet.

Petitioner's son Michael's affidavit, attached to the petition and dated September 24, 2005, does not deal with onset.

Petitioner's son Mark's affidavit, attached to the petition and dated September 28, 2005, states that, after she received flu vaccine, petitioner complained of depression, headaches and mild lower back pain. She really did not feel well in late February or early March 2004.

Petitioner filed an expert report from Dr. Thomas F. Morgan, a neurologist, dated November 28, 2005, stating that petitioner's fatigue and generalized weakness weeks after her flu vaccination were "vegetative" symptoms that were the beginning of an "insidious" or "subtle" onset of GBS. P. Ex. 13, pp. 1, 3.

Attached to Dr. Morgan's report are excerpts from the medical literature. The first is chapter 46, "Diseases of the peripheral nerves," which states that antecedent events, such as a respiratory or gastrointestinal infection, precede the neuropathic symptoms by one to three weeks, sometimes longer. *Id.* at p. 5. It goes on to state that paresthesias and slight numbness in the toes and fingers are the earliest symptoms. The major clinical manifestation is weakness that

evolves more or less symmetrically over a period of several days to a week or two, or somewhat longer. *Id.* at p. 7. The weakness progresses in a few days. *Id.* More than half the patients complain of pain in the muscles of the hips, thighs, and back. *Id.* By the end of the week, vibration and joint position sense in the toes and fingers are usually reduced. *Id.* Reduced and then absent tendon reflexes are consistent findings. *Id.* In most patients, the paralysis ascends from legs to trunk, arms, and cranial muscles and reaches a peak of severity within 10 to 14 days. *Id.* The axonal type of GBS represents 5 percent or fewer of cases. *Id.* In a few patients, the weakness evolves for three to four weeks or longer and from this group, a chronic form of demyelinative neuropathy (chronic inflammatory demyelinating polyneuropathy or CIDP) often emerges. *Id.*

For those with the acute axonal form of GBS, the report in the medical literature described five patients, all with a rapid evolution of polyneuropathy and very slow and poor recovery. *Id.* Unlike the common form of GBS, muscle atrophy became apparent early in the disease (within weeks). *Id.*

Dr. Morgan also attached a summary of the symptoms of depression from Psychiatry, 5th ed., by D.A. Tomb. P. Ex. 13, p. 8. Under "Vegetative features," the author lists fatigability, no energy, insomnia or hypersomnia, anorexia or hyperrexia, weight loss or gain, psychomotor retardation, psychomotor agitation, impaired libido, and frequent diurnal variation. *Id.* at p. 9.

Petitioner filed Dr. Morgan's supplemental expert report, dated January 31, 2006. P. Ex. 16, p. 1. Dr. Morgan agrees that petitioner's "first clear findings" of atypical GBS were reported around March 5, 2004. *Id.* However, because petitioner had either the Miller Fisher variant or the axonal variant, the fact that these were variants means, "by their nature," that they have

"prolonged insidious onsets." *Id.* He concludes that petitioner's fatigue and weakness after her flu vaccination were consistent with atypical GBS variant. *Id.* at p. 2. He finds Dr. Weiss's medical records, which "do not elaborate on vegetative symptoms and also do not mention neurological examinations that would detect insidious atypical Guillain-Barre syndrome variants" to be supportive of his opinion. *Id.* Because neurological complaints were not described, a neurological examination was not done and this delayed diagnosis. *Id.* Dr. Morgan opined that patients with depression "often develop neurological complaints or syndromes that are masked or unrecognized because of preexistent chronic depression." *Id.*

Attached to Dr. Morgan's supplemental report is the NINCDS "Criteria for Diagnosis of Guillain-Barré Syndrome" (P. Ex. 17, p. 1) which Dr. Morgan claims support his point that onset may be insidious in GBS. However the Criteria do not say onset may be insidious. The Criteria state that progression in variants (after onset) may exceed four weeks. *Id.* The Criteria state that the features required for diagnosis are: (a) progressive motor weakness of more than one limb; and (b) areflexia. *Id.* Features strongly supportive of the diagnosis of GBS are progression (symptoms and signs of motor weakness develop rapidly but cease to progress by four weeks into the illness); relative symmetry; mild sensory symptoms or signs; cranial nerve involvement; recovery; autonomic dysfunction; and absence of fever. *Id.*

Another reference Dr. Morgan provides with his supplemental report, Adams and Victor's Principles of Neurology, 8th ed. (P. Ex. 17, p. 2) states that variants of GBS, including the acute axonal form, have an abrupt and explosive onset and a rapid evolution. *Id.* Muscle atrophy becomes apparent relatively early in the disease (within weeks). *Id.*

Dr. Morgan attaches another reference to subacute sensorimotor paralysis which evolves over four to eight weeks. *Id.* at p. 4.

Respondent filed a report from Dr. Gerald F. Winkler on May 26, 2006. R. Ex. A. Dr. Winkler states that he agrees with Dr. Morgan that the first clear symptoms of petitioner's atypical GBS variant began around March 5, 2004. He disagrees with Dr. Morgan when he states, without supporting evidence, that the axonal variant of GBS has a prolonged, insidious onset that makes diagnosis difficult. R. Ex. A, at p. 1. He also disagrees with Dr. Morgan when he states without supporting evidence that many of the early symptoms of GBS variants are not diagnosed, and that the medical onset of petitioner's GBS is consistent with the insidious nature of atypical GBS variants. All the medical literature that Dr. Morgan provided states that GBS may progress for longer than four weeks but they do not discuss the time interval between a proposed cause and the onset of GBS. *Id.* Dr. Winkler disagreed with Dr. Morgan that petitioner's fatigue and weakness were consistent with the diagnosis of GBS. The table listing depressive symptoms that Dr. Morgan provided lists fatigue, lack of energy, and somatic complaints as symptoms of depression, not of GBS. *Id.* at p. 2.

Dr. Winkler states that petitioner was in active treatment for depression. Dr. Morgan assumes, without evidence, that petitioner had symptoms of GBS before March 5, 2004, but she did not report them to Dr. Weiss. But this assumption is contrary to petitioner's history. If Dr. Morgan is suggesting petitioner had symptoms of GBS but did not perceive she had any symptoms, that would contradict the definition of a symptom. *Id.* at p. 3. A symptom is what the patient perceives.

Dr. Winkler also states that Dr. Morgan assumes, without evidence, that petitioner had objective symptoms of GBS before March 5, 2004, but Dr. Weiss did not find them because she did not perform the necessary examinations. Dr. Morgan assumes they must have been there even though they were not discovered. *Id.* There is also no evidence that petitioner's depression before March 2004 was worse than her prevaccination depression. *Id.* Dr. Winkler concludes that petitioner's flu vaccine did not cause her GBS whose symptoms began in late February or early March 2004.

Petitioner filed Dr. Morgan's second supplemental report, dated June 26, 2006. P. Ex. 20. He disagrees with Dr. Winkler that flu vaccine did not cause petitioner's GBS. She had an axonal variant of GBS, which is difficult to diagnose. *Id.* at pp. 1-2. Dr. Morgan claims that atypical GBS of the axonal variant would require months to develop. *Id.* at 2. Fifty percent of axons would need to be damaged before symptoms and signs arose. *Id.* Atypical syndromes require clinical judgment and "clinical dictums." *Id.* He insists petitioner's depression masked her symptoms of slowly progressive atypical GBS, and that chronic depression "often masks a hidden neurological condition due to the emotional and cognitive components associated with the depression and will interfere with the interpretation of neurological and vegetative symptoms." *Id.* Because petitioner's GBS was subtle and slowly progressive, this interfered with Dr. Weiss's ability to detect the signs and symptoms.

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

Dr. Morgan's medical analysis contradicts both the evidence in Ms. Schoeppner's medical records as well as the medical literature which he supplies in supposed confirmation of his analysis. Rarely has the undersigned read an expert's report which is so blithe in postulating an opinion that ignores both the pre- and postvaccination medical records and medical literature. Ms. Schoeppner had a history of depression before she ever received the flu vaccine. Dr. Weiss was her treating physician. No visit that Ms. Schoeppner made to Dr. Weiss reflects a worsening of her depression or weakness or fatigue until April 2004 when petitioner recounts a one-month history of back pain and tingling. The only different history in the medical records between the flu vaccination in October 2003 and the onset of her GBS in March 2004 was her allergic reaction to a vitamin E and aloe cream. In addition, there was one mention of eczema. It beggars credulity to assume that petitioner would report her eye swelling, but keep silent about any neurologic symptoms during these six months. And when she did begin to have neurologic symptoms (pain in her back and tingling), she reported them to Dr. Weiss in April 2004.

A perusal of petitioner's medical records shows a classic case of GBS, even of the variant known as axonal GBS: an abrupt onset of symptoms, with progression of symptoms over weeks to a few days from back pain and tingling with normal DTRs, but absence of numbness, to lessened DTRS, numbness, increased weakness, culminating in inability to walk. None of petitioner's treating physicians ever opined that her onset of GBS occurred before March 2004.

Dr. Morgan's hypothesis that petitioner's longstanding depression after her vaccination was any different than her depression before the vaccination comes from his imagination. Dr. Weiss, who was petitioner's primary care physician, saw petitioner frequently and noted no difference in petitioner's mental state before April 2004. The list of "vegetative symptoms"

which Dr. Morgan provided, which includes anorexia, insomnia, and a whole laundry list, are not applicable in this case because petitioner never complained of them. His thesis that for people who are depressed, their depression frequently masks neurologic symptoms is totally unwarranted and he does not support this assertion with any medical literature.

Petitioner's course of GBS is completely typical, according to the "Criteria for Diagnosis for Guillain-Barré Syndrome," which Dr. Morgan provided:

> 1. *Features Required for Diagnosis*
>
> A. Progressive motor weakness of more than one limb. ...
>
> B. Areflexia (loss of tendon jerks). ...
>
> 2. *Features Strongly Supportive of the Diagnosis*
>
> A. Clinical features (ranked in order of importance)
>
> 1. Progression. Symptoms and signs of motor weakness develop rapidly....

The undersigned notes that petitioner herself considered the onset of her GBS to be March 2004, when she filled out her VAERS report in December 2004. Although in her affidavit, petitioner states that, by mid-October 2003, she had headaches, depression, anxiety and trembling, she told Dr. Susan Steen, a neurologist at St. Joseph's Hospital, on April 12, 2004, that she had had four migraines in her life and, otherwise, had no history of headaches.

The undersigned would expect that if someone had a neurologic condition, she would have neurologic symptoms. The undersigned does not expect petitioner to diagnose herself. The undersigned just expects that if a symptom existed, petitioner would have informed Dr. Weiss

about it. A review of petitioner's medical records shows no neurologic symptoms until March 2004 according to the history petitioner gave in April 2004 to Dr. Weiss.

Petitioner did not have GBS during October 2003 through January 2004 when she saw Dr. Weiss for an allergic reaction to eye cream, and for her pre-vaccination symptoms of depression, hypertension, and hypothyroidism, and for eczema, a skin condition. Nothing in the medical literature that Dr. Morgan provided supports the idea that depressed people often have neurologic symptoms, that their depression masks these neurologic symptoms, that one can have a neurologic disease without complaining to a doctor of symptoms of a neurologic condition such as burning, tingling, numbness, or gait disturbance. Dr. Morgan's opinion is not credible because it flies in the face of petitioner's medical records and the medical literature he provided.

There is no evidence in this case that petitioner ever had chronic inflammatory demyelinating polyneuropathy (CIDP) which does progress over months. This is the chronic form of polyneuropathy, whereas GBS is the acute form of polyneuropathy. Dr. Morgan has not asserted petitioner has CIDP and no treating doctor ever diagnosed petitioner with CIDP.

Dr. Morgan's serious deficiencies in opining contrary to both what petitioner's medical records and medical literature clearly show necessitates dismissal of this case. Respondent's Dr. Winkler astutely explained that GBS is known for its rapidity of onset, even though, once there is onset, symptoms may progress longer than a few weeks, that Dr. Weiss did not fail to elicit symptoms about which petitioner never complained, that the records clearly note when petitioner's neurologic symptoms began (in March 2004), and that there is no causation of petitioner's GBS from the flu vaccine.

Petitioner has failed to make a prima facie case of causation in fact. This petition must therefore be dismissed.

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.[3]

IT IS SO ORDERED.

_____ _____

DATE Laura D. Millman
Special Master

[3] 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.