In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 13-818V
April 11, 2014
Not to be Published

ALANNA SULLIVAN BARKER,	*	
	*	
Petitioner,	*	
	*	
v.	*	FluMist; GBS; no credible proof
	*	of GBS; no proof of neurologic injury
SECRETARY OF HEALTH	*	
AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

Alanna Sullivan Barker, Englewood, CO, for petitioner (pro se).
Justine E. Daigneault, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION[1]

On October 21, 2013, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10–34 (2006), alleging that the FluMist vaccine she received on October 20, 2010 caused her to develop Guillain-Barré Syndrome ("GBS").

[1] Because this decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this 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 constitute a clearly unwarranted invasion of privacy. When such a decision is filed, petitioner has 14 days to identify and move to redact such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the categories listed above, the special master shall redact such material from public access.

On January 16, 2014, the undersigned issued an Order to Show Cause why this case should not be dismissed during the first telephonic status conference scheduled for Friday, January 17, 2014.

On January 17, 2014, petitioner's counsel stated he had not yet discussed the undersigned's Order to Show Cause with petitioner and explained that he had filed the petition on her behalf shortly before the statute of limitations would have run, based on petitioner's representation that she had GBS. Petitioner's counsel said he did not disagree with the undersigned's analysis of petitioner's medical records.

On January 24, 2014, the undersigned held another telephonic status conference during which petitioner's counsel stated petitioner had asked for more time to speak to her doctors before deciding whether or not to dismiss her case. Petitioner's counsel stated he gave petitioner the undersigned's Order to Show Cause.

On February 7, 2014, the undersigned held another telephonic status conference during which petitioner's counsel stated petitioner had not contacted him although he gave her a deadline in a letter he sent her. He said he plannedto file a motion to withdraw as counsel that day, which he did.

On February 11, 2014, the undersigned granted counsel's motion to withdraw, making this case pro se. The undersigned attached to that order a list of attorneys admitted to practice in the Vaccine Program in case petitioner wanted to find another attorney to represent her.

On February 12, 2014, the undersigned issued an order setting a telephonic status conference with petitioner and respondent's counsel for March 18, 2014, at 2:00 p.m. At the subsequent request of petitioner, however, the undersigned issued a new order on March 18, 2014, rescheduling the telephonic status conference with petitioner and respondent's counsel for April 9, 2014.

On April 9, 2014, the undersigned held a status conference with petitioner and respondent's counsel, which was digitally recorded. During a lengthy discussion of the contents of the undersigned's Order to Show Cause, petitioner orally moved to dismiss.

The undersigned **GRANTS** petitioner's motion to dismiss and **DISMISSES** this case.

FACTS

Petitioner was born on September 2, 1978.

On August 2, 2010, petitioner saw her personal care physician Dr. Lawrence Frerker. Med. recs. Ex. 3, at 14. She had anxiety panic attacks and anorexia. Id. She requested some paperwork regarding disability from Dr. Frerker. Id. He diagnosed petitioner with anorexia

nervosa, malaise and fatigue, anxiety, migraine, insomnia, unspecified functional disorder of the stomach ("functional" means there is no physical basis for it[2]), epigastric abdominal pain, unspecified backache, and panic disorder. Id. He refilled her Xanax prescription (Xanax is prescribed for anxiety and panic disorder) and encouraged her to follow up with a psychiatrist. Id.

On August 26, 2010, petitioner returned to Dr. Frerker to follow up on her anxiety and anorexia. Id. at 16. She complained of diarrhea, abdominal discomfort, and joint pain in her shoulders, hips, knees, ankles, elbows, and fingers. Id. Her rheumatology lab results two months previously were normal. Id. Petitioner was having problems with her migraine headaches. Id. She also complained of fatigue and malaise. Id.

On September 28, 2010, petitioner saw Dr. Frerker. Id. at 18. Her disability status was confirmed. Id. She was seeing a psychiatrist. Id. She needed paperwork completed for an extension of her disability. Id.

On October 20, 2010, petitioner received FluMist. Med. recs. Ex. 2, at 2.

On October 26, 2010, petitioner saw Dr. Robert T. Spencer, a rheumatologist. Med. recs. Ex. 18, at 9. Petitioner had a long-standing history of anxiety disorder. Id. She had significant life stressors over the last few years, which led to a recent exacerbation. Id. She moved to Southern California for a job, but because of her children's health issues, she decided to move from Los Angeles back to Colorado in 2010. Id. Petitioner's four-year-old daughter has partial deletion of chromosome 17, causing an autistic-like syndrome. Id. Her fourteen-year-old daughter had scoliosis that required surgery. Id. Petitioner's anxiety disorder worsened after her move. Id. She had been seeing Dr. Frerker and a psychiatrist for this problem. Id. While dealing with this, she started noticing pain and weight loss beginning perhaps in February 2010. Id. Dr. Frerker wondered if she had anorexia nervosa, although her psychiatrist, Dr. King at Lutheran Hospital, had not corroborated this diagnosis. Id. Petitioner said her pain started in her shoulder but spread to her hips and back. Id. She had mild morning stiffness lasting no longer than an hour. Id. She had no neurological complaints.[3] Id. Petitioner had a history of headaches. Id. For medications, she took Vivelle (estradiol), testosterone, progesterone, Xanax, Adderall (an amphetamine psychostimulant), Trazodone (an antidepressant used for insomnia), and Tramadol (a narcotic pain reliever). Id. Petitioner's weight had been stable the last four

[2] A functional disorder is "a disorder of physiological function having no known organic basis. . . . [T]he term is often used in psychiatry as roughly equivalent to 'psychogenic disorder'. . . ." Dorland's Illustrated Medical Dictionary 550 (32d ed. 2012) ("Dorland's").

[3] In petitioner's affidavit, she states that before FluMist, she was healthy, but on October 22, 2010 (four days before she saw Dr. Spencer), she had flu-like symptoms (fever, cough, sore throat, chills, body aches, diarrhea, and fatigue). Med. recs. Ex. 1, at 2. She says she telephoned Dr. Frerker's office to report this, but there is no record of any such call in Dr. Frerker's office notes. Id. Moreover, she never mentioned any of these symptoms to Dr. Spencer. Id.

months. Id. at 10. She had fatigue and sleep issues, but they had improved. Id. She complained of constipation. Id. Her right shoulder bothered her the most. Id. She had modest-moderate tenderness in the most typical trigger point areas. Id. A complete range of systems was otherwise unrevealing. Id. Petitioner's muscle bulk and tone were symmetrical. Id. Her strength was normal. Id. Dr. Spencer diagnosed petitioner with myofascial pain syndrome/fibromyalgia,[4] anxiety disorder for which she was under psychiatric care (and said she had improved on Xanax and Adderall), and right shoulder pain consistent with rotator cuff tendinitis. Id.

On November 12, 2010, petitioner returned to Dr. Spencer, the rheumatologist. Id. at 11. She told him her symptoms were unchanged. Id. Most of her pain was localized to her neck and superior trapezius regions. Id. Her right shoulder was still the source of her discomfort. Id. She was seeing a chiropractor who did acupuncture massage. Id. On physical examination, petitioner had symmetric and above average muscle bulk and tone. Id. Her strength was 5+/5+. Id. Dr. Spence diagnosed petitioner with diffuse pain syndrome. Id. She had a clinical constellation of sleep disturbance, psychiatric disease, fatigue, diffuse pain, and myofascial tenderness, strongly supportive of a diagnosis of myofascial pain syndrome/fibromyalgia. Id.

On November 22, 2010, petitioner telephoned Dr. Frerker's office, complaining of an awful migraine that started the day before (i.e., November 21, 2010), which was getting worse.[5] Med. recs. Ex. 3, at 1. Petitioner requested a prescription for Percocet (oxycodone, which is a narcotic, and acetaminophen, which is an analgesic or pain reliever[6]), which Dr. Frerker approved. Id.

Petitioner stated in her affidavit that she saw Dr. Frerker in early December 2010. Med. recs. Ex. 1, at 2. Dr. Frerker's medical records do not reflect that petitioner saw him in early December 2010.

The next medical record reflecting petitioner's seeking medical assistance is dated January 13, 2011, which is twelve weeks or three months after petitioner received her FluMist

[4] Fibromyalgia is "pain and stiffness in the muscles and joints that is either diffuse or has multiple trigger points." Dorland's, supra, at 703.

[5] Although petitioner states in her affidavit that she telephoned Dr. Frerker's office a few days after October 22, 2010, when she purportedly had flu symptoms of fever, cough, sore throat, chills, body aches, diarrhea, and fatigue, not only does this alleged phone call not appear in Dr. Frerker's records, but the one phone call that does appear in his records (the one on November 22, 2010) does not contain any complaint about flu-like symptoms. Petitioner instead complains of a severe migraine.

[6] Dorland's, supra, at 1409.

vaccine.[7] On January 13, 2011, at 2:13 p.m., petitioner went to Sky Ridge Medical Center Emergency Room ("ER"). Med. recs. Ex. 4, at 1. Upon initial examination, petitioner was mildly tremulous and had difficulty speaking, but when the examiner Gerald A. Ashbeck got her talking about her children, she could speak without difficulty. Id. Petitioner was acting very odd to the staff, saying that she needed three times normal medication to affect her. Id. On examination, petitioner's vital signs were stable, and her neurological examination was normal. Id. The diagnosis was that her clinical picture did not suggest GBS, encephalitis, or meningitis. Id.

One hour and twenty-five minutes later, on January 13, 2011, at 3:38 p.m., petitioner returned to Sky Ridge Medical Center ER, where she complained to RN Trina Shook that she was acting differently, vomiting, had tremors, and had trouble walking. Id. at 3. Her temperature was 98.4 degrees Fahrenheit. Id. She said the onset was two weeks prior. Id. She reported her pain level upon examination was ten out of ten. Id. Petitioner gave a past medical history of having multiple sclerosis (which is untrue). Id. She had had a hysterectomy and was a current smoker, smoking one pack of cigarettes a day. Id. She had a history of marijuana use. Id. The functional assessment was that petitioner had no impairments. Id. Petitioner reported anxiety and was speaking in sentences that did not make sense. Id. She had rapidly changing ideas. Id. Petitioner complained of difficulty walking which started one year prior. Id. at 6. The current episode started two weeks ago and was still present. Id. She had had weakness, numbness, and tingling. Id. She had difficulty with speech and a recent fall. Id. She had difficulty walking. Id. She did not have any visual disturbance or impaired swallowing. Id. Petitioner stated that every three to four weeks, she felt as if she had the flu and became very tired. Id. She would sleep for two to three days and then get better. Id. She reported this had been going on for one year. Id. She reported symptoms of nausea, left-sided headache, speech difficulty, body aches, left-sided weakness, and vomiting several times, but no fever. Id. On physical examination, petitioner's extremities exhibited a normal range of movement. Id. at 7. She was alert and oriented. Id. Her speech was normal. Id. Petitioner had no motor deficit, no sensory deficit, and normal reflexes. Id. An addendum to this record, on January 13, 2011, at 6:00 p.m., states that petitioner refused a wheelchair as she was leaving the ER. Id. She was arguing with her husband and walked out to the car from the ER on her own. Id.

On January 14, 2011, petitioner saw Dr. Ronald S. Murray, a neurologist, complaining of a possible demyelinating disease and concerned that she might have MS. Med. recs. Ex. 5, at 1. She was self-referred, meaning petitioner referred herself to Dr. Murray. Id. She had not

[7] If petitioner had GBS more than two months after receiving flu vaccine, the undersigned would not rule in her favor because the undersigned has never gone beyond two months in finding a causal nexus between a vaccination and a demyelinating disease, such as GBS. See Corder v. Sec'y of HHS, No. 08-228V, 2011 WL 2469736 (Fed. Cl. Spec. Mstr. May 31, 2011) (flu vaccine did not cause petitioner's GBS four months later). But petitioner never had GBS or any nervous system disease.

previously seen a neurologist or had a brain MRI. Id. Petitioner went to the ER the day before in both the afternoon and the evening. Id. Her brain CT scan was normal. Id. Her blood tests noted macrocytic anemia. Id. Her urine drug screen was positive for opiates. Id. Petitioner's history was very complicated. Id. She said her problems had been present since February 2010, but were mild in nature. (February 2010 is eight months before her FluMist vaccination.) Id. Over the prior two to three weeks, her problems accelerated. Id. Her symptoms were primarily left-sided and involved eye pain, numbness on the left side of her face and left body with left bodily weakness. Id. She was sensitive to light. Id. She said she had extreme fatigue and was exhausted. Id. She did not sleep well. Id. She complained of headache and said her balance was off. Id. She felt she was deteriorating rapidly. Id. She developed a lumbar puncture headache after an epidural anesthetic procedure during a delivery of her baby. Id. She saw Dr. Robert Spencer, a rheumatologist, recently who diagnosed her with fibromyalgia. Id. She also stated she was diagnosed with vitamin D deficiency, vitamin C deficiency, and vitamin B12 deficiency. Id. Four years ago, after delivery of her child, she was told that she had a pituitary adenoma, but she never followed up on that. Id.

On physical examination, petitioner was distressed and gave a history with many tangential components. Id. She was alert and oriented. Id. Her speech was at times slurred and, at other times, very clear. Id. Her motor examination revealed five out of five strength in her upper extremities and lower extremities. Id. Her deep tendon reflexes and tone were within normal limits in the upper extremities and lower extremities. Id. Her coordination was grossly intact. Id. Her sensory examination was unremarkable, except for a mildly diminished vibration loss at the ankles bilaterally. Id. Her gait was unusual in that she thrust her hips forward as she walked and had a slight high step that was wide-based. Id. The Romberg test was positive with her eyes closed. Id.

Dr. Murray stated: "I do not see any objective evidence of neurologic damage although she has an unusual gait." Id. He thought it very unlikely that she had a condition such as MS. Id. It was possible that she had a pituitary tumor that was causing hormonal instability. Id. He wanted her to undergo a brain MRI. Id. She could have cervical spinal disease and/or demyelinating disease. Id. He also wanted her to undergo a brain and cervical spine MRI. Id. Dr. Murray posited that petitioner's positional complaints could be secondary to a spontaneous cerebrospinal fluid leak causing intracranial hypotension. Id. at 3. A brain MRI might be helpful to show diffuse meningeal enhancement, indicating a low-pressure syndrome. Id. She did have macrocytic anemia and had not received intramuscular vitamin B12 replacement therapy. Id. She needed regular IM B12 shots at her personal care physician. Id. In an addendum dated January 15, 2011, Dr. Murray noted that petitioner's MRIs of her brain and cervical spine with and without gadolinium enhancement were normal. Id. She did not have meningeal enhancement or changes in her pituitary glands. Id. Petitioner had no signs of demyelinating disease or other central nervous system processes. Id.

Petitioner's husband left a message with Dr. Murray that petitioner's left eye was worsening in visual loss, and her left facial numbness was worsening, as were her left-sided

symptoms. Id. They were on their way to the University of Colorado Medical Center ER when petitioner's husband left the message. Id.

On January 15, 2011, Dr. David Solsberg interpreted a brain MRI with and without contrast. Med. recs. Ex. 6, at 1. She had no abnormal enhancement, no space-occupying lesion, and no demyelination. Id. On the same date, Dr. Solsberg interpreted a cervical spine MRI with and without enhancement. Id. at 2. There was no current lesion. Id.

On January 15, 2011, petitioner was at the University of Colorado Hospital ED where she spoke to Dr. Ben Honigman. Med. recs. Ex. 7, at 9. He noted that she was a very complicated and difficult patient to evaluate. Id. She claimed to have two weeks of progressive neurologic symptoms culminating in hemi-anesthesia on the left side of her body in a straight line down the middle of her face and body. Id. She also claimed to have blurred vision in her left eye. Id. The MRI noted no lesions that were stroke-like or consistent with MS. Id. The hospital's neurological examination showed no objective findings aside from weakness in the left arm, hand, and leg, "but it was not clear if it was volitional or real." Id. Petitioner was able to ambulate with assistance. Id. Neurology "also found an exam that was not consistent with anatomic neuropathology." Id. Her central nervous system was intact, as were her reflexes. Id. The question was whether this was an organic or a functional (i.e., not physically real[8]) pathology. Id. She had been under significant stress that might be contributing to these issues. Id. The staff explained to her husband that they had no explanation at this time for her symptoms. Id. On physical examination, petitioner's eyes were normal to inspection. Id. Her upper extremities were normal. Id. Her lower extremities were normal. Id. Her deep tendon reflexes were normal without left facial droop, but petitioner stated she was weak and could see only black with her left eye. Id. The symptoms did not make sense for a singling lesion anywhere in her brain. Id. Neurology was consulted, which also felt petitioner's symptoms were unrelated to a neurologic issue. Id. The doctor's suspicion was that the symptoms might be more related to stress and anxiety, as the patient had multiple recent life stressors with sick children. Id. Petitioner agreed that stress might be playing a role in her current symptoms. Id.

On January 15, 2011, petitioner was seen by a neurologist at the University of Colorado Hospital. Id. at 1. She complained of left-sided weakness and numbness, vision loss, headache, vertigo, and difficulty concentrating. Id. This had been ongoing for two weeks. Id. Rheumatology, neurology, and her personal care physician had all done physical examinations, which were unremarkable. Id. She has a history of medical visits for functional (i.e., not physically real[9]) symptoms. Id. Her stressors were that two out of her three children had chronic illnesses. Id. She had a recent move. Id. She had a history of depression and anxiety. Id. She had a B12 deficiency. Id. She quit work in December 2010. Id. The diagnosis was that petitioner had a myriad of neurological complaints without any objective findings on physical

[8] See supra, note 1.

[9] See supra, note 1.

examination, apart from functional slow movements on the left and left hemi-anesthesia "which is impossible to get objective evidence for." Id. at 5.

On January 17, 2011, petitioner returned to her personal care physician, Dr. Frerker, complaining of left-sided numbness and weakness. Med. recs. Ex. 3, at 20. She said the symptoms came on relatively gradually over the past few weeks. A rheumatologist she saw diagnosed her with fibromyalgia. Id. "She states that she first became ill December 30[, 2010] with headache, difficulty with depth perception, body aches, fatigue, malaise, and fever[.]" Id. She complained that the symptoms were worsening. Id. She said she had no sensation on the left half of her body. Id. She had fatigue and weakness of the left upper and lower extremities. Id. She also stated she had some temporary blindness in her left eye. Id. Dr. Frerker noted that a complete review of her systems was negative. Id.

On January 28, 2011, petitioner saw Dr. Frerker again. Id. at 22. She requested he refill her medications. Id. She complained of ongoing pain all over and difficulty sleeping at night. Id. She said her energy levels had improved since she received a shot of vitamin B12. Id. She said that neurology wanted her to get weekly B12 shots. Id. She had no other complaints. Id. Dr. Frerker gave her a B12 shot. Id. He diagnosed her with disturbance of skin sensation, migraine, generalized muscle weakness, malaise, fatigue, and unspecified myalgia and myositis. Id.

On March 15, 2011, five months after petitioner received FluMist, petitioner saw another neurologist, Dr. Justin S. Moon.[10] Med. recs. Ex. 8, at 10. She told him that she had lost twenty-five pounds in the past year, and that in December 2010, she had an episode where she became very fatigued and weak, particularly on her left side. Id. She said she experienced significant dizziness with left-sided numbness of her face, hand, and leg, and she felt spasms in these extremities. Id. She said that both legs were affected, but the left leg greater than the right. Id. She also said that she had visual loss, which she described as graying of her visual field that went from blurring to a complete visual deficit, but the vision came back within the course of a week. Id. She said she was having memory problems, foot drop, hoarseness, and some swallowing difficulties. Id. These symptoms gradually improved over a four-week course. Id. It was not until January when she made an appointment to see Dr. Ronald Murray, a neurologist and MS specialist, for evaluation. Id. Dr. Murray did not believe she had MS. Id. He diagnosed her with B12 deficiency and she received intensive levels of B12, which led to weight gain and some

[10] Dr. Moon has a subspecialty in headaches and is part of the Headache Clinic on the website of the Denver Neurological Clinic. Our Physicians, Denver Neurological Clinic, http://denverneuroclinic.com (last visited Jan. 15, 2014). He had a fellowship at the Mayo Clinic in headache and facial pain in June 2008. Med. recs. Ex. 8, at 4. He has been in practice since 2008. Id. Thus, when he saw petitioner, he had been in practice for less than three years. Dr. Moon lists on page two of his CV that he has been an expert witness in six legal cases and advises the Attorney General of Colorado, listing a legal case in which he gave advice to the AG. Id. at 5.

diminishment of symptoms. Id. University Hospital then evaluated her and again diagnosed her with likely B12 deficiency. Id. They dismissed her and she came to Dr. Moon for another opinion, especially since she started getting worse the prior week. Id. As of the prior Wednesday, she felt that the paresthesia on the left appeared somewhat worse, and her gait abnormality was worse. Id. She was very unsteady in her gait. Id. During December through January, she had some personality changes. Id. She was much less inhibited in using foul language and was very irritable. Id. She also noted she was under a lot of stress during this time. Id. She told Dr. Moon that her past medical history was unremarkable (which was untrue). Id. She said she had poor sleep, from seven to fifteen hours. Id. at 11. On physical examination, Dr. Moon found petitioner's deep tendon reflexes were slightly diminished on her left knee relative to her right knee. Id. The rest of her reflexes were unremarkable. Id. The sensory examination showed diminishment to cold temperature, vibration, and pinprick on the left. Id. Dr. Moon diagnosed petitioner with ataxia, MRI abnormality, fatigue, weakness, and visual loss. Id. He stated in his notes that he did not agree with the radiologist's prior interpretation of petitioner's brain MRI as normal. Id. at 12. His review of the brain MRI seemed to indicate leptomeningeal enhancement in the bilateral frontal regions. Id. There was also an area in the posterior brainstem and the base of the cerebellar tonsils that seemed to enhance on MRI. Id. Dr. Moon was highly concerned that petitioner had carcinomatous meningitis (cancer that has spread to the membranes surrounding the brain), and this was the potential etiology for her various symptoms. Id.

On March 15, 2011, Dr. Phillip B. Gunther interpreted an MRI of petitioner's brain and cervical spine. Med. recs. Ex. 6, at 8. Dr. Gunther said the MRIs of her brain and cervical spine were negative (i.e., normal). Id.

On March 30, 2011, petitioner saw Dr. Moon again. Med. recs. Ex. 8, at 13. She said she was much improved on the three days of Solu-Medrol (corticosteroid) therapy he had prescribed for her. Id. On physical examination, Dr. Moon noted that her reflexes were clearly brisk on the right. Id. She had +3 at the biceps, brachioradialis, triceps, and petalla with an abnormal Babinski on the right. Id. On the left, Dr. Moon noted a trace reflex at +1 throughout. Id. (Dr. Moon's results indicate petitioner had hyperreflexia (overactive reflexes) on the right and hyporeflexia (underactive reflexes) on the left, as if petitioner had a central nervous system disease on the right side of her body and a peripheral nervous system disease on the left side of her body, a unique result.) Id. Her gait testing was normal. Id. He looked for etiologies of a tumor with a CT scan of petitioner's entire body and did not find any abnormality. Id. A repeat brain MRI showed no evidence of pachymeningitis (inflammation of the dura mater, which is the outermost of the three membranes or meninges covering the brain and spinal cord). Id. The results of her lumbar puncture were negative. Id. at 14. Dr. Moon did an antibody panel, which he said showed a significantly positive GM1[11] antibody. Id. (Later on, petitioner went to the Mayo Clinic for testing, and the Mayo Clinic found none of her gangliosides abnormal and her physical examination normal as well. Dr. Moon chose to ignore the Mayo Clinic findings.) Dr.

[11] GM1 is a ganglioside. Dorland's, supra, at 760.

Moon considered a positive GM1 antibody indicative of petitioner having an antibody-mediated phenomenon. Id. He noted petitioner clearly got better on steroid therapy, but not 100 percent better regarding cognition, weakness on her left side, hyperreflexia on her right, or speech coordination. Id. Dr. Moon prescribed IVIG (intravenous immunoglobulin, which contains pooled IgG antibodies) for petitioner with one full 2-gram course. Id. For her headaches, Dr. Moon prescribed Protriptyline (an antidepressant) which he stated would help petitioner's anxiety. Id. He stated in his records, "The important issue is, however, that she has had a history of cervical cancer. Autoimmune disorders/paraneoplastic phenomenon can precede a solid tumor by up to 5 years. Therefore, we must be vigilant if there is any clinical change at all in the patient." Id. (In other words, Dr. Moon associated petitioner's symptoms with an autoimmune disorder that presaged another cancer petitioner might have up to five years later, although she had had a hysterectomy previously for her cervical cancer.)

On April 5, 2011, CG Care Management wrote a letter stating that IVIG treatment is not authorized for petitioner's diagnosis. Id. at 17.

On April 7, 2011, CG Care Management wrote a letter stating IVIG treatment is not authorized for GBS. Id. at 18.

On April 19, 2011, petitioner saw Dr. Moon. Id. at 19. Toward the end of the GM1 antibody workup, petitioner started having some shortness of breath, became more tired, and started relapsing with her symptoms. Id. She was given three days of Solu-Medrol. Id. At this visit, she had paresthesias of her right hand, swallowing difficulties, gait abnormality, overall weakness, coordination problems, and subtle dysarthria. Id. Her deep tendon reflexes were +2 on the patella and right upper extremity, and slightly brisk on the left brachioradialis and biceps. Id. Her sensory examination was grossly symmetric. Id. Dr. Moon's diagnosis was antibody-mediated weakness and ataxia. Id. He felt petitioner likely had an antibody disorder "somewhat akin to GBS," and maybe an offshoot of Miller-Fisher syndrome. Id. She relapsed in a short period of time. Id. "We had considered demyelinating disease but this seems much less likely given our overall negative workup." Id. (It is a mystery why Dr. Moon thinks that petitioner has a disease somewhat akin to GBS, since he recognizes that her overall negative workup shows a low likelihood of her having a demyelinating disease. It is as if Dr. Moon is unaware that GBS is a demyelinating disease.) Dr. Moon decided that petitioner needed "strong therapy." Id. He gave her IVIG, but she seemed to relapse a little bit toward the end of it. Id. He wondered if he should give her another round of IVIG or maybe plasmapheresis therapy (plasmapheresis removes harmful antibodies from plasma). Id. He considered giving her Acthar (corticotropin, which prompts the production of steroids). Id. He noted he would double check to see if petitioner had myasthenia gravis (an autoimmune disease of neuromuscular function[12]). Id.

On April 21, 2011, petitioner saw Dr. Moon. Id. at 21. He gave her another course of Solu-Medrol for three days. Id. Petitioner said she continued to have paresthesias in her right

[12] Dorland's, supra, at 1214.

hand, but no other significant abnormalities. Id. Dr. Moon considered her to have an antibody abnormality "loosely associated" with GBS, more like Miller-Fisher syndrome. Id.

On April 21, 2011, Dr. Moon wrote a letter to Case Management to attempt to get them to pay for petitioner's IVIG. Id. at 21. He stated that her clinical diagnosis is "much akin" to Miller-Fisher syndrome, a variant of GBS. Id. He recommended that Case Management reconsider covering her IVIG treatment. Id.

On April 27, 2011, Dr. Adam Wolff, a neurologist who is a colleague of Dr. Moon at Denver Neurological Clinic, did a nerve conduction study and electromyography ("EMG") of petitioner's nerves. Id. at 1. He performed motor nerve conduction studies on petitioner's left peroneal and tibial nerves. Id. They were within normal limits, including normal F wave minimum latencies. Id. He did sensory nerve conduction on petitioner's left sural nerve, and it was within normal limits. Id. He did concentric needle EMG on petitioner's left vastus lateralis, rectus femoris, tibialis anterior, peroneus longus, and medial gastrocnemius. Id. There was no abnormal spontaneous activity, and the motor units showed normal morphology and recruitment. Id. Dr. Wolff's impression was that this was a normal EMG of petitioner's left lower extremity. Id. Dr. Wolff states there was no evidence that petitioner had peripheral nervous system disease. (Dr. Moon seems to have ignored his colleague Dr. Wolff's report, as he never mentions it once in his records for petitioner.)

On May 19, 2011, Commerce Benefits Group wrote a letter saying IVIG is not approved for petitioner's condition. Id. at 25.

On September 8, 2011, petitioner saw Dr. Moon. Id. Petitioner lost her health insurance. Id. She continued to have problems with ambulation. Id. She continued to drop things and had numbness on her left side. Id. Dr. Moon diagnosed her with antibody-mediated disorder in which her GM1 antibody was abnormal. Id. On physical examination, Dr. Moon stated that her reflexes were +2 without evidence of hyperreflexia. Id. He wrote that this is "a very perplexing case." Id. He noted that "some of her exam findings are somewhat unusual." Id. Nevertheless, he prescribed another round of IVIG for petitioner. Id.

On September 15, 2011, Dr. Moon wrote a letter to United Healthcare, prescribing IVIG for petitioner's GBS. Id. at 35.

On October 10, 2011, petitioner saw Dr. Moon. Id. at 36. She had had some improvement, particularly with speech. Id. Petitioner continued to have weakness. Id. She received IVIG, which led to headache. Id. Dr. Moon put her on steroid therapy for the headache. Id. She was not to continue IVIG. Id. He would prescribe plasmapheresis for her. Id. He noted, "I do not know what the end goal will be for Ms. Barker since her clinical symptoms and her examination do not match up very well." Id.

On December 8, 2011, petitioner saw Dr. Moon. Id. at 39. Since undergoing plasmapheresis, petitioner stated she had been doing very well. Id. She said she was feeling forty percent better. Id. She ambulated without significant problems. Id. This was the best Dr. Moon had seen her. Id.

On March 8, 2012, petitioner saw Dr. Moon. Id. at 40. Her GM1 antibodies were elevated at 64. Id. Dr. Moon wrote, "This is a very challenging case." Id. Petitioner applied to have the Mayo Clinic evaluate her. Id. Dr. Moon noted, "We have used different terms to describe her problem, but we believe that this is likely autoimmune related, but there also have been recurrent questions of patient effort on testing." Id. (In other words, petitioner has been faking weakness and sensory perception on physical examination.)

On May 8, 2012, petitioner saw Dr. Nathan P. Staff, a neurologist at the Mayo Clinic. Med. recs. Ex. 15, at 3. Petitioner told him her symptoms started in October 2010 after a flu vaccination. Id. She said she had flu-like symptoms with weight loss, diarrhea, confusion, and prickling of her left hand, which spread to her face and left foot. Id. Over weeks, she developed progressive weakness on the left side of her body. Id. On physical examination, petitioner had give-away weakness (i.e., weakness that petitioner pretends to have on testing) throughout her left body, but on focusing, she had normal strength throughout. Id. Petitioner's reflexes were normal and symmetric. Id. at 4. Dr. Staff writes, "It is unclear what the process is that is going on here." Id.

On May 10, 2012, Dr. Staff noted results of testing on petitioner and recommendations for her future care. Id. at 2. The results of a ganglioside panel, which includes GM1 antibody, were normal. Id. Her EMG was normal. Id. Her evoked potentials on her left lower extremity were normal. Id. Her ANA (antinuclear antibody) was normal. Id. She had normal neurologic studies. Id. He found there was no role for petitioner receiving further immunotherapy. Id. It was unclear what the initial inciting event was two years previously. Id. Dr. Staff recommended that petitioner should be weaned off Prednisone, and she should start physical therapy to retrain her nervous system. Id.

On August 7, 2012, petitioner saw Dr. Spencer, the rheumatologist. Med. recs. Ex. 18, at 13. Petitioner told Dr. Spencer that pain was her main complaint and that her neurological symptoms had subsided. Id. On physical examination, she had symmetrical and above-average muscle bulk and tone. Id. She exhibited decreased reflexes and a slight decrease in strength in her left upper extremity and lower extremity. Id. The lab data from her May 2012 visit to the Mayo Clinic showed her serum GM1 antibodies were negative (i.e., normal). Id. The working diagnosis for her had been atypical GBS v. CIDP. Id. at 14. She appeared to have improved significantly since last year. Id. She had myofascial pain syndrome. Id. Her weight loss had resolved. Id. She had anxiety disorder, but she had not followed up with a psychiatrist for the last several years. Id. She remained on around-the-clock Xanax. Id. Dr. Spencer wrote that psychiatric follow up needed to be considered. Id.

On August 30, 2012, petitioner saw Dr. Moon. Med. recs. Ex. 8, at 39. She had been to the Mayo Clinic and saw Dr. Nathan Staff, who did not find any neurologic phenomenon and, on testing of the GM1 antibody, found it was normal. Id. Petitioner complained of a recent exacerbation of her left-sided weakness and sensory loss. Id. She had recently been prescribed Cymbalta (used to treat major depressive disorder, general anxiety disorder, and fibromyalgia), and Dr. Moon agreed she should be on Cymbalta "and pursue psychological counseling." Id. Dr. Moon still persisted in his view that petitioner had a GM1 antibody, but from the beginning, her clinical exam seemed to be more functional (i.e., not based on physical problems) than neurological in nature. Id. He did not believe that further IVIG, plasmapheresis, or steroids should be pursued. Id. He had no further recommendations for petitioner. Id.

On September 21, 2012, petitioner saw Dr. Spencer, the rheumatologist. Med. recs. Ex. 18, at 15. She had not seen a psychiatrist. Id. Her final SSI disability hearing was late the prior week. Id.

On December 5, 2012, petitioner saw Dr. Moon. Med. recs. Ex. 8, at 41. She said that, since her last visit, she had seen numerous specialists for her various problems, including arthritis pain, weakness, head pain, and body pain. Id. Dr. Moon noted that petitioner had "unusual weakness of the left upper and lower extremity that is associated with an abnormal anti-GM1 antibody but with somewhat of a peculiar neurological exam." Id. Petitioner said her left toes curled up frequently and could cause spasmatic pain. Id. She complained of weakness on her left side and asked for a prescription for Acthar. Id. On physical examination, Dr. Moon noted that petitioner had give-away weakness on the left, and her reflexes were +2 in all extremities. Id. He had no clear recommendation for her, but since petitioner said she responded well to Acthar, it would be clinically reasonable. Id. He prescribed Flexeril for her leg cramps. Id.

On April 29, 2013, petitioner saw Dr. Moon. Id. at 43. Petitioner said she had another relapse of her symptoms lasting the prior three weeks. Id. She said she had weakness of the eye, tremor of the hand, and cramping of the hand and foot. Id. She said she could not lift her left arm above her head. Id. This was similar to what she had reported previously. Id. Dr. Moon wrote, "At this point, again, Ms. Barker is very challenging. We do not have a clear understanding of what is going on. She has already gone to the Mayo Clinic for a consultation. It is, I think, challenging to do Acthar every time we have a relapse, which is approximately once a year." Id. Dr. Moon prescribed, instead, Decadron (a corticosteroid). Id.

On May 10, 2013, petitioner saw Dr. Moon. Id. at 44. She told him she had not improved on Decadron. Id. She was receiving botulinum toxin for headaches through Dr. Hsu. Id. Dr. Moon prescribed Cytoxan (a chemotherapy used to treat cancer and autoimmune disorders) therapy from Dr. Thomas Kenney for neurologic autoimmune disease, which Dr. Moon was willing to diagnose because he still believed she had a GM1 antibody. Id.

On May 13, 2013, Dr. Moon discussed petitioner's case with Oncology. Id. at 45. He noted petitioner had a very unusual autoimmune/inflammatory neuropathy that might be causing some of her weakness. Id.

On May 13, 2013, Dr. Todd F. Capizzi, an oncologist, noted Dr. Moon's request that he administer Cytoxan as an immunosuppressive agent for GM1 antibodies and motor dysfunction. Med. recs. Ex. 19, at 1. He performed a physical examination of petitioner and found weakness on the left side of her body but no real sensory deficits. Id.

On June 4, 2013, Dr. Moon noted that in the two weeks since petitioner had been receiving Cytoxan therapy, she felt strength had returned to her left hand, and she was getting some sensation in her hand and leg. Id. at 46.

On July 9, 2013, Dr. Moon noted that petitioner had received three treatments of Cytoxan and was feeling much better. Id. at 47. He, instead of Dr. Hsu, was going to start botulinum toxin treatments for petitioner the next week. Id.

On August 29, 2013, Dr. Moon noted that petitioner recently had a bout of narcotic overdose and was trying to wean off narcotics. Id. at 48. He was going to perform a botulinum injection for her headaches. Id.

On October 16, 2013, Dr. Jay Krakovitz wrote a brief statement saying that FluMist caused petitioner's GBS. Med. recs. Ex. 17, at 1. (He gives no basis for his opinion.)

On October 17, 2013, Dr. Moon noted that petitioner was continuing with Cytoxan therapy. Id. at 49. She informed him that she was applying for compensation from the federal vaccine program since she took a flu shot just prior to these symptoms in December 2010. Id. (She received flu vaccine in October 2010.)

Also, on October 17, 2013, Dr. Moon wrote a letter, in connection with a VAERS Report,[13] that petitioner developed a very unusual GM1 antibody disorder, causing her weakness, after she received flu vaccine on October 20, 2010. Id. at 50. He states, "This GM1 antibody disorder is not too dissimilar to, in essence, a variant of Guillain-Barre syndrome. We believe there is a likely correlation given the timeline of symptoms." Id.

Did Petitioner Have GBS?

In order for someone to have GBS, a person must lose her deep tendon reflexes, or they must diminish. Clinical Manifestations. Acute Inflammatory Demyelinating Polyneuropathy, in 2 Peripheral Neuropathy 2199 (P.J. Dyck & P.K. Thomas eds., 4th ed. 2005). The single most helpful diagnostic approach is electrodiagnostic, as in electromyography ("EMG") and nerve

[13] Petitioner did not file the VAERS report in this proceeding.

conduction studies. Id. at 2200. For ninety percent of patients, evolution of symptoms reaches its nadir within one month. Id. Hospitalization of a patient suspected of having GBS is imperative because the disease can lead to respiratory paralysis. Id. Hospitalization is almost always required at the time the initial diagnosis of GBS is made. Id.

Dorland's Illustrated Medical Dictionary defines GBS as a "rapidly progressive ascending motor neuron paralysis of unknown etiology, frequently seen after an enteric or respiratory infection. . . . It begins with paresthesias of the feet, followed by flaccid paralysis of the entire lower limbs, ascending to the trunk, upper limbs, and face; other characteristics include slight fever, bulbar palsy, absent or lessened tendon reflexes, and increased protein in the cerebrospinal fluid without a corresponding increase in cells." Dorland's, supra, at 1832.

GBS is progressive, symmetrical (affecting both sides of the body), involving absent or lower reflexes, requiring hospitalization, and resulting in abnormal EMG and nerve conduction studies and elevated protein in the cerebrospinal fluid. The pathological process involves demyelination[14] of the myelin sheath of the peripheral nerves. When a person recovers from GBS, the myelin sheath remyelinates.[15]

Petitioner's clinical examinations for five months after vaccination do not show that she had any neurologic abnormality. She complained of solely left-sided paralysis whose described placement (a straight line down the center of her body) was anatomically impossible. All of her neurological examinations were normal. Someone with normal neurological examinations cannot have GBS.

Her first visit to a doctor after receiving FluMist on October 20, 2010 was with the rheumatologist Dr. Spencer on October 26, 2010. That is only six days after vaccination, but unlike petitioner's claim in her affidavit that she came down with flu-like symptoms on October 22, 2010, she complained to Dr. Spencer about shoulder pain. Dr. Spencer saw petitioner again on November 12, 2010, again for her pain. There were no neurologic deficits.

On November 22, 2010, petitioner telephoned Dr. Frerker to complain about a severe migraine. She never mentioned any flu-like symptoms since the FluMist or any neurological complaints.

On January 13, 2011, almost three months after receiving FluMist, petitioner went to the emergency room of Sky Ridge Medical Center with a panoply of neurologic complaints, none of

[14] Demyelination is the "destruction, removal, or loss of the myelin sheath of a nerve or nerves." Dorland's, supra, at 486.

[15] Remyelination is "restoration of a myelin sheath after demyelination has taken place from a disease or injury." Dorland's, supra, at 1623.

which had any objective basis. She stormed out of the hospital emergency room during an argument with her husband, something a person who was paralyzed on her left side could not do.

On January 14, 2011, she saw the neurologist Dr. Murray, a specialist in MS, and he found her to be neurologically normal.

On January 15, 2011, petitioner went to the University of Colorado Hospital where she saw Dr. Ben Honigman and a neurologist. Both examined her separately and found nothing wrong with her neurologically.

On January 17, 2011, she saw Dr. Frerker and told him that the onset of her neurologic problems was December 30, 2010, but that they really began a year earlier, and that she had had these problems every few weeks. He found her completely normal.

Only five months after receiving FluMist did petitioner get a physician to consider her neurologically abnormal. Dr. Moon first misdiagnosed her with cancer of her meninges. He disbelieved the brain MRI analysis that depicted her brain as normal. A subsequent normal brain MRI forced him to change his diagnosis, but he prescribed a total body CT scan to look for tumors, which proved negative.

Dr. Moon ignored the findings of his colleague Dr. Adam Wolff on April 27, 2011, that EMG and nerve conduction studies did not show petitioner had any neurologic abnormality or peripheral nervous system disease.

Subsequently, Dr. Moon believed that petitioner had a positive GM1 antibody, even though the Mayo Clinic said she did not, and his medical records include highly peculiar physical examinations of petitioner, indicating that she had elevated reflexes on her right side and decreased reflexes on her left. Over time, he realized that petitioner was faking her results, because he noted in his records that she had give-away weakness. But he did not change his diagnosis of or treatment for an autoimmune disease, even though he admitted that her case was challenging and that her physical examinations did not merit the drugs he was prescribing. He explained his reason for prescribing them was that petitioner said she felt better on them. Eventually, after prescribing Solu-Medrol, IVIG, plasmapheresis therapy, Acthar, and other drugs, he prescribed Cytoxan, a chemotherapy drug used on cancer patients and patients with autoimmune disease. Petitioner was treated years ago for cervical cancer with a hysterectomy, and she does not have an autoimmune disease.

DISCUSSION

To satisfy her burden of proving causation in fact, petitioner must prove by preponderant evidence: "(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. Sec'y

of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of Health and Human Services, 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[.]"

Althen, 418 F.3d at 1278.

Without more, "evidence showing an absence of other causes does not meet petitioner's affirmative duty to show actual or legal causation." Grant, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. Id. at 1148.

The Vaccine Act does not permit the undersigned to rule for petitioner based on her claims alone, "unsubstantiated by medical records or by medical opinion." 42 U.S.C. § 300aa-13(a)(1) (2012).

The medical records do not support petitioner's allegation that FluMist vaccine caused her GBS or any neurologic problem. Petitioner went to treating doctors Dr. Spencer, Dr. Murray, and Dr. Frerker, and to two hospitals where she saw Dr. Ashbeck at Sky Ridge Medical Center and Dr. Honigman At University of Colorado Medical Center during the three months after her FluMist vaccination, and none of them opined that she had any neurologic problem, much less GBS. Nearly five months after her vaccination, petitioner saw Dr. Moon, who diagnosed her at first with brain cancer. He ignored the findings of his colleague Dr. Wolff, who performed an EMG and nerve conduction study that showed she was normal neurologically and did not have peripheral nervous system disease. Eventually, based solely on a positive anti-GM1 antibody test, which conflicted with the results of the Mayo Clinic tests showing no abnormality, formed the opinion that petitioner had GBS. In one medical record, he opined that petitioner did not have a demyelinating disease and also opined in the same record that she had GBS, even though GBS is a demyelinating disease. Dr. Moon's diagnosis of GBS is completely untenable because petitioner never had the clinical signs of GBS. He recognized this problem eventually, stating in one record that the case was challenging.

An analysis of the three prongs of Althen yields the following conclusions. The undersigned has no problem in general with the proposition that flu vaccine, whether injected or by nasal spray (FluMist), can cause GBS. Therefore, prong one of Althen is not at issue.

However, prong two of Althen is in issue. Petitioner has not provided an expert medical opinion that FluMist caused her to have GBS. Dr. Moon, although dancing around whether or not petitioner had GBS (finding her illness was "GBS-ish," "GBS-like," or "akin to GBS"), ultimately opined that petitioner did have GBS. Dr. Moon's opinion is worthless. His own

records belie his opinion. All the medical records show that petitioner did not have a neurological disease after she received FluMist. It is worth noting that Dr. Moon, when he opined she had a reaction to her vaccination, was relying on petitioner's oral representation to him of a history of illness following the flu vaccination that is inconsistent with her medical records. Petitioner did not provide Dr. Moon with her medical records. Dr. Jay Krakowitz submitted a one-sentence opinion that flu vaccine caused petitioner's GBS without giving a basis. An expert's opinion is only as good as the basis for it. Perreira v. Sec'y of HHS, 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (affirming the refusal to award attorneys' fees and costs for expert testimony that had no reasonable basis). Petitioner has failed to prove that FluMist caused her GBS or any illness. Petitioner has failed to satisfy prong two of Althen.

Prong three of Althen is also in issue. Petitioner has failed to prove that five months, which is when she saw Dr. Moon after receiving FluMist, is an appropriate time interval to support a holding of causation of GBS from FluMist. As the undersigned held in Corder,[16] the outside limit of causation of a demyelinating disease from vaccination is two months. Petitioner did not see Dr. Moon until five months after vaccination. Thus, she has failed to satisfy prong three of Althen.

Petitioner has failed to make a prima facie case. The undersigned **GRANTS** her oral motion for dismissal. This petition is hereby **DISMISSED.**

CONCLUSION

This petition is **DISMISSED**. In the absence of a motion for review filed pursuant to RCFC, Appendix B, the clerk of the court is directed to enter judgment herewith.[17]

IT IS SO ORDERED.

April 11, 2014
DATE

/s/ Laura D. Millman
Laura D. Millman
Special Master

[16] See supra note 7.

[17] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party, either separately or jointly, filing a notice renouncing the right to seek review.