

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 15-635V

Filed: July 6, 2016

Not to be Published

JENNIFER SCHAEFER,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

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Petitioner's motion to dismiss;
flu vaccine; immediate onset of
abdominal pain; chronic pain;
vomiting; left rib pain; neck pain;
leg numbness; numbness and tingling
in left arm; severe upper thoracic chest
pain, symptoms of shingles; fatigue;
insomnia; weakness; post-traumatic
neuralgia; small fiber neuropathy

Darren Keith Short, Collinsville, IL, for petitioner.

Lisa A. Watts, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION¹

On June 19, 2015, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012), alleging that immediately after she received influenza ("flu") vaccine on October 26, 2012, she had abdominal pain, chronic pain, vomiting, left rib pain, neck pain, leg numbness, numbness and tingling in her left arm, severe upper thoracic chest pain, symptoms of shingles, fatigue, insomnia, weakness, post-traumatic neuralgia, lymphadenopathy, numbness and tingling in her lips and tongue, facial pain, hyperesthesia, paresthesias, polyarthritis, polyneuritis, autoimmune neuritis, hot flashes, sharp foot pain, radiculitis, glossopharyngeal neuralgia, burning sensations in her feet and ankles, small fiber

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' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). 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, petitioners have 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.

neuropathy, and polyneuritis neuralgia. Pet. Preamble and ¶¶ 4, 5.

Petitioner filed medical records with her petition including a statement dated December 3, 2012 from a neurologist specializing in sleep medicine, Dr. Venkat K.C. Rao, who wrote that petitioner had a normal electromyography (“EMG”) and normal nerve conduction study. Med. recs. Ex. 3, at 4 (petitioner did not number the pages of the exhibit; the undersigned numbered the pages so as to refer to them). Dr. Rao also wrote that petitioner had small fiber neuropathy “status-post flu shot.” *Id.* Dr. Rao gave no basis for his conclusion that petitioner had small fiber neuropathy. None of petitioner’s medical records diagnose her with small fiber neuropathy. The only conclusion anyone familiar with petitioner’s medical records can make is that she is normal neurologically. Moreover, Dr. Rao’s statement that petitioner’s purported small fiber neuropathy occurred after a flu shot is not proof that the flu vaccine caused it. In order to satisfy petitioner’s burden of proof in the Vaccine Program, Dr. Rao had to give a credible basis for his opinion. An expert’s opinion is only as good as the basis for it. *Perreira v. Sec’y of HHS*, 33 F.3d 1375, 1377 (Fed. Cir. 1994). Temporality is not a sufficient basis to conclude causation.

Moreover, in his notes for petitioner’s normal EMG and nerve conduction study on December 3, 2012, Dr. Rao states the study did not show any evidence that petitioner had sensorimotor polyneuropathy, myopathy, or cervical or lumbar radiculopathy. Med. recs. Ex. 3 at 15. Yet, while he found petitioner normal neurologically, Dr. Rao then concluded she had “post flu polyneuritis, mainly small fiber polyneuritis.” *Id.* Dr. Rao’s conclusion contradicts his own study findings and is not plausible. Moreover, on May 30, 2013, Dr. Rao wrote petitioner’s counsel, stating that petitioner’s workup did not show any abnormalities and all her symptoms were subjective. Med. recs. Ex. 3, at 39.

On July 5, 2016, petitioner filed a Motion to Dismiss Without Prejudice.

The undersigned **GRANTS** petitioner’s Motion to Dismiss and **DISMISSES** the petition for failure to make a prima facie case of causation in fact.

FACTS

Pre-Vaccination Records

On September 10, 2012, petitioner saw her personal care physician, Dr. Tanin Parich, and complained of three days of flu symptoms with an increase in temperature to 100 degrees. Med. recs. Ex. 3B, at 8 (since petitioner did not number her exhibit pages, this page number reflects the one in CM-ECF). She was unable to sleep. *Id.* She started to have a low-grade fever, nausea, vomiting, loose watery stool, and a sore throat about three days previously. *Id.* She had many stresses at home, including her mother-in-law living with petitioner’s parents, and work made her feel so tired, she did not want to get up, clean up, or take a shower, and felt so depressed, she was hardly able to sleep. *Id.* Since June 2010, she had an almost daily pink vaginal discharge for which she should have seen her gynecologist. *Id.* Dr. Parich advised petitioner to take Xanax. He diagnosed her with acute anxiety related to her situation and her

recovering from clinically acute gastroenteritis. Id. He also diagnosed her with menometrorrhagia, for which she would likely need a dilatation and curettage. Id.

On October 16, 2012, petitioner told Dr. Parich that she had seen a chiropractor twice in the past week because of two dislocated ribs. Id. Petitioner said she had been cutting something on a cutting board when her ribs dislocated. Id. She had been nauseated and not sleeping well. Id. She had been spotting menstrually for about three months and had an appointment with her gynecologist the following week. Id. Petitioner also complained of neck and back pain. Id. (The bottom of the record on page 8 is missing.)

Post-Vaccination Records

On October 30, 2012, four days after her flu vaccination, petitioner saw Dr. Parich. Id. at 7. Petitioner told Dr. Parich that, on October 6, 2012, while she was cooking, she had a sudden onset of left-sided neck pain and upper back pain and left arm pain, which lasted about a day. Id. The chiropractor told her that she had dislocated her cervical and upper thoracic vertebrae. Id. Petitioner also had some tingling sensation in her left lower lateral chest in conjunction with left arm paresthesia and lower neck and upper back pain, but no motor weakness. Id. She was concerned about intermittent dry mouth for the past month or so, and about having a scattered area of tenderness over her anterior and posterior chest wall with no symptoms of morning stiffness or rash. Id. She had a family history of an uncle with lupus and other family members with some form of autoimmune disease. Id. Petitioner told Dr. Parich that she had a flu vaccination on October 26, 2012 with no side effects. Id. On physical examination, Dr. Parich found no focal neurological deficit. Id. Petitioner had localized tenderness over her upper thoracic spine in the T-2 and T-3 area. Id. Dr. Parich suspected petitioner probably had fibromyalgia, but he needed to rule out a herniated disc on her left upper thoracic spine area. Id.

On November 12, 2012, petitioner phoned Dr. Parich to tell him she was having joint pains and nerve problems. Id. at 6. On November 14, 2012, petitioner again phoned Dr. Parich to tell him that Dr. Reed saw her and thought she had shingles. Id.

On November 27, 2012, petitioner saw PA Elaine Rynders and asked for a referral to a neurologist. Id. at 5. Petitioner said she had a series of episodes starting around October 16, 2012 (ten days before her flu vaccination), with overall general myalgias. Id. On October 30, 2012, she had left-sided neck pain, upper back pain, and left arm pain. Id. An MRI showed she had mild degenerative disc disease of the central spine. Id. Shortly after the flu vaccination on October 26, 2012, she had left-sided arm pain, numbness, and tingling. Id. Her skin hurt to the touch. Id. The Pain Clinic thought she had shingles without rash. Id. The Wednesday (November 21, 2012) before Thanksgiving (November 22, 2012), she experienced more pain mostly in the upper torso. Id. On November 26, 2012, she had pain when she ate. Id. Her whole mouth burned and her esophagus felt on fire. Id. On November 27, 2012, she had joint pain in all her joints. Id. PA Rynders diagnosed petitioner with generalized pain with some numbness and tingling. Id.

On November 29, 2012, petitioner saw Dr. Priya Kumaraguru. Id. at 4. She complained of fever and chills and had 99.9 degree low-grade fever. Id. On physical examination, petitioner reported that one of her anterior cervical lymph nodes was enlarged, but Dr. Kumaraguru could not feel it. Id. Petitioner reported pain in her bilateral axillary area (arm pits). Id. Dr. Kumaraguru wrote petitioner did have some tenderness in the pectoralis major muscles, but no lymphadenopathy. Id. Petitioner's axilla were free and Dr. Kumaraguru found no lymph nodes palpable. Id. Neurologically, petitioner appeared grossly intact although petitioner complained of tingling and numbness all over her body. Id. Petitioner did not have any trigger points or tender points. Id. Dr. Kumaraguru's diagnosis was generalized paresthesias, bilateral axillary pain, fibromyalgia, low-grade fever, and possible sequelae of the flu vaccine. Id. Petitioner thought all her symptoms were related to the flu shot, but Dr. Kumaraguru wrote "though I tried to explain to her that she possibly has fibromyalgia. She does not want to agree that she has fibromyalgia." Id. Dr. Kumaraguru diagnosed petitioner with an underlying component of anxiety and stress. Id.

On November 30, 2012, petitioner saw Dr. Venkat K.C. Rao, a neurologist, giving him a history of sudden onset of pain and paresthesias after a flu vaccination on October 26, 2012. Med. recs. Ex. 3, at 1. Petitioner told Dr. Rao that immediately after the vaccination, she had left chest pain that started around the rib area, and left arm numbness and tingling. Id. She said that on November 5, 2012, she started having joint pain, pressure in her left rib area, and upper back pain. Id. On physical examination, petitioner had 5/5 strength in all extremities, her sensation was intact to touch, and her deep tendon reflexes were 2/4 throughout with bilateral flexor plantar responses. Id. at 2. Dr. Rao diagnosed petitioner with polyneuritis in a subacute to chronic state as well as small fiber neuritis. Id. at 3.

On December 2, 2012, Dr. Rao conducted an EMG and nerve conduction study on petitioner which was normal, yet he diagnosed her with small fiber neuropathy even though he recognized there was no evidence of sensorimotor polyneuropathy. Id. at 4, 8.

On December 18, 2012, petitioner returned to her personal care physician Dr. Parich and told him that Dr. Rao diagnosed her with Guillain-Barré Syndrome² due to flu vaccine. Med. recs. Ex. 3B, at 3. Dr. Parich examined petitioner and found that her lower extremities had brisk reflexes. Id.

On February 8, 2013, Dr. Rao wrote a note that the intravenous immunoglobulin ("IVIG") he had prescribed for petitioner was refused by petitioner's insurance company even when he explained that petitioner had a variant of GBS. Med. recs. Ex. 3, at 25. He diagnosed her with variant of GBS, unspecified neuralgia, neuritis, and radiculitis. Id. at 26.

² Guillain-Barré Syndrome is a "rapidly progressive ascending motor neuron paralysis of unknown etiology, frequently seen after an enteric or respiratory infection. An autoimmune mechanism following viral infection has been postulated. 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 Illustrated Medical Dictionary 1832 (32nd ed. 2012).

On May 30, 2013, Dr. Rao wrote a letter to petitioner's counsel, stating that petitioner's workup did not show any abnormalities. Id. at 39. Dr. Rao told petitioner's counsel that all of petitioner's symptoms were subjective. Id.

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 of and effect showing that the vaccination was the reason for the injury [,]” the logical sequence being supported by a “reputable medical or scientific explanation[,]” i.e., “evidence in the form of scientific studies or expert medical testimony[.]”

418 F.3d at 1278.

Without more, “evidence showing an absence of other causes does not meet petitioners’ 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.

Petitioner must show not only that but for her flu vaccination, she would not have had abdominal pain, chronic pain, vomiting, left rib pain, neck pain, leg numbness, numbness and tingling in her left arm, severe upper thoracic chest pain, symptoms of shingles, fatigue, insomnia, weakness, post-traumatic neuralgia, lymphadenopathy, numbness and tingling in her lips and tongue, facial pain, hyperesthesia, paresthesias, polyarthritis, polyneuritis, autoimmune neuritis, hot flashes, sharp foot pain, radiculitis, glossopharyngeal neuralgia, burning sensations in her feet and ankles, small fiber neuropathy, and polyneuritis neuralgia, but also that her flu vaccination was a substantial factor in causing her abdominal pain, chronic pain, vomiting, left rib pain, neck pain, leg numbness, numbness and tingling in her left arm, severe upper thoracic chest pain, symptoms of shingles, fatigue, insomnia, weakness, post-traumatic neuralgia, lymphadenopathy, numbness and tingling in her lips and tongue, facial pain, hyperesthesia, paresthesias, polyarthritis, polyneuritis, autoimmune neuritis, hot flashes, sharp foot pain, radiculitis, glossopharyngeal neuralgia, burning sensations in her feet and ankles, small fiber neuropathy, and polyneuritis neuralgia. Shyface v. Sec’y of HHS 165 F.3d 1344, 1352 (Fed. Cir. 1999).

Moreover, there is no proof in the medical records that flu vaccination significantly aggravated any pre-vaccination illness petitioner may have had. 42 U.S.C. § 300aa-33(4):

The term “significant aggravation” means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.

The Vaccine Act does not permit the undersigned to rule for petitioner based on “the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” 42 U.S.C. § 300aa-13(a)(1). In the instant action, petitioner’s Dr. Rao at first thought she had a small fiber polyneuropathy and diagnosed her with a variant of GBS, unspecified neuralgia, neuritis, and radiculitis, and then changed his mind and wrote petitioner’s attorney that petitioner did not have any abnormalities and all her symptoms were subjective. Neither petitioner’s medical records nor her putative expert supports her allegations. In addition, she told Dr. Parich four days after flu vaccination that she had no side effects, casting doubt on her subsequent claims that she had an immediate reaction to her flu vaccination.

The undersigned **GRANTS** petitioner’s Motion to Dismiss and **DISMISSES** this case for petitioner’s failure to make a prima facie case under the Vaccine Act.

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.³

IT IS SO ORDERED.

Dated: July 6, 2016

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

³ Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party, either jointly or separately, filing a notice renouncing the right to seek review.