In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 16-0225V
Filed: November 9, 2018
Unpublished

ELIZABETH SCHANDEL,	*	
	*	
Petitioner,	*	Finding of Fact; Influenza ("Flu")
v.	*	Vaccine; Shoulder Injury Related to
	*	Vaccine Administration ("SIRVA");
SECRETARY OF HEALTH	*	Proof of Vaccination; Onset; Lack of
AND HUMAN SERVICES,	*	Prior Condition; Clinical Course for
	*	SIRVA; Special Processing Unit ("SPU")
Respondent.	*	
	*	

Bruce William Slane, Law Office of Bruce W. Slane, P.C., White Plains, NY, for petitioner.
Amy Paula Kokot, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON FACTS[1] AND SCHEDULING ORDER– SPECIAL PROCESSING UNIT

Dorsey, Chief Special Master:

On February 16, 2016, Elizabeth Schandel ("petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq*.,[2] (the "Vaccine Act" or "Program") "for injuries, including a torn rotator cuff in her right shoulder, resulting from adverse effects of a trivalent influenza vaccination received on October 20, 2011." Petition at 1 (ECF No. 1). Petitioner filed amended petitions on March 20 and June 20, 2018, asserting that she suffered a shoulder injury related to vaccine administration ("SIRVA"), which included a

[1] The undersigned intends to post this ruling on the United States Court of Federal Claims' website. **This means the ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access. Because this unpublished ruling contains a reasoned explanation for the action in this case, undersigned is required to post it on the United States Court of Federal Claims' website in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).

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

strain/sprain, tendinopathy, and tear of her right rotator cuff, bursitis, and adhesive capsulitis, caused-in-fact by the influenza vaccination she received on October 20, 2011. (ECF Nos. 52, 57). The case was assigned to the Special Processing Unit ("SPU").

On October 1, 2018, respondent filed a motion for a factual ruling, requesting that the undersigned make formal rulings regarding the informal factual rulings she made in April 2018. (ECF No. 65). The same day, petitioner filed a status report indicating he did not anticipate opposing respondent's request. (ECF No. 66).

Based on the record as a whole and for the reasons set forth below, the undersigned finds by preponderant evidence that (1) the record of vaccination is sufficient to establish petitioner received, intramuscularly, the vaccination alleged as causal; (2) there is sufficient other evidence to establish the vaccination was administered in petitioner's right arm; (3) the onset of petitioner's pain occurred within 48 hours, specifically on the day of vaccination; (4) petitioner had no prior problem with her right shoulder/upper arm; and (4) the clinical course of petitioner's injury mirrored what is seen typically in a SIRVA.

I. Procedural History

Prior to the original petition in this case, in 2014, petitioner filed a petition seeking compensation for her right shoulder injury, alleged as vaccine caused.[3] When petitioner failed to provide evidence regarding the date of dismissal of her prior civil action, this earlier case was dismissed without prejudice. *See Schandel v. Sec'y of Health & Human Servs.*, No. 14-1010V, 2015 WL 2260424 (Fed. Cl. Spec. Mstr. Apr. 21, 2015).

Petitioner filed the original petition in this case on February 16, 2016. (ECF No. 1). On February 29, 2016, she filed documentation showing petitioner's civil claim was dismissed on August 4, 2014. (ECF No. 8-3). Along with the documentation regarding petitioner's earlier civil action, petitioner filed medical records from two orthopedic visits on November 7 and 14, 2011, the results of an MRI performed on November 12, 2011, and medical and billing records from physical therapy ("PT") attended in October 2011 through February 2012. (ECF No. 8-4). The same day, she filed these records a second time, this time without the civil case documentation. (ECF No. 9-1). In both instances, these partial medical records were filed as one exhibit without proper labeling.

Over the subsequent year, petitioner attempted to file the required affidavit and medical records. *See* § 11(c) (petition requirements); Vaccine Rule 2(c)(2) (petition attachments); SPU Initial Order, issued Feb. 17, 2016 (ECF No. 5). During this time, petitioner was represented by two different attorneys at the law firm of Mayer, Ross, &

[3] Petitioner's earlier case was designated Schandel No. 14-2010V.

Hagan. P.C., initially Damon Hagan and then Christopher Ross.[4] On thirteen different occasions, in orders or during status conferences, Mr. Hagan and Mr. Ross were provided guidance regarding the medical records still needed, specifically those records needed to establish vaccination, to show petitioner's prior condition, and to satisfy the statutory six month requirement. *See, e.g.,* Order, issued Apr. 1, 2016, at 1 (ECF No. 11); Order, issued Aug. 28, 2016, at 1 (ECF No. 17); Order, issued Jan. 3, 2017, at 1 (ECF No. 22). After failing to file properly the required medical records, on March 1, 2017, Mr. Ross was ordered to associate with another attorney familiar with the Vaccine Program. (ECF No. 25).

From March through August 2017, petitioner managed to file, but not properly label, her affidavit and some of the medical records still outstanding. (ECF Nos. 28, 34). During this time, Mr. Ross failed to associate with another attorney. Instead, he filed several status reports indicating he conferred with several attorneys, not admitted to practice before the United States Court of Federal Claims, and one attorney, Bruce Slane, who has and continues to practice in the Vaccine Program. (ECF Nos. 29, 35). In July 2017, petitioner sought and was granted subpoena authority for her vaccine record from Genovese Drugstore (Rite Aid). (ECF Nos. 32-34, 36-37).

On September 13, 2017, the undersigned conducted a status conference in this case. Noting petitioner's inability to file the medical records required and multiple failures to comply with orders, the undersigned ordered Mr. Ross to associate with another counsel who would be lead attorney for the case and to file a copy of the subpoena served on Genovese Drugstore (Rite Aid). *See* Order, issued Sept. 14, 2017, at 2 (ECF No. 39). On September 25, 2017, petitioner filed the subpoena, labeled as additional documentation. (ECF No. 40). Bruce Slane entered an appearance on November 15, 2017.

The next day, the OSM staff attorney managing this SPU case held a status conference with the parties. The staff attorney noted petitioner had previously filed an affidavit and documentation regarding the dismissal of her civil case but that additional medical records were still needed. All agreed petitioner should re-file all medical records previously filed, along with any additional medical records obtained. (ECF No. 44).

Petitioner filed her medical records in late February and early March 2018. *See* Exhibits 1-12 (ECF Nos. 47-48, 50-51); Statement of Completion (ECF No. 49). Petitioner filed an amended petition on March 20, 2018.

A status conference was held with the undersigned on April 19, 2018. Due to the length of time the case had been pending, the undersigned proposed that she give her initial, informal findings during the call. Both counsel agreed, but respondent's counsel qualified her lack of objection as being given prior to the completion of respondent's

[4] When referring to these attorneys, the individual attorney's name will be used. The term "petitioner's counsel" will be used only for petitioner's current counsel, Bruce Slane.

review. The undersigned expressed her understanding of respondent's circumstances and position. She then made informal findings regarding the proof of vaccination, onset of petitioner's pain, prior condition, and progression of petitioner's injury. *See* Order, issued Apr. 26, 2018, at 2-3 (ECF No. 53). She also questioned petitioner's counsel regarding some of the specifics of petitioner's treatment, possible missing medical records, and the type of compensation being sought. *Id.* at 3. In particular, the undersigned noted that it appeared the record from a November 4, 2011 visit to petitioner's primary care provider ("PCP"), Dr. Chan, when she first complained of her right shoulder pain, was not included in the more recently filed medical records.[5] Petitioner was ordered to file a status report, medical records, and an amended petition which addressed the issues discussed. *See* Order, issued Apr. 26, at 3-4 (ECF No. 53). Respondent was ordered to file a status report providing his tentative position regarding the case within 30 days thereafter. *Id.* at 4.

During the subsequent two months, petitioner filed several status reports (ECF Nos. 55-56), the outstanding medical records from petitioner's November 4, 2011 visit to Dr. Chan (Exhibit 13, ECF No. 58-1), and another amended petition (ECF No. 57). The only difference between the amended petitions filed on March 20 and June 20, 2018 is an additional paragraph included in the later filed June 20, 2018 petition, describing the November 4, 2011 visit to Dr. Chan. *See* Second Amended Petition at ¶ 6 (ECF No. 57). In her May 24, 2018 status report, petitioner indicated she had submitted a demand to respondent. (ECF No. 55).

On July 23, 2018, respondent filed a status report indicating he was willing to engage in settlement discussions. (ECF No. 61). Approximately one month later, he informed the undersigned that he responded to petitioner's May 24, 2018 demand. Status Report, filed Aug. 28, 2018 (ECF No. 63).

On October 1, 2018, in lieu of the joint status report which was ordered, respondent filed a motion for a factual ruling. (ECF No. 65). Respondent indicated the parties had reached an impasse in their settlement discussions. Referencing the informal factual findings made by the undersigned in April 2018, respondent requested "a formal ruling on the factual issues only." *Id.* at 2. Respondent proposed that, following the undersigned's fact ruling, he could "put his position with regard to entitlement on the record via a written brief." *Id.* In his motion, respondent indicated petitioner had no objection to his proposal. *Id.* Additionally, later that same day, petitioner filed a status report confirming his lack of objection. (ECF No. 66).

During a status conference held with the OSM staff attorney on October 31, 2018, the parties confirmed petitioner was seeking compensation for pain and suffering and unreimbursable expenses, and that the main area of disagreement involved the appropriate amount of compensation for petitioner's pain and suffering. Respondent's

[5] The record from this visit was filed by petitioner's former counsel, Mr. Ross, on May 10, 2017. *See* Exhibit G at 44 (ECF No. 28-3). Petitioner also described this visit in her supplemental affidavit, filed on July 28, 2017. *See* Supplemental Affidavit at ¶¶ 7-9 (ECF No. 34).

counsel further indicated respondent could file his Rule 4(c) report within 45 days of the undersigned's fact ruling.

II. Factual History

The medical records from petitioner's PCP, Dr. Enoch Chan at Best Choice Medicine, P.C., show that, prior to the vaccination alleged as causal, petitioner suffered from gastroesophageal reflux disease (GERD) and several common illnesses. *See generally* Exhibits 1, 6.[6] In March of 2008, petitioner was seen by Dr. Chan for facial numbness and a lump (determined to be a cyst) under her right arm. *See* Exhibit 6 at 32, 34. After petitioner complained of vertigo in September and October 2008, Dr. Chan referred her to a neurologist. *See id.* 10-12.[7]

For her vertigo, petitioner saw Dr. Augustine Romano at Sound Neurology of Port Jefferson, L.L.P ("Sound Neurology"). *See* Exhibit 6[8] at 5-6 (Dr. Romano's November 19, 2008 letter to Dr. Chan). Petitioner informed Dr. Romano that she had suffered from dizziness for six months and had also experienced numbness in her upper extremities upon waking. She described her numbness as worse on her left side. *Id*. Dr. Romano diagnosed petitioner with likely benign positional vertigo, left side, and possible bilateral carpal tunnel syndrome. *Id.* at 6. He noted petitioner was currently working as a piano tuner. *Id.* at 5. He provided petitioner with exercises to perform at home to treat her vertigo and instructed her to return in four weeks. He indicated he would address further petitioner's hand numbness at the next appointment and may order a nerve conduction study. *Id.* at 6.

It appears that petitioner did not follow-up with Dr. Romano, and there is no evidence that her dizziness and numbness continued. In February 2009, petitioner's heartburn was evaluated by Dr. Buscaglia, at Stony Brook University Physicians. *See* Exhibit 6 at 1. She received further treatment for her GERD at Brookhaven Gastroenterology Associates in 2010. *See* Exhibit 7. The same year, she underwent a

---

[6] The majority of petitioner's PCP records are contained in Exhibit 1 which is labeled as "Medical Records from Best Choice, P.C." However, it appears some are contained in Exhibit 6 which is labeled "Medical Records from Stony Brook University Physicians." It is not clear if the records were erroneously combined or the Best Choice Medical Records appearing in Exhibit 6 are simply copies of Dr. Chan's records which were provided to this other provider. The undersigned will cite to the exhibit and page number of each record as filed.

[7] Because petitioner had multiple complaints at these visits, referrals also were given to an orthopedist for what appears to be an injury and to a gastroenterologist for a routine colonoscopy. Exhibit 6 at 11. For the injury, petitioner saw Dr. B. Thomas Kempf, a podiatrist, twice in October 2008, for what appears to have been an injury to her left toe. *Id.* at 7-9; *see* https://www.healthcare4ppl.com/physician/new-york/sayville/brent-thomas-kempf-1659483246.html (indicating Dr. Kempf is a podiatrist, last visited Nov. 2, 2018). Like some of petitioner's PCP records, Dr. Kemp's records were filed as part of the Stony Brook records, Exhibit 6. *See supra* note 6.

[8] Like some of petitioner's medical records from her PCP, Dr. Chan, Dr. Romano's medical records from Sound Neurology of Port Jefferson, L.L.P., were filed as part of the medical records from Stony Brook University Physicians. *See supra* notes 6-7.

cardiac evaluation after experiencing pressure and pain in the left precordial area. *See* Exhibit 8.

Petitioner received the influenza vaccination alleged as causal on October 20, 2011. Ultimately, petitioner obtained documentation which showed the type of vaccine, the manufacturer, and the date of administration. *See* Exhibit 2. Although the documentation showed the vaccine was administered intramuscularly, it did not specify the exact location, in which arm it was given. *Id.* at 3.

Two weeks later, petitioner first complained of residual pain and reduced right shoulder range of motion ("ROM") since receiving the influenza vaccine in her right deltoid to her PCP, Dr. Chan. Exhibit 13 at 1. At that November 4, 2011 visit, Dr. Chan also noted that petitioner had been sick for two weeks. He diagnosed her with bronchitis, prescribed medication to include Prednisone and Augmentin, and referred her to an orthopedist. *Id.*

Petitioner was seen for her right arm/shoulder pain by Dr. Patricia DeRosa at DeRosa Orthopedic Services, P.C. on November 7, 2011. At that visit, petitioner reported sharp, constant, and severe pain in her right arm since her flu shot on October 20, 2011, and an inability to move or lift her arm. Exhibit 3 at 18. She indicated the flu shot "was given in [her] upper arm on [the] shoulder." *Id.* Dr. DeRosa described petitioner's ROM as limited externally and internally to 0 and 10 degrees respectively. *Id.* Noting that petitioner was left handed, Dr. DeRosa diagnosed petitioner with adhesive capsulitis and a possible rotator cuff tear in her right shoulder. She ordered an MRI. *Id.* at 19.

The MRI of petitioner's right shoulder was performed on November 10, 2011. It revealed "[a] partial thickness 0.7 cm tear at the bursal surface of the supraspinatus tendon," subscapularis tendinosis, subacromial/subdeltoid bursitis, "[a] laterally down sloping type II acromial configuration," and "some synovial fluid at the glenohumeral articulation." Exhibit 5 at 1. "Muscular and tendinous structures including remaining portions of the rotator cuff" were noted to be "unremarkable in signal and morphology." *Id.*

Petitioner was seen again by Dr. DeRosa on November 14, 2011. Stating that she felt the same, petitioner described her pain as constant and complained of an inability to move her right arm/shoulder. Exhibit 3 at 17. Dr. DeRosa recorded the results of petitioner's MRI and her physical examination and diagnosed her with adhesive capsulitis and a rotator cuff sprain. She prescribed physical therapy. *Id.*

On November 18, 2011, petitioner attended her first PT session at NY Physical Therapy and Wellness. The medical record from that visit accurately reflects Dr. DeRosa's diagnosis of right shoulder adhesive capsulitis and rotator cuff strain and notes an onset date of October 20, 2011. Exhibit 9 at 9. Petitioner described her pain as a sharp, stabbing pain in her right shoulder which occurred immediately upon

vaccination and intensified over the subsequent few days and/or weeks.[9] Petitioner was noted to have a limited ROM in her right shoulder, difficulty performing many tasks, and an inability to sleep at night. *Id.* at 7, 9. In the initial evaluation by the physical therapist, Robert Fazio, DPT, it was also noted that petitioner had an inability to dress herself and had been unable to work for the past month. *Id.* at 7.

From November 18, 2011 through the end of February 2012, petitioner attended 39 PT sessions. Exhibit 9 at 1-4. In the latest progress note dated February 15, 2012, petitioner was reported to have improved ROM, mobility, flexibility and strength. *Id.* at 5. Her pain was reduced, and petitioner was able to do more around the house and to sleep better at night. *Id.* It appears that petitioner's last session was on February 27, 2012. *See id.* at 1.

While attending PT, petitioner had follow-up appointments with Dr. DeRosa on January 6 and February 24, 212. *See* Exhibit 3 at 8, 14. It appears that, during this time, she also sought a second opinion from Dr. Stephen Kottmeier at Stony Brooks Orthopaedic Associates, on January 11, 2012. Exhibit 4 at 4-5. In the record from that visit, petitioner's injury is described as "painful [and] limited right shoulder ROM . . . coincident with a flu shot received on 10/20/2011." *Id.* at 4. Dr. Kottmeier opined that the immediateness of petitioner's symptoms "suggest[ed] either issues from a mechanical aspects [sic] of the injection or potentially post-injection adhesive capsulitis or even more commonly of brachial neuritis." *Id.* While noting that petitioner described occasional pain beyond her elbow joint, Dr. Kottmeier noted petitioner did not have a "history of cervical, radicular or likely neurogenic discomfort of other origin." *Id.* Dr. Kottmeier observed the results of petitioner's MRI suggested "features of rotator cuff tendinopathy, potentially a partial articular surface tear." *Id.* He concluded petitioner "has signs and symptoms of adhesive capsulitis, potentially coincident with regional injection" but acknowledged an alternative source of brachial neuritis. *Id.* at 5. He offered petitioner a neurologic assessment and/or subacromial injection, both of which she declined. Instead, petitioner indicated that she preferred to continue her PT. *Id.*

Petitioner had one more visit with Dr. DeRosa on July 6, 2012. At that visit, she reported that she was "doing better," but her ROM was described as poor. Exhibit 3 at 6. Petitioner indicated that her shoulder "pops [and] snaps," and that she goes to PT three times a week.[10] *Id.*

While receiving treatment from Dr. DeRosa, petitioner was not seen by her PCP, Dr. Chan. She returned to Dr. Chan on December 15, 2012 for a cold and cough. Exhibit 1 at 98. Dr. Chan diagnosed her with bronchitis and prescribed medication. Although parts of this record are difficult to read, it appears there is no mention of ongoing shoulder pain at this visit. *See id.* at 98-99.

[9] In two different places in the record from this visit, the intensifying of petitioner's pain is described as occurring over the next few days and then the next few weeks. *Compare* Exhibit 9 at 7 *with id.* at 9.
[10] No PT records from this time frame were filed.

On February 8, 2013, petitioner was treated by Dr. Chan for shooting pain down her right leg. Exhibit 1 at 93. He diagnosed her with back pain and ordered a nerve conduction study. *Id.* The results of the study, performed on February 23, 2013, were normal. *Id.* at 89. Petitioner saw Dr. Kottmeier on April 19, 2013 for bilateral pain in her hands. Exhibit 4 at 1. She reported that this pain caused her difficulty with her work as a piano tuner. *Id.* X-rays were taken, showing no abnormalities. *Id. at 2-3.*

On three more occasions in 2013, twice in 2014, four times in 2016, and once in early 2017, petitioner was treated by Dr. Chan for various illnesses. *See* Exhibit 1 at 2-3, 5-6, 9, 10, 12-13, 70, 85. Right shoulder pain was not mentioned in the medical records from any of these visits. However, the medical records from Dr. Chan include a letter, dated May 14, 2016, indicating petitioner was "under [his] care for right shoulder pain due to flu vaccine [which] [t]o this date still causes her pain and discomfort." *Id.* at 1.

On November 29, 2017, petitioner saw Dr. Barry Kleeman at Advanced Orthopedics, for an evaluation of her right shoulder pain. She told Dr. Kleeman that "she believe[d] her shoulder pain started after she had a flu shot for her right shoulder approximately 3 years ago." Exhibit 10 at 1. Describing pain with overhead activities, petitioner indicated she had been unable to take care of her shoulder pain because she was caring for her sick parents. After examining petitioner, Dr. Kleeman reported that she had full, but painful, forward flexion and abduction of her right shoulder, internal rotation on the left to mid-thoraic level and on the right to L1, no weakness on internal rotation, and some pain on external rotation. He also noted that petitioner showed "a positive Neer's and Hawkins sign and she is neurovascularly intact." *Id.* X-rays showed no fractures, dislocations, or injuries. Dr. Kleeman ordered an MRI and prescribed over the counter NSAIDs. *Id.*

III. Parties' Arguments

The parties have not set forth any arguments regarding the factual issues in this case. Rather, they request that the undersigned address the issues and make any findings she deems appropriate based on the record as it currently stands.

IV. Discussion

A. Applicable Legal Standard

A petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding her claim. § 13(a)(1)(A). To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs.,* 3 F.3d 415, 417 (Fed.Cir.1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. *See Cucuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

To overcome the presumptive accuracy of medical records testimony, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Human Servs.,* No. 11–685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Human Servs.,* No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

Although this petition was filed prior to the inclusion of SIRVA on the Table, the Qualifications and Aids to Interpretation ("QAI") for SIRVA should be considered instructive regarding the criteria for determining whether a SIRVA exists. Effective for petitions filed beginning on March 21, 2017, SIRVA is an injury listed on the Table. *See* National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Final Rule, 82 Fed. Reg. 6294 (Jan. 19, 2017); National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Delay of Effective Date, 82 Fed. Reg. 11321 (Feb. 22, 2017) (delaying the effective date of the final rule until March 21, 2017). The QAI for SIRVAs states:

> *Shoulder injury related to vaccine administration (SIRVA).* SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time frame;
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
>
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10) (2017).

B. Factual Findings

During a status conference with the parties, held telephonically on April 19, 2018, the undersigned made informal factual findings regarding the proof of vaccination, onset of her pain, prior condition, and clinical course of her injury. (ECF No. 53). The undersigned sets forth those findings in this section. Additionally, she finds there is preponderant evidence to establish petitioner received the influenza vaccination alleged as causal in her right arm.

1. Vaccination

Petitioner first attempted to file her proof of vaccination on January 15, 2017, almost eleven months after filing her petition. (ECF No. 24-1). Unfortunately, the record filed was a billing record which appears to be for another individual. *Id.* Petitioner filed a record with additional information on May 10, 2017, but that record also was for the individual on the earlier billing record. (ECF No. 28-1).

While still represented by former counsel, Mr. Ross, petitioner sought and was granted subpoena authority to obtain the correct vaccine record on July 24 and 28, 2017.[11] After Mr. Slane entered his appearance, petitioner filed a billing record with her name on it and a vaccine record providing further information, such as the fact that the vaccine was administered intramuscularly. *See* Exhibit 2, filed Feb. 22, 2018 (ECF No. 47-2). Although the page containing the additional information did not include petitioner's name, the prescription number on both records match. *Compare id.* at 1 *with id.* at 3.

The undersigned finds the vaccine record sufficient to establish petitioner received the influenza vaccination alleged as causal, intramuscularly on October 20, 2011.

2. Site of Vaccination

Even though the vaccine record does not indicate in which arm the vaccination was administered, there is sufficient evidence in the record to establish that petitioner received the influenza vaccination in her right injured arm. At her initial visit with the three medical providers who treated her injury within one month of vaccination, petitioner identified her pain and/or vaccination as occurring in her right arm/shoulder. *See* Exhibits 13 at 1; 3 at 18; 9 at 9 (ordered by date, earliest to latest). When she first sought treatment, petitioner told Dr. Chan she had received the vaccination in her right deltoid. This record also identifies petitioner's pain and limited ROM as occurring in her right shoulder. Exhibit 13 at 1. When she first saw Dr. DeRosa on November 7, 2011,

[11] Petitioner filed a motion for subpoena authority on July 19, 2017 which included only the names of the two companies on which the subpoena was to be served. (ECF No. 33). After the OSM staff attorney informed Mr. Ross that more information would be needed, petitioner filed an amended motion on July 28, 2017 (ECF No. 34). Petitioner's motion was granted in two separate orders, one for each company named. (ECF Nos. 36-37).

petitioner complained of severe right arm pain after receiving the influenza vaccination given in her upper arm on the shoulder. Exhibit 3 at 18. To her physical therapist on November 18, 2011, petitioner reported sharp stabbing pain in her right shoulder when receiving the influenza vaccination. Exhibit 9 at 9.

Throughout her treatment, petitioner consistently identified her influenza vaccination as occurring in her right arm and attributed her pain and limited ROM to this vaccination. Even in more recent medical records, when seeking treatment, petitioner reported the site of administration as her right arm. *See* Exhibit 10 at 1. There are no entries which refer to the vaccination as being administered in any other site.

The undersigned finds there is preponderant evidence to establish petitioner received the vaccination alleged as causal in her right injured arm.

3. Onset

Likewise, regarding the onset of petitioner's pain, petitioner consistently reported that it was immediate, upon vaccination. The record from petitioner's initial visit with Dr. Chan indicates she had residual pain after her vaccination. It appears to indicate petitioner had felt the pain since vaccination but the writing and abbreviations used are unclear. Exhibit 13 at 1. The medical records from Dr. DeRosa, however, more clearly conveys this information. In that record, petitioner reported pain "since my flu shot." Exhibit 3 at 18. At her first appointment with her physical therapist on November 18, 2011, petitioner stated that her "symptoms started immediately upon getting the flu shot this year . . . [when] she "felt sharp stabbing pain in her [right shoulder[12]]." Exhibit 9 at 9. In the record from petitioner's January 11, 2012 visit to Dr. Kottmeier, it is noted that petitioner's "symptoms were rather immediate." Exhibit 4 at 4. All medical records indicate petitioner's pain was immediate, none show a delay in her pain.

The undersigned finds the onset of petitioner's pain was immediate and thus, within 48 hours of vaccination.

4. Prior Condition

Petitioner has filed medical records from her PCP from as far back as 2008. These records show that petitioner, a piano tuner, complained of bilateral numbness in her upper extremities and a cyst under her right arm in 2008. Exhibit 6 at 5, 32. In a letter to Dr. Chan, Dr. Romano, the neurologist who evaluated petitioner for both dizziness and her numbness, diagnosed her with vertigo and possible bilateral carpal tunnel syndrome. *Id.* at 5-6. He provided petitioner with exercises to perform at home to treat her vertigo and instructed her to return in four weeks. He indicated he would address further petitioner's hand numbness at that appointment and may order a nerve conduction study. *Id.* at 6. There is nothing in the medical records to show that petitioner followed up on these issues at that time.

[12] The medical record contains a capitalized R in a circle and the abbreviation "Shld". Exhibit 9 at 9

In April 2013, 18 months after vaccination and approximately nine months after her last visit with Dr. DeRosa regarding her right shoulder pain, petitioner returned to Dr. Kottmeier, the orthopedist she saw, in early January 2012, for a second opinion regarding her right shoulder pain. At this April 19, 2013 visit, she complained of bilateral pain in her hands. Exhibit 4 at 1. The pain was described as located in her thumbs and wrists. Petitioner indicated the pain had begun over the last few months and was interfering with her work as a piano tuner. *Id*. Dr. Kottmeier ordered x-rays, the results of which were normal. *Id.* at 2-3. The notes regarding Dr. Kottmeier's impression and proposed treatment are illegible. *Id.* at 1 (lower right side of this document).

Although it is clear petitioner had pain or numbness in her hands both before and after vaccination, these symptoms appear to be independent of her right shoulder/upper arm pain and, most likely, due to carpal tunnel syndrome caused or exacerbated by petitioner's vocation as a piano tuner. In contrast, the pain, described by petitioner as occurring immediately upon vaccination and suffered by petitioner through at least July 2012, appears to be independent of any pain or numbness petitioner suffered in her hands. Petitioner consistently described her right shoulder/upper arm pain as sharp, constant, and located only in that area. *See, e.g.,* Exhibit 13 at 1.

The only exception is one description provided to Dr. Kottmeier in early January 2012. At that visit, petitioner reported that her pain occasionally radiated below her elbow. *See* Exhibit 4 at 4. However, petitioner did not indicate that the pain reached her hands. Additionally, she was not complaining of or being treated for pain or numbness in her hands at that time. There is nothing in the medical records from prior to vaccination to indicate petitioner had any pain or difficulties with her right upper arm or shoulder prior to vaccination.

After reviewing the record as a whole, the undersigned finds there is preponderant evidence that petitioner did not experience any prior issues with her right shoulder/upper arm.

5. Clinical Course

Petitioner's clinical presentation and diagnosis when she was seen by Dr. DeRosa on November 7, 2011, and Dr. Kottmeier on January 11, 2012, are consistent with a SIRVA injury. *See* Exhibits 3 at 18-19; 4 at 4-5. Petitioner's pain occurred primarily in her right shoulder and progressed to the point that she developed adhesive capsulitis. Petitioner presented with pain at her follow-up visits and attended approximately 39 physical therapy sessions in 2011-12. *See* Exhibit 9 at 1-3. She was very compliant with her physical therapy and showed good range of motion ("ROM") at her last visit. *See id.* at 5.

Furthermore, the results of petitioner's November 10, 2011 MRI are compatible with a SIRVA injury. The MRI showed a partial thickness tear in the bursal surface of the supraspinatus tendon, tendonitis, and bursitis. *See* Exhibit 5 (MRI results). There is no potential alternative cause for petitioner's right shoulder/arm pain.

The undersigned finds the clinical course of petitioner's injury mirrored what is seen typically in a SIRVA.

V. Conclusion

Thus, the undersigned finds, based on the record as a whole, there is preponderant evidence to establish that petitioner received the vaccination alleged as causal intramuscularly in her right injured arm; that the onset of petitioner's pain was immediate, definitely within 48 hours of vaccination; that petitioner had no prior condition involving her right shoulder/upper arm; and that the clinical course of petitioner's injury mirrored what is seen typically in a SIRVA.

Respondent shall file his Rule 4(c) report by no later than Friday, December 21, 2018.

The undersigned notes that the medical records show that since 2008, petitioner has suffered from a variety of conditions, several of which involved pain in petitioner's back, right leg, and hands. She also received regular medical care from Dr. Chan throughout this time, with the primary exception being a gap in treatment during 2015. While engaging in informal discussions regarding the appropriate amount of compensation in this case, the parties shall consider the factual history set forth and findings made in this ruling. **Petitioner shall file any additional updated medical records, such as the results of the second MRI ordered by Dr. Kleeman in late 2017, by no later than Monday, December 10, 2018.**

Any questions about this ruling and order or about this case generally may be directed to OSM staff attorney, Stacy Sims, at (202) 357-6349 or email: Stacy_Sims@cfc.uscourts.gov.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Chief Special Master