In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 20-0215V

UNPUBLISHED

PATRICIA ALEX FREEMAN, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: May 31, 2022 Special Processing Unit (SPU); Dismissal; Statutory Six-Month Requirement; Insufficient Evidence; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Douglas Lee Burdette, Burdette Law, Sahuarita, AZ, for Petitioner.

James Vincent Lopez,[1] *U.S. Department of Justice, Washington, DC, for Respondent.*

DECISION[2]

On February 26, 2020, Patricia Alex Freeman filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[3] (the "Vaccine Act"). Petitioner alleges that she suffered the Table injury of left shoulder injury related to vaccine administration ("SIRVA") after receiving the influenza ("flu") vaccine on October 4, 2018. Petition at 1, ¶¶ 3, 9. Additionally, she alleges that "she still suffers from the ill effects of SIRVA" more than six months post-vaccination, and thus can establish sufficient severity. *Id.* at ¶ 10; *see* Section 11(c)(1)(D)(i).

[1] Until earlier today, Wei Kit Tai was the attorney of record for Respondent. *See* Notice of Appearance, ECF No. 37 (designating James Lopez as attorney of record).

[2] Because this unpublished Decision contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in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). **This means the Decision 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, I agree that the identified material fits within this definition, I will redact such material from public access.

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

For the reasons set forth below, I hereby DENY entitlement in this case, due to Petitioner's inability to preponderantly establish severity. Section 11(c)(1)(D)(i) (statutory six-month requirement).

I. Relevant Procedural History

Shortly after the claim's initiation, Ms. Freeman filed some of the medical records required by the Vaccine Act. Exhibits 1-5, filed Mar. 9, 2020, ECF No. 7. After providing her Pre-Assignment Review ("PAR") Questionnaire, Petitioner's case was activated and assigned to the Special Processing Unit, since it appeared likely to present a Table claim that might easily be resolved. Exhibit 6, filed June 22, 2021, ECF No. 12; Order, issued June 26, 2021, ECF No. 14.

During the initial status conference held on August 21, 2020, Respondent's counsel requested that Petitioner file all medical records related to her diagnoses of rheumatoid arthritis and osteoporosis. Order, issued Aug. 21, 2020, at 1, ECF No. 17. After missing several deadlines, Petitioner filed the additional medical records on April 21, 2021. Exhibit 7, ECF No. 25.

On July 26, 2021, Respondent indicated that he opposed compensation in this case. ECF No. 28. To that end, on September 15, 2021, Respondent filed his Rule 4(c) Report setting forth his specific objections. ECF No. 30. Respondent questioned whether severity was established, as well as whether Petitioner could more generally meet the core requirements for a Table SIRVA claim. *Id.* at 11.

After reviewing the entire record, I issued an order requiring Petitioner to provide briefing and evidence addressing the noted deficiencies –the atypical presentation of her symptoms, other conditions she suffered which would explain her left shoulder pain, the mildness of the symptoms she was exhibiting in November 2018 through February 2019, and the lack of medical records regarding treatment or even any mention of left shoulder symptoms *after* February 2019. Order to Show Cause, issued Dec. 14, 2021, at 6-7, ECF No. 31. At a minimum, I instructed her to provide the evidence needed to satisfy the six-month severity requirement, or to otherwise show cause why her claim should not be dismissed. *Id.* at 8.

In response, Petitioner filed a request for additional time which was struck because it was filed as a response to the December order, rather than a motion for additional time which comported with the requirements of Vaccine Rule 19(b). Order to Show Cause and Striking Response, issued, Feb. 4, 2022, ECF No. 33. I also set a new deadline of March 23, 2021, for Petitioner to respond to my December order. *Id.*

On March 23, 2022, Petitioner filed several pages of handwritten entries - ranging from October 23, 2018, through July 16, 2019 - and a two-page response to the order. Petitioner's Personal Health Journal, filed as Exhibit 8,[4] ECF No. 35; Petitioner's Response to the Order to Show Cause ("Response"), ECF No. 36. There is no accompanying narrative indicating when or how the journal pages were created or explaining why only the entries from this period were submitted.

The matter is now ripe for adjudication.

II. Medical History

The medical records from Ms. Freemen's primary care provider ("PCP") establish that she was almost 77 years old at the time of vaccination, with a prior medical history that included arthritis, osteoporosis, carpal tunnel syndrome, and giant cell arteritis ("GCA").[5] Exhibit 5 at 12-15, 54 (for summary of prior medical history). In January 2017, it was noted that Petitioner had numbness in her hands, a previous surgery for carpal tunnel syndrome, and limitations which prevented her from engaging in past activities such as gardening. *Id.* at 54. Petitioner also had experienced difficulties with her sight and underwent cataract surgery in February 2018. *Id.* at 103.

In March 2018, Petitioner reported paresthesia in both hands, but without weakness. Exhibit 5 at 115. In this record, it was noted that she had a left carpal tunnel repair in 2008 and a carpal tunnel release in 2013. *Id.* at 116. Later filed surgical records show a right carpal tunnel release was performed on December 19, 2013. Exhibit 7 at 64-65, 227.

In late May 2018, Petitioner visited her PCP complaining of swelling and pain in her legs and difficulties walking. Exhibit 5 at 124. Although Petitioner believed these symptoms were related to her GCA medication,[6] her PCP disagreed – encouraging her to continue to take her medication until seen by a rheumatologist. Exhibit 5 at 124.

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[4] The Bates stamped pagination provided for this exhibit ranges from P1000001 through P1000016. Since the exhibit number is "8", the meaning of the beginning portion "P1000" is unclear. However, the later portion of the pagination corresponds to the correct page number and will be cited for that purpose. Additionally, pages 8 and 9 contain the most recent entries from April 23 through July 16, 2019, and thus should have been located on the last two pages of the exhibit. Otherwise, the pages appear in chronological order. Thus, it appears these two pages were erroneously filed out of order. *See generally* Exhibit 8.

[5] Giant cell arteritis "is a chronic vascular disease in the elderly, of an unknown origin, often associated with polymyalgia rheumatic, seen usually in the external carotid arteries but sometimes in other arteries." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY ("DORLAND'S") at 144 (32th ed. 2012).

[6] Petitioner was taking Actemra to treat her GCA. *See* https://www.actemra.com (for information about this medication) (last visited Dec. 8, 2021).

When seen by the rheumatologist on June 11, 2018, Petitioner indicated she had stopped taking her medication and had noticed "some worsening pain in the last week in the left weist [sic] with some mild swelling." Exhibit 5 at 128.[7] The rheumatologist observed synovitis in Petitioner's left wrist. *Id.* at 130. Regarding her knee pain and swelling, the rheumatologist thought it was unrelated to Petitioner's medication but may be due to a ruptured Baker's cyst[8] or osteoarthritis and venous stasis.[9] Exhibit 5 at 129-131. An MRI performed on December 12, 2018, revealed physiological conditions including a meniscus tear, a large Baker's cyst, and moderate joint effusion. *Id.* at 1,059.

Petitioner received the flu vaccine on October 4, 2018. Exhibit 3 at 1; Exhibit 7 at 7. The pharmacy vaccine record shows the flu vaccine was administered intramuscularly in Petitioner's left deltoid. Exhibit 3 at 1. Approximately two weeks later, on October 17, 2018, she again sought treatment for her leg pain, described as worsening in the last week. Exhibit 5 at 132. Noting that Petitioner previously suffered from arthritis in her cervical spine and lumbar radiculopathy, Petitioner's PCP prescribed additional medication and ordered physical therapy ("PT"). *Id.* at 132-133; Exhibit 4 at 35. Although the PCP did not include any information regarding shoulder pain in the record from this visit, on the PT referral he checked back, shoulder, and other with the accompanying notation of "hamstring/calf." Exhibit 4 at 35.

During the early morning hours of the next day (October 18, 2018), Petitioner emailed her PCP regarding her continued leg pain, reporting that it was severe enough to cause her to almost fall and to prevent her from walking. Exhibit 5 at 194. She asked for further testing, but did not mention any shoulder pain in this email. *Id.* A follow-up email later that day indicated a nurse had spoken to Petitioner, who was in the clinic having bloodwork drawn. Petitioner was using a cane to walk, reported that she had managed to pick up her pain medication, and indicated she was not interested in PT at that time because she could barely move. *Id.* Her PCP ordered thyroid testing. In an email later that evening, titled "[m]y excruciating body pain," Petitioner indicated her "symptoms have been going on for years and now the muscle pain for most of this year." *Id.* at 196.

It appears that Petitioner visited the emergency room at Overlake Medical Center on November 8, 2018, complaining of leg pain. Exhibit 5 at 1,096. The medical records

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[7] Petitioner's rheumatologist, Dr. Vivian Stone, practices at the same medical center as her PCP. Thus, the records from Petitioner's PCP and rheumatologist are both contained in Exhibit 5.

[8] A Baker's cyst is "a swelling behind the knee, caused by escape of synovial fluid which becomes enclosed in a membranous sac." DORLAND'S at 458.

[9] Venous stasis is the "cessation or impairment of venous flow, such as with venous insufficiency." DORLAND'S at 1766.

from this facility have not been filed, but this information is contained in an After Visit Summary found at the end of Petitioner's PCP's records. *Id.* at 1,096-1,100. This record indicates that an ultrasound doppler venous study and x-rays on Petitioner's left leg were performed, and the results of both tests were normal. *Id.* at 1,099-1,100. An instruction sheet for myalgias was provided to Petitioner, and she was prescribed oxycodone.[10] Exhibit 5 at 1,096-1,098.

Petitioner returned to the rheumatologist on November 12, 2018, for follow-up of rheumatoid arthritis and possible GCA. Exhibit 5 at 136. At this visit, she described her worsening leg pain which had failed to decrease with medication and prompted her ER visit, plus (for the first time in the records chronology) pain in her left shoulder and with range of motion ("ROM") issues in all directions since receiving the flu vaccine, as well as "[s]ome pain in [her] neck [and] right shoulder blade." *Id.* Upon examination, Petitioner's pain was rated as ten out of ten. *Id.* at 138. Her leg pain was assessed as being more muscular in the calf and hamstring – rather than from the knee joint and possibly connected to radiculopathy in her back, but not a classic presentation for either condition. Her left shoulder pain was thought to be due to rotator cuff tendinitis or possible adhesive capsulitis. X-rays of her shoulder were ordered, and a PT referral was provided for both conditions. *Id.* at 139.

In the results from the left shoulder x-rays, taken the same day - November 12, 2018, it was noted that Petitioner described an inability to lift small objects past chest level and reported hearing a popping sound when moving her arm. Exhibit 5 at 1,056. The x-rays revealed no acute osseous abnormality and mild progression of degenerative changes previously observed. *Id.*

At her first PT session on November 16, 2018, Petitioner reported leg pain ranging from zero to ten out of ten, currently at zero, and left shoulder pain ranging from zero to eight, currently at one. Exhibit 4 at 1. Her inability to lift a coffee cup was characterized as resolved. *Id.* Most of the discussion and treatment described in this record was related to Petitioner's lower extremity pain. *Id.* at 1-8. Similarly, the email and phone communications between Petitioner and her PCP and rheumatologist in November and December contain mostly discussions of Petitioner's leg swelling and pain. Exhibit 5 at 160-188. However, there are a few mentions of arm pain, linked to accompanying neck pain. *Id.* at 179, 182.

By her next PT session on December 3, 2018, Petitioner reported that "she felt much better after last session," but that "[h]er arm pain ha[d] moved up into her neck." Exhibit 4 at 9. At her December 6, 2018 session, she indicated that "she felt great

[10] Oxycodone is "an opioid agonist analgesic derived from morphine." DORLAND'S at 1356.

following last session but then on Tuesday evening, everything was really, really bad – everything hurt – legs, knee, neck, shoulder." *Id.* at 11. Her greatest pain was in the back of her left calf. *Id.* On December 14, 2018, she again reported "a lot of pain in the back of her knee and calf." *Id.* at 13. Although this record includes left shoulder pain in the numerous listed diagnoses and contains one notation indicating Petitioner also suffered from "[l]eft shoulder pain" (*id.*), the remainder of the record refers to only Petitioner's knee and calf pain (*id.* at 13-14).

In the record from a January 14, 2019 visit to her PCP for treatment of her left knee pain, Petitioner's left shoulder pain is listed as a secondary concern. Exhibit 5 at 141. The record notes that Petitioner believed her left shoulder pain was related to her flu vaccine, that "[s]he has had no real treatment yet," and that she has contacted a lawyer "to pursue a legal resolution of this matter." *Id.* Petitioner is described as having "left lateral acromial, trapezial, and neck pain with use of her left shoulder." *Id.*

Like the most recent December PT record, the record from Petitioner's next session on January 15, 2019, focuses on Petitioner's leg pain and difficulties walking. Exhibit 4 at 15-16. There is one entry indicating Petitioner's "shoulder ha[d] been pretty sore until yesterday and today." *Id.* at 15.

Other than the inclusion of left shoulder pain in the list of numerous diagnoses, the record from Petitioner's next PT session on January 24, 2019, does not mention any left shoulder pain. Exhibit 4 at 17-18. Petitioner is described as having bilateral leg pain, swelling, and difficulties walking which have all improved, some general stiffness after each PT session, and more difficulty with right-sided trunk and hip rotation when compared to that on the left. *Id.*

The most recent medical record provided is from a February 27, 2019 visit to the rheumatologist, less than five months post-vaccination. Exhibit 5 at 145. At this visit, described as a follow-up visit for Petitioner's GCA and rheumatoid arthritis, it was noted that Petitioner continued to have "some residual shoulder and neck pain" but that her pain had improved with PT. *Id.*

Additional medical records, filed by Petitioner on April 21, 2021, are primarily comprised of medical records related to Petitioner's 2013 right carpal tunnel condition and release, performed on December 19, 2013. Exhibit 7 at 42-236. However, the initial pages contain a list of all medications, problems, immunizations, and entries titled "Health Maintenance" which appears to have been printed on March 26, 2021. *Id.* at 2-41. The list of problems includes Petitioner's GCA, carpal tunnel syndrome, osteoarthritis, and rheumatoid arthritis, but no mention of left shoulder pain. *Id.* at 4-6.

III. Applicable Legal Standards

Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV)(B). The specific criteria establishing a SIRVA are as follows:

> *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) (Qualifications and Aids to Interpretation ("QAI") for SIRVA).

If, however, a petitioner suffered an injury that either is not listed in the Table or did not occur within the prescribed time frame, she must prove that the administered vaccine caused injury to receive Program compensation. Section 11(c)(1)(C)(ii) and (iii). In such circumstances, petitioner asserts a "non-Table or [an] off-Table" claim and to prevail, petitioner must prove her claim by preponderant evidence. Section 13(a)(1)(A).

The Federal Circuit has held that to establish an off-Table injury, petitioner must "prove . . . that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1351 (Fed. Cir 1999). The received vaccine, however, need not be the predominant cause of the injury. *Id.* at 1351.

Additionally, for either a Table or causation-in-fact SIRVA, a petitioner must satisfy the Vaccine Act's severity requirement. *See* Section 11(c)(1)(D). As stated by Congress when amending the Vaccine Act in 1987, the six-month severity requirement was designed "to limit the availability of the compensation system to those individuals who are seriously injured from taking a vaccine." H.R. REP. 100-391(I), at 699 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313–1, 2313–373. The only exception is the alternative added in 2000, a showing that the vaccine injury required inpatient hospitalization and surgical intervention. *Children's Health Act of 2000*, Pub. L. No. 106–310, § 1701, 114 Stat. 1101, 1151 (2000) (codified as amended at 42 U.S.C. § 300aa–11(c)(1)(D)(iii)). This exception was added to allow compensation in intussusception cases which often required surgical intervention but then resolved in less than six months. *Id.*

IV. Parties' Arguments Regarding Severity

Stressing that Petitioner has provided no medical records after her last treatment and complaint of left shoulder pain on February 27, 2019 – four months and 24 days post-vaccination - Respondent argues that Petitioner has failed to demonstrate that she suffered more than six-months of sequela of her alleged SIRVA injury. Rule 4(c) Report at 7. Although "[P]etitioner avers that she continues to suffer pain in her arm, neck, and shoulder," Respondent insists that Petitioner "has not presented any support for this statement." *Id.*

In reaction, Petitioner relies upon the accompanying journal entries indicating she continued to complain of left shoulder pain throughout the spring and summer of 2019. Response at 2. She offers no additional medical records or other evidence regarding the duration of her sequela.[11]

[11] Acknowledging that the timing of her first complaint is not relevant to the severity requirement, Petitioner also mentions evidence in the medical records showing that she complained of shoulder pain, along with back, hamstring, and calf pain, as early as early as October 17, 2018. Response at 1 (citing Exhibit 4 at 35). I agree the cited record, her October PT referral, includes shoulder pain in the list of reasons for the referral.

V. Analysis

There is record evidence that Petitioner experienced pain in multiple locations, including the left shoulder, from October 2018 through February 2019. However, these same records also show that Petitioner, who suffered from rheumatoid arthritis and GCA, complained of pain in multiple locations of her body during this time, and that her primary complaint was the leg and knee pain and difficulty walking that she had experienced since May 2018 - more than five months *prior* to vaccination. *See,* e.g., Exhibit 5 at 195 (reporting "excruciating body pain" on October 17th) and 194 (describing an inability to walk on October 18th). Additionally, the left shoulder pain and popping that Petitioner reported during the month following vaccination were described as resolved four days later. Exhibit 5 at 1,056 (report); Exhibit 4 at 1 (resolution reported). And in early December, Petitioner indicated that her shoulder pain had migrated into her neck. Exhibit 4 at 9.

The initial journal entries, from late October through early November 2018, reflect what was reported in the contemporaneously created medical records at that time. They contain descriptions of left arm pain, along with entries related to neck, upper back, lower back, hips, and leg pain, difficulties walking, shaky hands, headaches, feelings of unwellness, and dizziness. Exhibit 8 at 1-7. Furthermore, the journal entries from November 9, 2018, through January 5, 2019, support an absence of left *shoulder* pain, mentioning only Petitioner's feelings of sickness, head, neck, and leg pain, and issues with her knee. Exhibit 8 at 5-7, 10-11.

As reflected in the contemporaneously created medical records, later mentions of left shoulder pain were accompanied by back, trapezius, and neck pain, and Petitioner's leg and knee pain continued to be her primary complaints. *E.g.,* Exhibit 5 at 141. Additionally, Petitioner reported improvement in all sources of pain. Exhibit 4 at 9-15; Exhibit 5 at 141, 145. Records from PT sessions on January 15 and 24, include left shoulder pain in the list of diagnoses, but mention only one report of resolved soreness on January 15. Exhibit 4 at 15-18. And as reported in the most recent medical record filed – from Petitioner's February 27 visit to her rheumatologist, her shoulder and neck pain had improved with PT. Exhibit 5 at 145.

Petitioner's journal entries from January through February 2019, describe severe neck and shoulder pain which does not align with the information contained in the medical records created during that time. *Compare* Exhibit 8 at 11-13 *with* Exhibit 4 at 15-18; Exhibit 5 at 145. Moreover, beginning in early January 2019, the journal entries focus solely on reported neck, shoulder, and arm pain, reflecting a departure from the more comprehensive earlier entries. Exhibit 8 at 8-9, 11-16.

According to later journal entries, Petitioner neck pain was "terrible" on March 11 (Exhibit 8 at 13) and "excruciating" on April 21, on April 23, and on May 15 (*id.* at 16, 8-9 respectively). Numerous other entries from early January through July describe "really" or "very bad" upper back, shoulder, and neck pain. *Id.* at 8-9, 11-16. Unfortunately, because Petitioner has failed to file any medical records from this time which would support the information contained in the journal entries, or to explain the process by which these entries were created, I must treat them as uncorroborated witness assertions.

The most recent, detailed medical record filed in this case shows that as of February 27, 2019 (four months and 24 days post-vaccination), Petitioner suffered from rheumatoid arthritis, possible GCA, previous problems with her medications, headaches, left knee and leg pain which had improved after a cortisone injection, left shoulder pain after vaccination which improved with PT – leaving only some residual shoulder and neck pain, and intermittent left wrist and ulnar side pain. Exhibit 5 at 145. Other than lists of medications, problems, and immunizations – which do not include any mention of left shoulder pain, Petitioner has not provided more recent medical records.

Petitioner alleges that she suffered the residual effects of a Table SIRVA injury for more than six months, but does not address the atypical presentation of her symptoms, the other conditions she suffered which would explain her left shoulder pain, the mildness of the symptoms she exhibited (especially after early December 2018), or the lack of medical records regarding treatment or even any mention of left shoulder symptoms *after* February 2019. Given these omissions, but most especially Petitioner's failure to provide any medical records from treatment she received after February 27, 2019, I cannot conclude that Petitioner suffered the residual effects of her SIRVA Injury for more than six months.

VI. Conclusion

To date, and despite ample opportunity, Petitioner has failed to provide preponderant evidence that she suffered the residual effects of her injury for more than six months or suffered an in hospital surgical intervention. Section 11(c)(1)(D).

Petitioner was informed that failure to provide preponderant to satisfy the Vaccine Act's severity requirement would be treated as either a failure to prosecute this claim or as an inability to provide supporting documentation for this claim. Accordingly, this case is DISMISSED for failure to prosecute. The Clerk of Court shall enter judgment accordingly.[12]

[12] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by the parties' joint filing of notice renouncing the right to seek review.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master