

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 21-1815V

UNPUBLISHED

MARIA ALSIP,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: March 22, 2023

Special Processing Unit (SPU);
Findings of Fact; Statutory Six Month
Severity Requirement; Influenza (Flu)
Vaccine; Shoulder Injury Related to
Vaccine Administration (SIRVA)

Laura Levenberg, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Voris Edward Johnson, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT¹

On September 7, 2021, Maria Alsip filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the “Vaccine Act”). Petitioner alleges that she suffered a left shoulder injury related to vaccine administration (“SIRVA”), a defined Table injury, after receiving the influenza (“flu”) vaccine on October 23, 2020. Petition at 1, ¶ 1. In particular, she maintains her “SIRVA symptoms persisted for more than six months.” *Id.* at ¶ 9; *accord.* Exhibit 8 at ¶ 9 (Petitioner’s signed declaration).

¹ Because this unpublished Fact Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims’ website in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 Fact 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, I agree that the identified material fits within this definition, I will redact such material from public access.

² 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).

A fact dispute between the parties has arisen regarding Petitioner's ability to meet one of the elements of her claim. For the reasons discussed below, I find the Petitioner continued to suffer the residual effects of her alleged SIRVA for more than six months. See Section 11(c)(1)(D)(i) (statutory six-month severity requirement).

I. Relevant Procedural History

Along with the Petition, Ms. Alsip filed the medical records required under the Vaccine Act. Exhibits 1-6, ECF No. 1; see Section 11(c). She failed, however, to provide the affidavit required by the Vaccine Act, filing instead an electronically-signed statement which was not notarized or signed under penalty of perjury as required by 28 U.S.C.A. § 1746. Exhibit 7, ECF No. 1-10. On February 10, 2022, the case was activated and assigned to the "Special Processing Unit" (OSM's adjudicatory system for resolution of cases deemed likely to settle). ECF No. 8.

Over the subsequent four-month period, the deficiency in Petitioner's statement, and a potential factual issue related to severity, were identified. ECF Nos. 11, 13. In mid-September 2022, Petitioner file a declaration signed under penalty of perjury as required by 28 U.S.C.A. § 1746 and a motion requesting a factual ruling on the severity. Exhibit 8, ECF No. 14; Petitioner's Motion for a Factual Ruling ("Motion"), ECF No. 15.

In her motion, Petitioner maintains that she continued to suffer the residual effects of her injury for more than six months. Motion at 8. Emphasizing descriptions of improving, but not resolved, symptoms during orthopedic appointments and a primary care provider ("PCP") appointment in February and March 2021 (four- and five-months post-vaccination), Petitioner primarily relies upon an early May 2021 PCP appointment when she sought pain medication for her left shoulder pain. *Id.* at 3, 8-9. She explains that she did not return to her orthopedist because "her shoulder pain had improved after physical therapy, . . . she was not a candidate for surgery, . . . [and she] was told by her orthopedic surgeon that she needed to continue her care . . . with her primary care physicians." *Id.* at 3. Relying upon her assertion that lifting her left arm above her head and rotating continued to be uncomfortable, Petitioner insists that she continued to experience symptoms even after May 2021. Motion at 3 (referencing Exhibit 8 at ¶ 7).

Respondent, by contrast, "contends that [P]etitioner has failed to present preponderant evidence that she experienced the residual effects of her alleged SIRVA for more than six months." Respondent's Response to Motion ("Response"), ECF No. 16. He stresses the lack of any evidence of adhesive capsulitis or rotator cuff tendinitis at Petitioner's last orthopedic visit five months post-vaccination (in late March 2021), the lack of left shoulder pain and evidence of a normal range of motion ("ROM") at a PCP

visit in early April 2021, and that a request for pain medication made to Petitioner's PCP more than six months post-vaccination occurred only after she retained counsel. *Id.* Respondent requests that I issue a finding consistent with the arguments he advances or, at a minimum, that I defer my fact ruling until after the HHS review (*id.* at 1 n.1).

II. Issue

At issue is whether Petitioner continued to suffer the residual effects of the alleged SIRVA injury for more than six months. Section 11(c)(1)(D)(i) (statutory six-month severity requirement).

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. "Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, *4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that

happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such fact testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id.*

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Finding of Fact

I make this severity finding after a complete review of the record to include all medical records, statements, declarations, briefing, and additional evidence filed. Specifically, I highlight the following evidence:

- Prior to receiving the flu vaccine on October 23, 2020, Ms. Alsip (then 37 years old) suffered from lower and right-sided thoracic back pain, allergies, headaches and syncope events, depression, and anxiety. Exhibit 2 at 13-81. Noted to drive a forklift and to cut carpet at work, she treated her back

pain (which appeared muscular in nature) with stretching. Petitioner's observed syncope events were usually preceded by tingling and numbness in her right arm, a headache, and vomiting. See, e.g., *id.* at 55-56. To treat her allergies, Petitioner took medication and received injections every two weeks. *E.g., id.* at 13, 17.

- During a visit to her allergist on October 23rd, Petitioner received the flu vaccine alleged as causal in her left deltoid. Exhibit 1 at 1; see *also* Exhibit 3 at 10.
- Approximately two weeks later (on November 9th), Petitioner visited her PCP complaining of continued left shoulder pain following the flu vaccine administered at her allergist's clinic.³ Exhibit 2 at 10. She indicated that she had called her allergist, who instructed her to seek treatment from her PCP. *Id.* The PCP administered a steroid injection and prescribed Ibuprofen and stretching exercises. *Id.* at 11.
- On November 13th and December 8th, Petitioner's allergist attempted to call Petitioner to follow-up on the condition of her left shoulder. Exhibit 3 at 10.
- After speaking to her allergist by phone on December 11th, Petitioner visited the clinic a few days later. Exhibit 3 at 14. At this visit, she described intermittent sharp, aching pain and limited movement with pain – especially when lifting her arm overhead. Indicating that the steroid injection administered by her PCP “helped some,” she characterized her pain as “getting better, but not resolved.” *Id.* After discussing the possible reasons for persistent pain post-vaccination and the lack of any symptoms of tenderness or warmth at the injection site or suggestive of infection or malignancy, the allergist opined that Petitioner was suffering from “rotator cuff inflammation.” *Id.*
- At her first orthopedist appointment on January 15, 2021, Petitioner reported that in addition to several days of pain relief obtained by the steroid injection she received, she also had experienced “near complete resolution of her pain” while taking steroid medication prescribed by the nurse practitioner at her PCP's clinic.⁴ Exhibit 4 at 23. Petitioner's returned pain occurred at rest and with movement. *Id.* at 21, 23. Noted to have moderate

³ The medical record mistakenly listed the date of vaccination as October 30th. Exhibit 2 at 10.

⁴ It is not clear when this medication was prescribed.

discomfort with macro movements of her arm, but no evidence of arthritis, Petitioner was diagnosed with adhesive capsulitis and administered a second steroid injection into her shoulder joint. *Id.* at 21-22.

- When she returned to the orthopedist three days later, Petitioner reported increased pain the day after the steroid injection, no pain the second day, and a return of “some discomfort” thereafter. Exhibit 4 at 18. She described a current feeling of heaviness but no overt pain. *Id.* She was referred to physical therapy (“PT”) and encouraged to take over the counter pain medication. *Id.* at 17.
- When evaluated at her first PT session on January 25th, Petitioner exhibited decreased ROM and increased pain. Exhibit 5 at 37. She reported current pain at a level of three out of ten and assessed as having mildly decreased ROM – 150 degrees vs. 160 degrees in her right shoulder, and strength – four out of five. *Id.* at 29.
- By her sixth PT visit on February 8th, Petitioner reported no pain in her left shoulder over the weekend or difficulties performing household chores. Exhibit 5 at 20. She was observed as having full ROM and strength. *Id.* Although Petitioner indicated she was very satisfied with her current level of function, she stated that she had some pain with strenuous activity. *Id.* at 16.
- By February 10th, Petitioner reported only some muscle fatigue. Exhibit 5 at 15. However, two days later, she again was assessed as having mild reduction in strength – four of out five. *Id.* at 14.
- When discharged from PT on February 22nd, Petitioner reported no pain at rest but pain at a level of five out of ten with activity. Exhibit 5 at 12. Her only remaining functional limitation was noted to be “lifting overhead.” *Id.* Petitioner’s decreased ROM and strength were still apparent but even milder than previously assessed. *Id.* This record indicated that, on February 12th, Petitioner had stopped attending PT “due to financial concerns and insurance miscommunication.” *Id.* Stating that she was currently having left shoulder pain that started this past weekend, Petitioner indicated she would be returning to her doctor for treatment. *Id.*
- When seen by her orthopedist on February 23rd, Petitioner reported improvement with PT, but a return and worsening of her pain over the

weekend. Exhibit 4 at 13. Opining that there was no evidence of adhesive capsulitis or significant evidence of adhesive capsulitis, the orthopedist noted that all of Petitioner's pain "appear[ed] to be localized to her bicipital groove." *Id.* Because Petitioner was also suffering from symptoms of a possible urinary tract infection ("UTI") and had been unable to get an appointment with her PCP, the orthopedist suggested she go to the emergency room. He prescribed an anti-inflammatory for her left shoulder pain. *Id.*

- On March 8th, Petitioner sought treatment from a new PCP. Exhibit 6 at 30. The medical record from this visit contains entries related to Petitioner's high cholesterol, allergies, earlier syncope events, and recent ovarian cyst and kidney stones. *Id.* at 31. It does not mention Petitioner's left shoulder or back pain.
- On March 13th, Petitioner returned to this PCP for thoracic back pain, located mid-back between her shoulder blades and first occurring six-months ago – placing onset in mid-September 2020. Exhibit 6 at 23, 25. Opining that she did not believe Petitioner's back pain was related to her kidney stones, the PCP ordered x-rays, prescribed muscle relaxants and oral steroids, and referred Petitioner to her orthopedist. *Id.* at 23, 26. In the record from this visit, it was noted that Petitioner was being treated by her orthopedist for left shoulder pain following a flu vaccine. *Id.* at 23.
- At her next, and last, orthopedic appointment on March 22nd – approximately five months post-vaccination, Petitioner reported that she was diagnosed with kidney stones and a large ovarian cyst when seen at the ER after her last appointment on February 23rd. Exhibit 4 at 10. Regarding her left shoulder pain, she described it as significantly improved, adding that she "[wa]s able to move her arm in all directions without replication of any pain or mechanical symptoms." *Id.* at 9. The orthopedist characterized Petitioner's "shoulder discomfort [as] improving . . . [without] evidence of biceps tendinitis or capsulitis based upon today's history and physical exam findings." *Id.* Seeing no need to "keep rechecking" Petitioner, the orthopedist determined she could be transitioned to treatment on an as needed basis. *Id.*
- Seen by her PCP on April 5th for follow-up of her thoracic back pain, Petitioner reported improvement with the prescribed medication. Exhibit 6 at 14. It was again reported that she was being treated by her orthopedist

for left shoulder pain. *Id.* Noting there were no abnormalities shown on the ordered x-rays, the PCP instructed Petitioner to continue taking her current medication. *Id.* at 14, 17.

- On May 7, 2021, Petitioner returned to her PCP for treatment of elevated blood pressure and dizziness after her first and second doses of the COVID vaccine, and chronic left shoulder pain following the flu vaccine. Exhibit 6 at 7. Indicating she was “unable to get an appointment [with her orthopedist] until after [a planned] trip,” Petitioner requested a prescription for “short term pain meds.” *Id.* The PCP prescribed Tramadol and instructed Petitioner to return to her orthopedist if additional pain medication was needed. *Id.* at 10. This record is the most recent medical record filed.
- In her supplemental declaration, Petitioner asserts that she did not return to her orthopedist after March 2021 because her SIRVA injury had improved, but not resolved; she was informed she was not a good candidate for surgery; and her orthopedist indicated she should follow-up with her PCP. Exhibit 8 at 4-5. Stressing that she sought treatment from her PCP in May 2021 (*id.* at 7), Petitioner insists that she “suffered the residual effects or complications of SIRVA for more than six (6) months” (*id.* at 8).

To satisfy the Vaccine Act’s severity requirement in this case, Petitioner must show that she suffered symptoms of her alleged SIRVA beyond April 23, 2021 (assuming an immediate onset on October 23rd). The above medical entries preponderantly suggest that Petitioner was experiencing continued, albeit mild and intermittent, symptoms of her alleged left shoulder injury through *May 7th* – thus satisfying that severity requirement.

Admittedly, the record establishes that Petitioner’s injury was substantially resolved following her second steroid injection in January 2021. However, in PT sessions attended through mid-February 2021, Petitioner continued to experience mild pain, especially with movement, and slight limitations in ROM beyond that date. By the end of February 2021, she reported a worsening of her left shoulder pain. And despite improvements reported in March 2021, as well as the need for treatment of a cyst and kidney stones (serious but unrelated conditions), Petitioner again sought treatment from her orthopedist on March 22nd – five months post-vaccination. After recording the progress Petitioner reported, the orthopedist still characterized her left shoulder condition as *improving*.

I credit Respondent’s argument that Petitioner’s visit to her PCP on May 7th appears to have occurred after she retained counsel, thus casting some doubt on the

complete veracity of assertions made at that time. But coupled with the unresolved, albeit mild, nature of her condition as confirmed in records from approximately one month earlier, this later visit provides sufficient evidence of continued pain. Had the visit occurred after a longer gap in treatment, it would be less persuasive.

Overall, the record establishes that Petitioner's symptoms had not resolved by late March 2021, almost five months post-vaccination. It is reasonable to infer that she continued to experience some mild pain with movement for approximately one month thereafter. The mildness of Petitioner's later symptoms and intermittent nature of her pain are issues highly relevant to damages, and suggest any award in this case for pain and suffering should be modest. But it does *not* mean I cannot find the basic requirement of six months severity met. Although a close call, made while recognizing that the question of entitlement remains, I find there is preponderant evidence to establish Petitioner suffered the residual effects of her alleged SIRVA for more than six months.

V. Scheduling Order

Despite my factual finding, it is not assured that Petitioner will prevail. This case is complicated by the thoracic pain Petitioner appears to have experienced prior to and after vaccination. Additionally, the left shoulder pain and limitations in ROM which she experienced were particularly mild and limited in duration. Petitioner has provided no evidence that they continued beyond May 2021. Thus, I would expect the amount of any compensation awarded to be low.

In light of my finding regarding the Vaccine Act's severity requirement, Petitioner should forward a reasonable settlement demand and supporting documentation to Respondent. Respondent should consider his tentative position in this case.

Respondent shall file a status report indicating how he intends to proceed following my ruling by no later than Monday, April 24, 2023.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Chief Special Master