

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 21-0699V

UNPUBLISHED

KRISTINE LAW,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: February 23, 2023

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

Leigh Finfer, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Andrew Henning, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT¹

On January 12, 2021, Kristine Law 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 alleged that she suffered a left shoulder injury related to vaccine administration (“SIRVA”), a defined Table Injury, after receiving the influenza (“flu”) vaccine on September 20, 2020.³ Petition at 1, ¶ 1.

¹ Because this unpublished Fact Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in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).

³ Petitioner also filed an amended petition with additional detail and medical records citations on March 14, 2022. ECF No. 17.

Because Petitioner failed to seek treatment for her SIRVA injury during an almost five-month period (from mid-December 2020 through early May 2021), Respondent questioned whether Petitioner could satisfy the statutory six-month requirement. ECF No. 20. Petitioner maintains that the symptoms she experienced in May 2021 and later reflect a continuation of her SIRVA injury. Amended Petition at ¶ 5.

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

Based upon the prior concern that SIRVA was to be removed from the Vaccine Injury Table,⁴ Ms. Law filed her petition without medical records in January 2021. See Exhibit 3 (signed declaration⁵ of Petitioner's counsel). Along with the initial petition, she filed her vaccine record and signed declaration.⁶ Exhibits 1-2.

Approximately six months later, Petitioner filed the medical records required under the Act. Exhibits 4-12, ECF No. 8; see Section 11(c). On December 27, 2021, the case was activated and assigned to the Special Processing Unit (OSM's process for attempting to resolve certain, likely-to-settle claims). ECF No. 12. Less than three months thereafter, Petitioner filed an amended petition and updated medical records. Exhibits 13-16, ECF No. 16; Amended Petition, ECF No. 17.

On June 14, 2022, Respondent filed a status report identifying potential issues with the claim – in particular, the six-month severity requirement, plus questions regarding the location of her alleged SIRVA injury. ECF No. 20. In response, Petitioner filed a

⁴ On July 20, 2020, the Secretary of Health and Human Services proposed the removal of SIRVA from the Vaccine Injury Table. National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Proposed Rule, 85 Fed. Reg. 43794 (July 20, 2020). The proposed rule was finalized six months later. National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Final Rule, 86 Fed. Reg. 6249 (Jan. 21, 2021). Approximately one month later, the effective date for the final rule was delayed. National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Delay of Effective Date, 86 Fed. Reg. 10835 (Feb. 23, 2021) (delaying the effective date of the final rule until April 23, 2021). On April 22, 2021, the final rule removing SIRVA from the Vaccine Table was rescinded. National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Withdrawal of Final Rule, 86 Fed. Reg. 21209 (Apr. 22, 2021).

⁵ The declaration was signed under penalty of perjury pursuant to 28 U.S.C.A. § 1746. Exhibit 3.

⁶ Petitioner's declaration also was signed under penalty of perjury pursuant to 28 U.S.C.A. § 1746. Exhibit 2.

supplemental signed declaration and motion for a fact ruling on the severity issue. Exhibit 17; Petitioner's Motion for a Fact Ruling ("Motion"), filed Aug. 14, 2022, ECF Nos. 21, 23. Respondent filed his response to the motion on November 14, 2022, deferring the resolution of whether the Petitioner suffered six-months sequela to my discretion. Respondent's Response to Petitioner's Motion for a Ruling on the Record Regarding Severity ("Response"), ECF No. 26. Recently, Petitioner filed additional updated medical records. Exhibit 18, filed Feb. 9, 2023, ECF No. 27.

The matter is now ripe for adjudication.

II. Issue

At issue is whether Petitioner continued to suffer the residual effects of the SIRVA 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 finding after a complete review of the record, including all medical records, statements, declarations, briefing, and additional evidence filed. Specifically, I note as follows:

- Petitioner (36 years old at the time of vaccination) had previous diagnoses of multiple sclerosis, multiple skin lesions, melanoma, sciatica/back pain, and a right shoulder injury (a fracture of the right humerus with routine healing) sustained in 2016. *See generally*, Exhibits 4, 11-12, 16. While recovering from her right shoulder fracture – the result of a dirt bike accident, Petitioner reported hiking, running up to 7.5 miles a day, and lifting weights. Exhibit 4 at 18, 22, 24, 26, 28, 30, 38.
- Petitioner received the flu vaccine alleged as causal in her left deltoid on September 20, 2020. Exhibit 1.
- On October 5, 2020 (15-days post-vaccination), Petitioner visited her orthopedist and complained of “a constant aching and burning pain located to the lateral shoulder.” Exhibit 4 at 4. Indicating that her pain had persisted since her vaccination two weeks earlier, Petitioner described the vaccination as “very painful,” causing tingling throughout her arm. *Id.* After discussing likely diagnoses – “post injection bursitis versus a possible injection irritating the superior branch of the axillary nerve,” the orthopedist prescribed physical therapy (“PT”) and recommended anti-inflammatory medication. *Id.* at 5.
- At her initial PT session on October 20, 2020, Petitioner reported sharp pain in her left shoulder since receiving the flu shot. Exhibit 5 at 46. Describing her pain as decreasing, Petitioner rated its severity as ranging from zero to six. *Id.* She was noted to have accompanying limitations in strength and range of motion (“ROM”). *Id.*
- Throughout ten additional PT sessions, Petitioner continued to report the same severity of pain, good improvement, some soreness when working on her stretching exercises at home, and a setback at one point when she attempted to lift a box at Costco. Exhibit 5 at 20-45. She was described as motivated throughout her PT. *Id.*
- At her last PT session on December 16, 2020, Petitioner reported that her shoulder was doing well. Exhibit 5 at 20. Although she was currently

experiencing no pain, however, she again reported that her pain level could rise to six at its worst. *Id.* The physical therapist assessed her as “making good progress” and having “met all goals.” *Id.* at 21. However, he observed that Petitioner still lacked full range and overall strength and experienced difficulties with reaching, lifting, and driving. The therapist instructed Petitioner to continue her home exercise program (“HEP”). Indicating that any future PT attendance could be reduced to once a week, the therapist authorized one more week – through December 23rd, adding that he would keep Petitioner’s case open to allow for a possible setback. *Id.*

- Petitioner did not pursue additional treatment for the first four months of 2021. In her supplemental signed declaration, Petitioner insisted that she chose to focus on her HEP, rather than re-starting PT, because she “would need to meet [her] health insurance deductible again and did not wish to pay out of pocket when [she] could perform the same exercises at home.” Exhibit 17 at ¶ 4. She also “had not yet received [her] Covid vaccination at the time and was not comfortable continuing to put [her]self at risk during the pandemic.” *Id.*
- On May 3, 2021, Petitioner returned to her orthopedist “for recheck of her left shoulder and to establish care for her lumbar spine.” Exhibit 6 at 4. Although she described improvement since her last visit – the resolution of the burning and tingling sensation and “no pain or discomfort with overhead or behind the back motions” - Petitioner reported that she still felt stiffness with overhead motion and “ha[d] not regained full range of motion.” *Id.* Upon examination, she was observed to have a “limited arc of motion through 160 degrees actively and able to achieve 180 degrees passively with slight discomfort.” *Id.* The orthopedist deferred ordering any advanced imaging and recommended that Petitioner continue her HEP.
- The remainder of Petitioner’s May 3rd visit to the orthopedist was spent discussing her lumbar pain. Attributing her past sciatica pain to a skiing incident ten to twelve years ago, she described her current pain “localized to the left paraspinal region and into the gluteal area.” Exhibit 6 at 4. Rating her pain level as three out of ten, she indicated it had begun seven weeks ago, after skiing and running. *Id.* at 6. The orthopedist prescribed PT for Petitioner’s back pain. *Id.* at 5.
- During May and June 2021, Petitioner attended ten additional PT sessions. Exhibit 6 at 8-49. Although the PT was clearly focused on her back pain, Petitioner’s left shoulder bursitis was listed as a treating diagnosis, along

with “[a]cute bilateral low back pain without sciatica.” *E.g., id.* at 15, 46. At her initial session on May 12th, Petitioner described her vaccine-related injury in September 2020, improvement with PT through the end of December, and continued pain when fastening her bra or reaching overhead thereafter. *Id.* at 40. She characterized her lower back pain as debilitating, located in her lumbar spine, and currently nine out of ten. *Id.*

Emphasizing the reasons previously provided for her gap in treatment – the fact that she would have to pay the costs of her PT until satisfying her deductible for 2021, and fear of COVID exposure due to her unvaccinated status at that time⁷ - Petitioner insisted that “the preponderance evidence in this case demonstrates that she suffered the residual effects or complications of her shoulder injury for more than six (6) months after vaccination.” Motion at 1. She pointed to the symptoms she exhibited at her last PT session in December 2020, and her description of her later symptoms as a continuation of her injury despite the four and one-half months treatment gap. *Id.* at 5-6.

In his response, Respondent emphasized the progress Petitioner made while attending PT during October through December 2020. Response at 5. He also noted that the symptoms Petitioner reported in May 2021 were mild, and also accompanied by distinguishable lower back pain. *Id.* at 5-6.

In this case, to satisfy the Vaccine Act’s severity requirement Petitioner must show that she suffered symptoms of her alleged SIRVA beyond March 20, 2021. Thus, she must establish that the symptoms she complained of May 2021, were a continuation of her 2020 SIRVA injury - or that, at a minimum, that the symptoms she reported in September 2020 continued through at least until March 20th of the next year.

The above medical entries support the conclusion that Petitioner was experiencing only mild symptoms by her last PT session in December 2020, approximately three months post-vaccination. But she continued to exhibit limitations in her ROM and difficulties performing tasks such as reaching overhead and driving. And when she returned to the orthopedist in May 2021 (now more than six-months post-vaccination), she specifically included her left shoulder symptoms as a reason for her visit. Although those symptoms had become even milder than what she reported in December 2020, Petitioner reported that they had continued in unabated form.

Unquestionably, the gap in treatment (December 2020 through early May 2021), is highly relevant to damages, along with the fact that by May Petitioner was experiencing unrelated lower back pain. These factors not only support the conclusion that Petitioner’s

⁷ Motion at 3; Exhibit 17 at ¶ 4 (supplemental signed declaration).

SIRVA was mild (since she was able to tolerate her discomfort in the gap and self-treat symptoms), but also underscore the extent to which her subsequent symptoms were distinguishable (and hence not compensable). However, this does *not* mean I cannot find the basic requirement of six months severity met.

A treatment gap or unrelated co-morbidity does not automatically mean severity cannot be established. Rather, the Vaccine Act requires only that Petitioner in this case establish that she suffered the residual effects or complications of her alleged SIRVA injury beyond March 20, 2021. Section 11(c)(1)(D)(i). It does not demand that the effects or complications be notably “severe” on their own, or that the symptoms and treatment continue uninterrupted throughout the six-month period.

The medical records show Petitioner experienced continued, albeit mild, discomfort and limitations in her ROM through early May 2021. Accordingly, 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

As stated in the previous section, Petitioner’s symptoms in this case were mild, and she simultaneously suffered pain due to unrelated co-morbidities – specifically sciatica and lower back pain prior to and after vaccination. These matters are relevant when determining the appropriate amount of compensation – and thus despite my severity finding, Petitioner must take into account these factors in determining what kind of damages to seek in this case.

In light of my finding regarding the Vaccine Act’s severity requirement, 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, March 27, 2023.**

IT IS SO ORDERED.

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