In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 21-411V

UNPUBLISHED

ALYSSA SCHUTTE, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: May 29, 2024 Special Processing Unit (SPU); Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA); Six Month Severity Requirement

David John Carney, Green & Schafle LLC, Philadelphia, PA, for Petitioner.

Zoe Wade, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On January 8, 2021, Alyssa Schutte 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 shoulder injury related to vaccine administration ("SIRVA") caused by an influenza ("flu") vaccine administered on October 3, 2019. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

For the reasons discussed below, I find Petitioner has not established that she suffered the residual effects of her injury for more than six months, and therefore dismissal of the claim is warranted.

[1] 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 (2018).

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I. Relevant Procedural History

Following the initial petition, on May 3, 2021, Petitioner filed an amended petition with medical records. ECF No 6. On September 9, 2022, Respondent filed the Rule 4(c) Report opposing compensation. ECF No. 29. Specifically, Respondent argues that Petitioner has not meet the severity requirement of the Vaccine Act. *Id.* at 9-11.

Petitioner filed a Motion for a Ruling on the Record on October 21, 2022, arguing that she had met the severity requirement and otherwise established entitlement to compensation for a SIRVA Table Injury, including a specific compensation request. Petitioner's Motion for Ruling on the Record and Brief in Support of Damages ("Mot."), ECF No. 32. Respondent opposed the motion on February 3, 2023, reiterating the arguments set forth in the Rule 4(c) Report, and further arguing that if Petitioner is found entitled to compensation, the damages award should be lower than Petitioner's request. Respondent's Response to Petitioner's Motion for Ruling on the Record ("Opp."), ECF No. 36, at 1-6. Petitioner filed her reply on February 14, 2023. Petitioner's Reply Brief in Support of Petitioner's Motion for Ruling on the Record and Brief in Support of Damages ("Reply"), ECF No. 37. The matter is ripe for resolution.

II. Petitioner's Medical Records

Petitioner's past medical history shows no previous injury or complaints of right shoulder pain. Ex. 1 at 5-7.

Petitioner received a flu vaccine in her right shoulder on October 3, 2019. Ex. 8. On October 14, 2019, eleven days after receiving the vaccination, Petitioner went to urgent care. Joy Goben, Nurse Practitioner ("NP"), noted Petitioner was having "pain in upper right arm and shoulder after flu shot." The record also states "CONTEXT / MECHANISM: Receiving flu shot." Ex. 3 at 54. NP Goben's treatment plan included prescribing an anti-inflammatory, ice, rest, compression and elevation. *Id.* 57–58.

Petitioner returned to Urgent Care on October 17, 2019, and saw NP Jayma Schmidt. Petitioner's chief complaint was right upper arm pain "after receiving the flu vaccine." NP Schmidt noted that Petitioner's condition had improved, but she was still experiencing pain. Ex. 3 at 50-51. She was diagnosed with cellulitis and prescribed antibiotics and steroids. *Id.* Petitioner returned to Urgent Care on November 5, 2019, with continued complaints of right shoulder pain. *Id.* at 43. The pain was described as aching, dull, and ranged from two to six out of ten. *Id.* Physical therapy was prescribed to Petitioner at two to three times a week for four weeks. *Id.*

On November 21, 2019, Petitioner again complained of right shoulder pain. Ex. 3 at 79. She stated that she had attended physical therapy sessions that were "not helping." *Id.* An examination showed Hawkins and impingement tests were negative, but Petitioner had reduced range of motion and strength. *Id.* at 80. NP Mindy Shoulders recommended that Petitioner continue physical therapy three times a week for three weeks. *Id.* at 80-81.

Petitioner attended four physical therapy sessions between November 20, 2019, and December 6, 2019. Ex. 3 at 31–41. By December 6, 2019, Petitioner reported that her pain was no longer constant, and her range of motion had significantly increased. *Id.* at 31.

At a follow up visit on December 12, 2019, with Dr. Keith Baugh, Petitioner continued to describe a dull pain in her shoulder that was making it difficult for her to sleep and preform everyday activities. Ex. 3 at 24. Her pain was characterized as intermittent, and one to three out of ten. *Id.* An examination showed signs of impingement and reduced range of motion, but no specific diagnosis was noted, and Petitioner was told to continue resting and icing the injury. *Id.* at 25.

Petitioner had an MRI on December 13, 2019. The MRI showed "the rotator cuff tendons are intact," no edema, no signs of fluid within the soft tissues, but signs of a "tiny SLAP tear involving the superior labrum. Ex. 3 at 11.

On December 18, 2019, Petitioner had an appointment with Dr. Douglas Lowery at Orthopedic Associates. Petitioner was assessed with adhesive capsulitis in her right shoulder, and Dr. Lowery advised that her symptoms were consistent with an early frozen shoulder. Ex 3 at 18. Work restrictions were enacted to limit pushing, pulling, lifting, or tugging over ten pounds. *Id.*

Petitioner saw Dr. Lowery again on January 17, 2020, for shoulder pain. Dr. Lowery noted that Petitioner claimed she was "doing a lot better", and because her symptoms were resolving she could return to work without restrictions. Ex. 3 at 4-5. He also found Petitioner to have full range of motion, but mild discomfort with abduction. *Id.* at 4.

On February 6, 2020, Petitioner saw Dr. Renee Galen for her annual medical examination. Ex. 4 at 39. At this visit, Petitioner stated that she had been experiencing "urticaria" (rash) and "bursitis" that were due to a "severe allergic reactions" to the flu vaccine. *Id.* There is no report that she continued to experience pain or reduced range of motion at that time.

After a three-month treatment gap, Petitioner had appointments on May 14, 2020, and July 30, 2020, for medication reviews and renewals. Ex. 10 at 5, 9. There was no mention of shoulder pain at either of these visits.

Petitioner requested a doctor's note on October 12, 2020, "to omit her from [her employer's] flu vaccine requirement." Ex. 6 at 4. Petitioner stated that she had experienced a severe allergic reaction to the flu vaccine that caused "hives, welts, and radiating pain…." *Id.* The record does not note any joint pain, right shoulder symptoms, reduced range of motion, or edemas, however. *Id.* at 6.

Over six months later, on May 20, 2021, Petitioner had an appointment with NP Rachel Roy regarding right shoulder pain. Ex. 9 at 1. Petitioner described her shoulder as feeling "full" and feeling as if she had limited range of motion since receiving a flu shot in 2019. *Id.* The pain was described as "recurrent", and the current episode "started more than 1 year ago." *Id.* An examination showed decreased range of motion and tenderness in her right shoulder. *Id.* at 3. NP Roy prescribed Meloxicam and recommended gentile stretching exercises. *Id.*

Between July 30, 2021, and February 2, 2022, Petitioner had four medical appointments for unrelated issues, including coordinating medication and COVID-19 care. Ex. 11 at 11–29. There was no mention of shoulder pain at these appointments.

On February 2, 2022, Petitioner tested positive for COVID-19. Ex. 11 at 29-30. On February 17, 2022, Petitioner saw Audra Douglas, Nurse Practitioner, for a follow up appointment regarding medication review and renewal. Ex. 11 at 6. Petitioner stated that her right shoulder had been hurting since the beginning of the month, seeming to have "started when she had COVID". *Id.* at 7. NP Douglass noted that Petitioner had no muscles aches, no stiff joints, and no swelling. *Id.* She was assessed with right shoulder pain, was provided bursitis exercises, and prescribed methylprednisolone. *Id.* at 8.

Petitioner's affidavits describe her continuing shoulder pain and how it has affected her life. Ex. 2; Supplemental Affidavit, Ex. 12. After several appointments, Petitioner stated, she was prescribed physical therapy but did not complete the sessions as she "found that it was not helpful and did not improve my symptoms." Ex. 12 at 3. In addition to describing her shoulder pain, Petitioner describes how the COVID 19 pandemic made it "impossible" to seek treatment. Ex. 2 at 4. In her supplemental affidavit, Petitioner also stated that she was unable to treat for most of 2020 due to Covid-19 restrictions. Ex. 12 at 2.

III. Fact Findings and Ruling on Entitlement

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). In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,[3] a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). 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). 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).

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

[3] In summary, a petitioner must establish that she received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of her injury for more than six months, died from her injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. *See* § 11(c)(1)(A)(B)(D)(E).

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, the Federal Circuit has recently "reject[ed] as incorrect the presumption that medical records are always accurate and complete as to all of the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021). Medical professionals may not "accurately record everything" that they observe or may "record only a fraction of all that occurs." *Id.*

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 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. Petitioner Does Not Meet the Severity Requirement

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

There is no dispute that Petitioner received the flu vaccine on October 3, 2019, and she therefore must demonstrate, by preponderant evidence, that her residual symptoms continued at least through April 3, 2020. *See, e.g., Herren v. Sec'y of Health & Human Servs.*, No. 13-100V, 2014 WL 3889070, at *2 (Fed. Cl. Spec. Mstr. July 18, 2014); *see also Hinnefeld v. Sec'y of Health & Human Servs.*, No. 11-328V, 2012 WL 1608839, at *4-5 (Fed. Cl. Spec. Mstr. Mar. 30, 2012) (dismissing case where medical history revealed that petitioner's injury resolved less than two months after onset).

The record establishes that Petitioner's initial treatment occurred over approximately three months, between October 14, 2019, and January 17, 2020, with no further treatment specific to concerns for shoulder pain until May 20, 2021 – well more than a year later. Ex. 9 at 1. Additionally, by January 17, 2020 (approximately four months post-vaccination), Petitioner was reportedly doing "a lot better," and returned to work

without any restrictions. Ex. 3 at 4-5. There are references to shoulder problems related to Petitioner's vaccination in February and October of 2020, but those records do not establish that her shoulder symptoms were ongoing at those times. Ex. 4 at 39 (record from February 6, 2020, noting that Petitioner had a rash and bursitis from a flu vaccine, but no indication that her symptoms were ongoing at that time); Ex. 6 at 4 (record from October 12, 2020, requesting that Petitioner be omitted from the flu vaccine requirement due to a prior allergic reaction).

Petitioner argues that COVID Pandemic closures in 2020 "prevented me from exhausting my formal treatment options," and that she attempted to treat her pain at home. Ex. 12 at 3. However, as Respondent notes in his briefing, Petitioner did not seek additional care until May 20, 2021, sixteen months after her last reported shoulder pain. Ex. 9 at 1. Moreover, she attended numerous medical appointments during this time, but did not describe any ongoing shoulder pain or range of motion issues. Petitioner next reported shoulder pain in February of 2022, an additional eight months after her last mention of shoulder pain. Ex. 11 at 6. Further, at that time she stated her right shoulder had been hurting since the beginning of that month, not since the October 2019 flu vaccination. Ex. 11 at 6.

Given the above, I cannot conclude that the record preponderantly establishes Petitioner's injury persisted for the six months required by the Act. Such lengthy treatment gaps are too large to ignore in this case and allow for the possibility of other intervening factors as more likely explanatory of Petitioner's subsequent shoulder complaints than her October 2019 injury.

Conclusion

Because Petitioner has failed to meet the severity requirement set forth in Section 11(c)(1)(D)(i), Petitioner cannot establish entitlement, and therefore I must **DISMISS** her claim in its entirety. In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk of Court shall enter judgment in accord with this Decision.[4]

IT IS SO ORDERED.

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

[4] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.