

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 21-0590V

CIARA NIELSEN,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: August 23, 2024

Amy A. Senerth, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Mallori Browne Openchowski, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT¹

On January 12, 2021, Ciara Nielsen 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”) resulting from an influenza (“flu”) vaccine received on December 13, 2019. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

¹ Because this Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at <https://www.govinfo.gov/app/collection/uscourts/national/cofc>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **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, 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).

For the reasons discussed below, I find that record evidence preponderantly establishes that Petitioner suffered the residual effects of her injury for more than six months, and has satisfied the remaining requirements for entitlement.

I. Relevant Procedural History

Two months after the case was activated, Respondent's counsel informally identified the statutory severity requirement as a possible obstacle to the claim (ECF No. 20). After Petitioner filed additional evidence, I reviewed the record and stated my preliminary view that the Petition was unlikely to be dismissed based on the severity requirement, and directed Petitioner to serve a demand (ECF No. 24). Over a year after the case was activated, Respondent stated that he would defend the claim, and filed his Rule 4(c) Report (ECF Nos. 32, 33). Thereafter, the parties briefed the issue of Petitioner's entitlement to compensation (ECF Nos. 35, 36).³ The matter is now ripe for resolution.

II. Factual Findings and Ruling on Entitlement

A. Legal Standards

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding his or her claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

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). "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 & 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.

³ Although the parties were directed to brief both Petitioner's entitlement to compensation and the amount of damages to which Petitioner was entitled, they briefed only the issue of whether Petitioner is entitled to compensation.

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)). The Federal Circuit has “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 & Human Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021) (explaining that a patient may not report every ailment, or a physician may enter information incorrectly or not record everything he or she observes).

In addition to requirements concerning the vaccination received and the lack of other award or settlement,⁴ a petitioner must establish that he or 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 he or she received. Section 11(c)(1)(C). The Vaccine Act further includes a “severity requirement,” pursuant to which a petitioner demonstrate that they:

- (i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention.

Section 11(c)(1)(D).

“[T]he fact that a petitioner has been discharged from medical care does not necessarily indicate that there are no remaining or residual effects from her alleged injury.” *Morine v. Sec’y of Health & Human Servs.*, No. 17-1013, 2019 WL 978825, at *4 (Fed. Cl. Spec. Mstr. Jan. 23, 2019); *see also Herren v. Sec’y of Health & Human Servs.*, No. 13-1000V, 2014 WL 3889070, at *3 (Fed. Cl. Spec. Mstr. July 18, 2014) (“a discharge from medical care does not necessarily indicate there are no residual effects”). “A treatment gap . . . does not automatically mean severity cannot be established.” *Law v. Sec’y of Health & Human Servs.*, No. 21-0699V, 2023 WL 2641502, at *5 (Fed. Cl. Spec. Mstr. Feb. 23, 2023) (finding severity requirement met where petitioner sought care for under three months and had met physical therapy goals but still lacked full range of motion and experienced difficulty with certain activities, then returned to care nearly five months later reporting stiffness and continuing restrictions in motion); *see also Peeples v. Sec’y of Health & Human Servs.*, No. 20-0634V, 2022 WL 2387749 (Fed. Cl. Spec. Mstr. May 26, 2022) (finding severity requirement met where the petitioner sought care for four months, followed by fifteen month gap); *Silvestri v. Sec’y of Health & Human Servs.*, No. 19-1045V, 2021 WL 4205313 (Fed. Cl. Spec. Mstr. Aug. 16, 2021) (finding severity

⁴ In summary, a petitioner must establish that he 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 and has not filed a civil suit or collected an award or settlement for his or her injury. Section 11(c)(1)(A)(B)(E).

requirement satisfied where petitioner did not seek additional treatment after the five month mark.

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 a flu vaccine. 42 C.F. R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying Qualifications and Aids to Interpretation (“QAI”) 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).

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.*

B. Relevant Factual History

This ruling contains only a brief overview of facts most relevant to the parties’ dispute.

1. Medical Records

Petitioner received the flu vaccine at issue in her left deltoid on December 13, 2019, during an urgent care visit for other concerns. Ex. 1 at 2. Two weeks later (December 27, 2019), she returned to urgent care, stating that since her vaccination two weeks earlier, she was experiencing progressively worsening pain originating at the injection site and radiating up over her shoulder. Ex. 2 at 6. The pain was slightly better in the morning, but by the evening her shoulder was “very painful” and she could not raise her arm, impairing her work as a hairstylist. *Id.* She had tried heat, ibuprofen, and Tylenol, with no improvement. *Id.* On examination, she was tender to palpation in her left bicep and above her shoulder joint, and her range of motion (“ROM”) was limited due to pain. *Id.* at 8. Petitioner was referred for an MRI of her shoulder. *Id.*

Five days later (January 2, 2020), Petitioner underwent a left shoulder MRI. Ex. 2 at 42. The MRI showed mild tendinosis of the supraspinatus and infraspinatus tendons without a tear. *Id.* Petitioner had a mild widening of the acromioclavicular joint without surrounding edema or fluid that was interpreted as a possible chronic joint separation. *Id.* Petitioner’s deltoid muscle and overlying subcutaneous tissues were normal. *Id.*

The following week (January 10, 2020), Petitioner saw orthopedic physician assistant (“PA”) Kelly O’Neal. Ex. 3 at 7. She explained that on December 13th, she received a flu vaccination in her left deltoid, followed by almost immediate pain that worsened over several days. *Id.* She was still having pain that she rated as six out of ten. *Id.* On examination, she had tenderness of the supraspinatus and deltoid, and pain with overhead motions. *Id.* at 9. Her active ROM was normal in forward flexion, extension, external rotation, internal rotation, and abduction. *Id.* PA O’Neal read her MRI as showing evidence of a chronic acromioclavicular joint sprain but no acute injury. *Id.* Her rotator cuff was fully intact without significant inflammatory process, and there were no soft tissue abnormalities. *Id.* PA O’Neal determined her symptoms were consistent with rotator cuff tendinitis that could have been brought on by the inflammatory process of her flu vaccination. *Id.* Petitioner was given exercises to do at home and referred to physical therapy (“PT”). *Id.* at 10.

Petitioner underwent a PT evaluation on February 7, 2020. Ex. 4 at 4. She complained of left shoulder pain that started after her flu vaccination in December 2019. *Id.* She described the pain as “constant achiness.” *Id.* Her pain was four out of ten at best

and seven out of ten at worst. *Id.* She had difficulty making her bed, lifting her shoulder, and dressing. *Id.* Her shoulder would sometimes start to feel better, but worsened by the end of the day. *Id.* Her left shoulder active ROM was within normal limits in flexion and extension, but limited to 150 degrees in abduction, and she had reduced strength. *Id.* at 4-5. She had positive results on the subscapularis lift off test on her left shoulder. *Id.* at 5. The therapist noted that her symptoms were consistent with a mild left rotator cuff strain. *Id.* She had painful active ROM at end-range and limited functional tolerances. *Id.*

Petitioner returned to orthopedic PA O'Neal on February 25, 2020, for a follow up on her left shoulder reporting "a little bit of improvement" with PT. Ex. 3 at 4. Her pain remained significant, seven out of ten, and she requested a cortisone injection. *Id.* Petitioner received a cortisone injection and was advised to continue PT. *Id.* at 6.

Petitioner continued PT, attending a total of five sessions between February 7 and March 18, 2020. Ex. 4 at 4-17. On March 10th, she told her therapist that she had received a cortisone injection on February 25th that helped alleviate her pain with sleeping. *Id.* at 12. However, raising her arm higher than shoulder level was worsening, and she was again having difficulty sleeping. *Id.* Her pain level was five out of ten, with a constant dull pain. *Id.* She had positive impingement signs on the Hawkins/Kennedy and Neer tests, and a positive subscapularis lift off test. *Id.* at 13-14. She was approved to continue physical therapy twice weekly until April 20, 2020. *Id.* at 14-15.

At her last PT session on March 18th, she said she had been "very sore" after her last session. Ex. 4 at 16. She felt relief two days later, and felt as though she was improving. *Id.* It was no longer painful to sleep on her left shoulder, but still hurt to reach overhead. *Id.* She tolerated treatment well with mild pain. *Id.* She continued to have decreased ROM and strength, pain with activities of daily living and decreased tolerance to sitting, standing, walking, and sleeping. *Id.* The therapist determined that she required continued skilled therapy to restore her prior level of function. *Id.* She had met two short term goals, but not met two others. *Id.*

Petitioner saw a gynecologist for a telemedicine visit on March 30, 2020, and an annual exam on August 18, 2020. Ex. 6 at 2, 13. At the August appointment three medications were prescribed. *Id.* at 2. She did not report any shoulder problems during these appointments, nor was a musculoskeletal examination done – nor would one be expected for this specialist. *Id.*

Petitioner returned to PT for left shoulder pain ten months after her last shoulder treatment, on January 19, 2021. Ex. 7 at 4. The record again noted an onset date of December 13, 2019 (the date of her flu vaccination). *Id.* Her left shoulder pain had improved overall. *Id.* She stated that she wanted to make sure her shoulder was okay, explaining that if she did too much or slept on her left shoulder her symptoms worsened, with her soreness increasing by the end of the day. *Id.* Her pain was one out of ten at best and three out of ten at worst. *Id.* By this time, her left shoulder active ROM was within

normal limits and impingement signs were negative, although she continued to have pain at end range in abduction and somewhat decreased strength. *Id.* at 4-5. She continued to have tenderness to palpation in her left rotator cuff biceps long head and the insertion at her greater tubercle and lesser tubercle. *Id.* She was assessed with mild left shoulder pain, limitations in left shoulder stabilization, and tenderness to palpation in her pectoralis major, subscapularis, and infraspinatus. *Id.* at 6. A treatment plan was established for her to undergo physical therapy once a week for four weeks. *Id.* Petitioner attended a total of five PT sessions between January 19 and March 17, 2021. Ex. 7 at 4-19; Ex. 8 at 4.

2. Petitioner's Statements

Petitioner filed two unsworn statements in support of her claim. Exs. 11, 12. Although both are titled as affidavits, neither is notarized or sworn under penalty of perjury pursuant to 28 U.S.C. § 1746.⁵ Instead, they acknowledge only that Petitioner understands they will be filed in this case. As such, they are treated as unsworn witness statements, and entitled to somewhat less weight.

Petitioner contends that she stopped formal physical therapy on March 18, 2020, due to the COVID-19 Pandemic. Ex. 12 at ¶ 4. Her pain had not really improved at that time, remaining at about seven or eight, and she still could not dress or undress by herself or work the same using her arm. *Id.* Throughout 2020, she continued to do stretches at home and use ice, heat, and ibuprofen for pain relief three to five times a week. *Id.* at ¶ 5. She returned to PT in January 2021 because the pain had not gone away. *Id.* at ¶ 6.

C. The Parties' Arguments

Petitioner argues that the medical records and statements demonstrate by preponderant evidence that she experienced residual effects and complications of her left shoulder injury for more than six months. Petitioner's Motion for a Ruling on the Record, filed July 31, 2023 (ECF No. 35) ("Mot."). Although Petitioner stopped treating after March 18, 2020, this was not voluntary, but was instead due to the COVID-19 Pandemic. Mot. at *7-8. Thereafter, she continued to follow her orthopedist's advice and continued with exercises at home three to five times a week. *Id.* at *8.

In January 2021, she returned to treatment because her pain had not yet abated. Mot. at *8. The PT record continued to note an onset date of December 13, 2019, further corroborating that this treatment was related to her SIRVA. *Id.* Although Petitioner saw her gynecologist twice in the interim, once virtually and once in person, she argues that it is "unreasonable" to assume that she would discuss her shoulder pain with her gynecologist, especially when she was already receiving treatment from an orthopedist and physical therapist. *Id.*

⁵ Counsel should ensure in the future to offer a either a proper affidavit or a declaration that complies with 28 U.S.C. §1746.

Respondent argues that Petitioner treated her left shoulder pain for only three months before stopping in March 2020. Respondent's Response, filed Sept. 29, 2023, at *5 (ECF No. 36) ("Resp."). In Respondent's view, the lack of objective evidence that Petitioner's pain persisted until June 13, 2020 (six months after vaccination) is fatal to Petitioner's claim. Resp. at *5.

Although Petitioner asserts that she discontinued care due to the Pandemic, the record reflects that she sought treatment from another provider – demonstrating her ability to obtain medical care, remotely or in person, during this time. Resp. at *5. Moreover, there is no corroboration of Petitioner's claim that she continued home exercises or otherwise treated during this time. *Id.* Instead, the record shows that Petitioner had substantially improved by March 18, 2020, making it more likely (in Respondent's view) that her pain abated on its own. *Id.* Respondent argues that the ten month treatment gap is too long to connect her January 2021 PT to her prior injury, especially given that she explained her visit then was to make sure her shoulder was okay. *Id.* Respondent further notes that this resumption of care occurred one week after this petition was filed. *Id.*

Respondent adds that Petitioner's statement is "particularly bare" in explaining the circumstances or deciding to terminate care and how she was impacted during this time. Resp. at *6. For instance, Petitioner asserts that she could not dress or undress by herself or work the same using her arm – but does not explain her work, the actual impact or impairment, or how she circumvented these deficits for ten months. *Id.* Under these circumstances, the medical records should not be evidentially outweighed by later testimony that is consistent, clear, cogent, and compelling. *Id.* (citing *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998)).

D. Factual Finding Regarding QAI Criteria for Table SIRVA

Respondent does not contest the four primary SIRVA QAI criteria, and I find that they are satisfied. There is no evidence that Petitioner had a pre-vaccination left shoulder condition, or another condition or abnormality, that would explain her symptoms after vaccination. Ex. 2. The onset of her shoulder pain most likely occurred within 48 hours of vaccination. Ex. 2 at 6; Ex. 3 at 9; Ex. 4 at 4. And her symptoms were limited to her left shoulder, where she received the flu vaccine. Exs. 2, 3, 4.

E. Statutory Severity Requirement

I find that preponderant evidence supports a finding that the statutory severity requirement is satisfied – although the temporal treatment gap and other evidence relating to the limited persistence of Petitioner's symptoms into 2021 all establishes a mild SIRVA, and therefore presents a case in which any pain and suffering award should be *minimal*.

Petitioner sought care two weeks after vaccination, complaining of shoulder pain since her flu vaccination. Ex. 2 at 6. Thereafter, she persistently sought care for her pain until March 18, 2020, just over three months after vaccination. At that point, she abruptly stopped seeking treatment – not because her shoulder pain resolved, but due to the COVID-19 Pandemic.⁶ Ex. 12 at ¶ 4. When she stopped PT due to the Pandemic on March 18th, her pain was still at a level of five out of ten, with a constant dull ache, positive impingement signs, and limited ROM. Ex. 4 at 12-16. Significantly, at the prior session, she had just been approved for another six weeks of PT. *Id.*

Petitioner did not again seek care for her shoulder pain until ten months later (January 19, 2021). Ex. 7 at 4. Importantly, however, at that time she continued to relate her pain to her December 2019 vaccination. *Id.* Although her ROM was now normal, she continued to have pain ranging between one and three out of ten. *Id.* at 4-5. Taken together, the March 2020 and January 2021 PT records support a finding that Petitioner's shoulder pain had *not* resolved in March 2020, then started anew sometime between that date and January 2021. Instead, the record suggests that her injury continued, albeit with demonstrated improvement, during the ten-month treatment gap.

This case has many similarities to *Black v. Sec'y of Health & Human Servs.*, No. 21-09V, 2023 WL 4446500 (Fed. Cl. Spec. Mstr. May 22, 2023). That petitioner also sought care for three months, until January 2020, followed by an 18 month gap in treatment for his shoulder pain. Additionally, the petitioner's return to care occurred after he filed his petition – as in this case. The petitioner in *Black* argued that he did not follow up after January 2020 due to the COVID-19 Pandemic. *Id.* at *4. I acknowledged that in many cases I had allowed that the Pandemic reasonably caused people to defer treatment, but found that an 18 month gap starting in January 2020 – somewhat before the more severe impacts of the Pandemic had begun – was simply too attenuated. *Id.* Here, the treatment gap was shorter, less than a year. And importantly, Ms. Nielsen abruptly stopped care in mid-March 2020 – shortly after COVID-19 was declared a pandemic.

I base my ruling primarily on the medical records, and place little weight on Petitioner's unsworn witness statements. That the statements were not made under penalty of perjury reduces their evidentiary value. And Respondent correctly notes that Petitioner's statements are not detailed. However, the statements are consistent with, and corroborate the medical records, and thus provide some weak support for Petitioner's severity contentions. Petitioner states that throughout 2020 she did her home exercises,

⁶ The World Health Organization declared COVID-19 a pandemic on March 11, 2020. Centers for Disease Control Museum COVID-19 Timeline, <https://www.cdc.gov/museum/timeline/covid19.html> (last visited Aug. 23, 2024).

ice/heat, and ibuprofen at home three to five times a week – which credibly explains the improvement in her shoulder condition during this time period.

Although Petitioner sought care during the ten-month treatment gap from a single other provider, her gynecologist, this does not negate a finding that her shoulder injury persisted for more than six months. That she sought other care does establish that she was able to obtain medical care during this time, as Respondent asserts. But it does not presumptively establish that her *failure* to do so means that her shoulder pain no longer existed. Instead, I interpret her seeking gynecological care – but not shoulder treatment – to mean that her shoulder condition was less pressing at the time.

F. Other Requirements for Entitlement

The record contains preponderant evidence that other requirements for entitlement are satisfied as well. Petitioner received a covered vaccine in the United States. Ex. 1 at 2. Petitioner states that she has never received an award or settlement, or filed a civil action, for her vaccine-related injuries. Ex. 11 at ¶ 7.

Conclusion

Based on my review of the record as a whole, I find that it is more likely than not that all SIRVA Table requirements are met. I find that the statutory severity requirement is satisfied by preponderant evidence, as are other requirements for entitlement. Therefore, Petitioner's motion for a ruling on the record that she is entitled to compensation is **GRANTED**.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Chief Special Master