In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 18-1572V
Filed: February 23, 2023
PUBLISHED

LEE MEAGHER, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Special Master Horner Shoulder Injury Related to Vaccine Administration ("SIRVA"); Influenza ("flu") vaccine; Ruling on the Record

Ronald Craig Homer, Conway, Homer, P.C., Boston, MA, for petitioner.
Kyle Edward Pozza, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT[1]

On October 10, 2018, petitioner, Lee Meagher, filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012)[2], alleging she suffered a shoulder injury related to vaccine administration ("SIRVA") following receipt of her October 15, 2015, influenza ("flu") vaccination. (ECF No. 1.) For the reasons discussed below, I find that petitioner is entitled to compensation for a Table Injury of SIRVA.

I. Applicable Statutory Scheme

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute;

[1] Because this document contains a reasoned explanation for the special master's action in this case, it will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. *See* 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the document 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 the special master, upon review, agrees that the identified material fits within this definition, it will be redacted from public access.

[2] Within this decision, all citations to § 300aa will be the relevant sections of the Vaccine Act at 42 U.S.C. § 300aa-10-34.

received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a causal link between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300 aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

As relevant here, the Vaccine Injury Table lists a Shoulder Injury Related to Vaccine Administration or "SIRVA" as a compensable injury if it occurs within 48 hours of administration of a vaccination. § 300aa-14(a) as amended by 42 CFR § 100.3. Table Injury cases are guided by "Qualifications and aids in interpretation" ("QAIs"), which provide more detailed explanation of what should be considered when determining whether a petitioner has actually suffered an injury listed on the Vaccine Injury Table. 42 CFR § 100.3(c). To be considered a "Table SIRVA," petitioner must show that her injury fits within the following definition:

> 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 . . . . 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 CFR §100.3(c)(10).

Vaccine Program petitioners must establish their claim by a "preponderance of the evidence". § 300aa-13(a). That is, a petitioner must present evidence sufficient to show "that the existence of a fact is more probable than its nonexistence . . . ." *Moberly v. Sec'y of Health & Human Servs.,* 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). A petitioner may not receive a Vaccine Program award based solely on her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1).

II. Procedural History

Based on the allegations in the petition, this case was initially assigned to the Special Processing Unit or "SPU" for potential informal resolution. (ECF No. 9.) Over several months, petitioner filed medical records and affidavits marked as Exhibits 1-16. (ECF Nos. 5-7, 10, 15.) She filed a Statement of Completion on January 22, 2019. (ECF No. 17.)

Thereafter, respondent took many months to review this case. Initially, respondent confirmed as of August 5, 2019, that he was willing to engage in settlement discussions. (ECF No. 27.) Petitioner provided a demand for damages to respondent on November 19, 2019. (ECF No. 36.) At that time, petitioner also filed updated medical records and workers' compensation records marked as Exhibits 17-19. (ECF Nos. 33-34.) The parties engaged in settlement discussions until July of 2020, at which point petitioner advised that the parties had reached an impasse. (ECF No. 44.)

Respondent then filed his Rule 4(c) Report on September 14, 2020. (ECF No. 45.) Respondent recommended against compensation. With regard to petitioner's Table SIRVA claim, he argued that she had not demonstrated her shoulder pain began within 48 hours of vaccination and that her injury did not appear to be limited to her affected shoulder (*i.e.*, issues relating to SIRVA QAI prongs one and three). With regard to any cause-in-fact claim, respondent noted that no expert report had been filed to provide a medical theory and he further suggested, consistent with his assessment of the Table injury claim, that a temporal relationship was not established. (*Id*. at 6-10.)

A follow up status conference was held within the SPU on November 23, 2020. (ECF No. 46.) The Chief Special Master advised that he felt that the petitioner could likely overcome the issues raised in respondent's report and instructed the parties to resume settlement discussions. (*Id.*) Petitioner subsequently filed additional updated medical records marked as Exhibits 20-21. (ECF No. 47.) However, as of January 29, 2021, the parties again advised that they had reached an impasse. (ECF No. 50.)

On February 9, 2021, the Chief Special Master issued a Finding of Fact holding that petitioner had established by preponderant evidence that she experienced onset of shoulder pain within 48 hours of the vaccination at issue, thereby resolving a significant point of litigation. (ECF No. 51.) However, he also determined that he would transfer

the case out of the SPU due to its age and other contested issues. (*Id*. at 2.) The case was reassigned to Special Master Roth on March 3, 2021. (ECF No. 53.)

On April 5, 2021, Special Master Roth held a status conference. She advised that:

> At today's conference, respondent's Rule 4(c) Report was discussed, including his concern about petitioner's report of pain radiating down her arm. I noted that petitioner's medical records do not contain any reference to cervical complaints, nor did she report tingling or numbness radiating down her arm indicative of a radiculopathy. Petitioner's complaints of arm pain appear, from the record, to stem from her shoulder injury and are consistent with complaints by many petitioners suffering from SIRVA injuries. Overall, the medical records, which are consistent with petitioner's petition and affidavit, are likely supportive of entitlement.

(ECF No. 54, p. 1.) Special Master Roth recommended mediation and expressed concern that litigation would not overcome the parties' fundamental difference on valuing the case and therefore ultimately waste judicial resources. (*Id*. at 2.)

After the parties remained unable to informally resolve the case, Special Master Roth held a further status conference on September 3, 2021. (ECF No. 59.) During that conference, the merits were further discussed and the parties agreed that expert reports would not be necessary to resolve entitlement. (*Id*. at 2.) Special Master Roth ordered the parties to file briefing on entitlement. (*Id*.)

The parties filed simultaneous briefs regarding entitlement on December 22, 2021. (ECF No. 63-64.) Thereafter, no action was taken in the case until it was reassigned to the undersigned on February 1, 2023. (ECF No. 65.) On February 2, 2023, I issued a Scheduling Order advising as follows:

> The parties filed simultaneous briefs regarding entitlement on December 22, 2021. (ECF Nos. 62-63.) The case was subsequently reassigned to the undersigned. The parties are hereby advised that after review of the procedural history, I have concluded that this case is ripe for resolution of entitlement and that the parties have had a full and fair opportunity to develop the record. Thus, I intend to resolve the question of entitlement pursuant to Vaccine Rule 8(d). If either party has any objection, they shall file a status report so advising by no later than Friday, February 17, 2023. If no objection is raised, I intend to resolve entitlement as soon as practicable based on the existing record and the parties' December 22, 2021 briefs.

(Scheduling Order (NON-PDF), 2/2/2023.)

In response to my order, petitioner filed an amended petition more explicitly delineating that she alleges both on- and off-Table claims for her shoulder injury. (ECF

No. 66.) However, she also filed a status report confirming the case is ripe for resolution. (ECF No. 67.) Respondent filed no objection. Accordingly, this case is now ripe for resolution.

III. Factual History and Respondent's Defense

Given the procedural posture of this case and the narrow basis for respondent's defense following the Chief Special Master's finding of fact, an exhaustive description of petitioner's medical records is not necessary. Instead, this summary will focus on the most pertinent points raised in respondent's December 22, 2021 brief on entitlement and his explanation of his defense based on those facts. I do note, however, that I have completed a review of the entire record of the case, including those medical records that are not explicitly discussed.

Petitioner received a flu vaccine in her right arm on October 15, 2015. (Ex. 1.) For the reasons discussed in the Chief Special Master's prior Finding of Fact, petitioner subsequently experienced onset of right shoulder pain within 48 hours of that vaccination. (ECF No. 51.) Although this fact finding is not binding on me, I agree with the Chief Special Master's conclusion based on my own review of the complete record and incorporate the Chief Special Master's recitation of the facts and analysis into this ruling on entitlement.

According to respondent's recitation of the facts, petitioner experienced reduced range of motion in her right shoulder that was confirmed as of a physical examination conducted January 5, 2016. (ECF No. 62, pp. 2-3 (discussing Ex. 12, pp. 3-4).) At that time, petitioner was diagnosed with a rotator cuff injury and physical therapy was recommended. (*Id.* at 3 (discussing Ex. 12, pp. 4-5).) When petitioner reported to physical therapy on January 28, 2016, she reported that over time her pain had begun to radiate into her arm and hand. (*Id.* (discussing Ex. 6, pp. 2-4).) Petitioner ultimately did not complete her recommended course of physical therapy. (*Id.* (discussing Ex. 19, p. 4; Ex. 12, p. 6).)

Petitioner returned to her primary care provider on March 31, 2016. (ECF No. 62, p. 4 (discussing Ex. 3, pp. 13-14).) At that time she had full range of motion, but reported pain with external rotation. She reported constant, dull, aching pain in her shoulder. She denied weakness, numbness, or tingling. (*Id.*) She was again referred to physical therapy. On July 25, 2016, she presented for a physical therapy assessment. (*Id.* (discussing Ex. 8, pp. 1-2).) This assessment demonstrated decreased strength and range of motion deficits. (*Id.*) Petitioner attended 36 physical therapy sessions, but still had pain and limited range of motion at discharge. (*Id.* (discussing Ex. 8, p. 53).)

On January 24, 2017, petitioner's right shoulder was again evaluated. (ECF No. 62, p. 5 (discussing Ex. 9, pp. 8-12).) Petitioner reported pain with internal rotation and mildly positive Hawkins impingement signs. She had near normal range of motion, except for mildly decreased abduction. She had no weakness. An MRI showed a high-

grade tear of the right supraspinatus tendon. (*Id.*) When petitioner returned for a follow up on February 1, 2017, she had trace weakness and mild right shoulder impingement. She was administered a subacromial cortisone injection. (*Id.* (discussing Ex. 9, p. 6).)

Petitioner returned for care on February 14, 2017, now reporting bilateral shoulder pain. (ECF No. 62, p. 5 (discussing Ex. 9, pp. 4-5).) The cortisone injection had not helped and petitioner felt her left shoulder pain was due to overuse from compensating for her right shoulder pain. She received a cortisone injection in her left shoulder. (*Id.*) Petitioner had fluoroscopic guided injections in the right shoulder on March 22, 2017, and November 30, 2017. (*Id.* at 5-6 (discussing Ex. 10, pp. 21-22; Ex. 3, p. 38).) Petitioner had an MRI of her left shoulder on December 18, 2017. (*Id.* at 6 (discussing Ex. 13, p. 3).) It showed "a moderate grade partial thickness tear at the posterior interval of the distal supraspinatus, . . . mild acromioclavicular join osteoarthritis, . . . [and] trace fluid within the subacromial bursa, compatible with early, resolving bursitis[.]" (*Id.*)

Petitioner had a further follow up on December 14, 2017, which showed that her condition had not resolved. (ECF No. 62, p. 6 (discussing Ex. 13, p. 1).) According to respondent, no further relevant medical records have been filed. (*Id.*)

Based on the above, respondent contends that petitioner "has not provided preponderant evidence demonstrating the requisite facts to establish compensation for petitioner's alleged SIRVA. Specifically, petitioner's pain does not appear to be limited to her right shoulder, as required by the QAI." (ECF No. 62, p. 8.) In support of this contention, respondent indicates that "[t]he first time she presented for PT, she reported that her right shoulder pain radiated down her right arm into her hand." (*Id.* at 8-9 (citing Ex. 6, pp. 2-4).) This is the sole argument respondent advances against petitioner's Table injury claim and the full extent of respondent's argument on that question. (*Id.*)

IV. Discussion

With regard to the third SIRVA criterion, which requires that the petitioner's pain and reduced range of motion be limited to the shoulder at issue, the government addressed this QAI criterion in response to public comment. 82 Fed. Reg. 6294 (Jan. 19, 2017). For clarity and context, the comment summary and response are worth quoting in full:

> Comment: A commenter suggested that shoulder injury related to vaccine administration (SIRVA) as defined in the QAI is too restrictive because the recipient's pain and reduced range of motion must be limited to the shoulder in which the intramuscular vaccine was administered. The commenter stated that such language was an artificial and unnecessary qualification, and expressed concern that recipients who have other symptoms, such as shoulder pain radiating to the neck or upper back, will not have the benefits

> of a Table injury. The commenter suggested that the QAI be expanded to include the shoulder and parts of the body attributed to that injury.
>
> Response: SIRVA is a musculoskeletal condition caused by injection of a vaccine intended for intramuscular administration into the shoulder, and, as its name suggests, the condition is localized to the shoulder in which the vaccine was administered. In other words, pain in the neck or back without an injury to the shoulder in which an individual received a vaccine would not be considered SIRVA. Shoulder injuries that are not caused by injection occur frequently in the population. Thus, it is important to have a definition of SIRVA that is clearly associated with vaccine injection. The portion of the QAI limiting the pain and reduced range of motion to the shoulder in which the vaccine was administered is necessary to accurately reflect the vaccine-associated condition.

82 Fed. Reg. 6294, 6296.

As I have indicated in prior cases, the government's comment response reveals that the third SIRVA criterion is intended to ensure that SIRVA claims are limited to instances in which "*the condition* is localized to the shoulder in which the vaccine was administered" (emphasis added). Thus, it is clear that the gravamen of this requirement is to guard against compensating claims involving patterns of pain or reduced range of motion indicative of a contributing etiology beyond the confines of a musculoskeletal injury to the affected shoulder. *Grossman v. Sec'y of Health & Human Servs*., No. 18-13V, 2022 WL 779666, at *15 (Fed. Cl. Spec. Mstr. Feb. 15, 2022). The Chief Special Master has reached the same conclusion on multiple occasions. *E.g., Cross v. Sec'y of Health & Human Servs*., No. 19-1958V, 2023 WL 120783, at *7 (Fed. Cl. Spec. Mstr. Jan. 6, 2023) (finding that "despite the notations of pain extending beyond the shoulder, Petitioner's injury is consistent with the definition of SIRVA and there is not preponderant evidence of another etiology."); *K.P. v. Sec'y of Health & Human Servs*., No. 19-65V, 2022 WL 3226776, at *8 (Fed. Cl. Spec. Mstr. May 25, 2022) (holding that "claims involving musculoskeletal pain primarily occurring in the shoulder are valid under the Table even if there are additional allegations of pain extending to adjacent parts of the body."); *Werning v. Sec'y of Health & Human Servs.,* No. 18-0267V, 2020 WL 5051154, at *10 (Fed. Cl. Spec. Mstr. July 27, 2020) (finding that a petitioner satisfied the third SIRVA QIA criterion where there was a complaint of radiating pain, but the petitioner was "diagnosed and treated solely for pain and limited range of motion to her right shoulder.")

Even by respondent's own recitation of the facts, post-vaccination petitioner had a multi-year course of treatment that focused exclusively on her condition as relating to her shoulder, inclusive of a diagnosis of a rotator cuff injury later confirmed by MRI. In the face of this history, respondent relies on a single notation by a physical therapist, not a physician, documenting an isolated subjective report by petitioner that "sometimes pain radiates all the way to R hand" and that "over time pain has radiated into arm → hand." (Ex. 6, pp. 2, 4.) Petitioner had been referred to this physical therapist with a

diagnosis of "right rotator cuff tendonitis" (Ex. 6, p. 7), and nothing in the physical therapist's records indicate that the physical therapist questioned that diagnosis based on petitioner's description of her symptoms or otherwise concluded the report had any specific diagnostic implications (Ex. 6, *passim*). Nor has respondent highlighted any instance where petitioner ever subsequently raised this concern with any of her treating physicians. And, as Special Master Roth previously observed, there is no other record that evidences any other condition that would explain this reported symptom. Respondent has provided no explanation to support his implicit contention that this isolated report is illuminating as to the nature of petitioner's injury given her overall treatment history.

V. Conclusion

In light of all of the above, respondent's argument against petitioner's Table claim of SIRVA is unpersuasive. Moreover, upon consideration of the record as a whole, I conclude that petitioner has preponderantly established that her injury meets all of the QAI requirements for a Table SIRVA and that the onset of her injury occurred within the requisite period required by the Vaccine Injury Table. Respondent has not demonstrated that her condition is due to any factor unrelated to vaccination. Accordingly, petitioner is entitled to compensation for a Table SIRVA.

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master