

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 20-0959V

UNPUBLISHED

MARLA MILLER,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: April 29, 2022

Special Processing Unit (SPU);
Findings of Fact; Onset; Influenza
(Flu) Vaccine; Ruling on Entitlement;
Table Injury; Shoulder Injury Related
to Vaccine Administration (SIRVA)

Anne Carrion Toale, Maglio Christopher & Toale, PA, Sarasota, FL, for Petitioner.

Mark Kim Hellie, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT AND RULING ON ENTITLEMENT¹

On August 3, 2020, Marla Miller 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”) caused by the influenza (“flu”) vaccine she received on November 14, 2017. Petition at ¶¶2, 15. The case was assigned to the Special Processing Unit of the Office of Special Masters (the “SPU”).

¹ Because this unpublished Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in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

For the reasons discussed below, I find that Petitioner has satisfied the requirements of a Table SIRVA, and is therefore entitled to compensation under the Vaccine Act.

I. Relevant Procedural History

Soon after filing her petition on August 3, 2020, Ms. Miller filed seven medical record exhibits and a Statement of Completion. ECF No. 6-7. Petitioner continued to supplement the record with additional medical records. See ECF No. 13, 17.

On October 4, 2021, Respondent filed a status report indicating that he was willing to engage in settlement discussions. ECF No. 21. After a short period of negotiation, however, the parties reached an impasse. ECF No. 26. Accordingly, on February 14, 2022, Petitioner filed a motion for a fact ruling on the issue of onset. ECF No. 30.

In his Rule 4(c) Report (filed on March 16, 2022, in response to Petitioner's motion), Respondent argued that Petitioner has failed to provide preponderant evidence that the onset of her pain occurred within 48 hours of her vaccination. Rule 4(c) Report at 5. Specifically, Respondent maintained that "although Petitioner claims that the onset of her symptoms was immediate, these claims were not corroborated by the contemporaneous medical records." *Id.* at 6.

Petitioner filed a reply on April 22, 2022 ("Rep."). ECF 34. Petitioner's Motion is now ripe for ruling.

II. Relevant Factual History

a. Pre-Vaccination Medical History

Petitioner's medical records from prior to her vaccination show no significant medical conditions, and specifically no injuries to or medical issues with her left shoulder, neck or arm. See Ex. 6.

b. Post-Vaccination Medical History

Petitioner received the flu vaccine in her left arm at Walgreens Pharmacy in Palm Springs, Florida on November 14, 2017. Ex. 4 at 5. She first sought medical treatment for her left shoulder pain from her primary care physician, Dr. Milena Jguenti, at Flagler Family Medicine, on November 30, 2017 - 16 days after her vaccination. Ex. 2 at 76. Dr. Jguenti reported that Petitioner complained of "pain in the L arm after flu vaccine 2 weeks

ago” and noted restricted range of motion. *Id.* (emphasis added). Dr. Jguenti diagnosed Petitioner with myositis, “most likely related to reaction to vaccine injection,” and recommended topical heat application and Voltaren gel. *Id.*

Ms. Miller returned to her primary care physician on December 19, 2017 for follow-up treatment for her left arm pain. Ex. 2 at 71. Nurse Practitioner Joann Fritsch, noted that Petitioner had previously been seen for “L arm pain that started *following* a flu injection.” *Id.* at 74 (emphasis added). She prescribed a Medrol Dosepak and ordered an MRI to further evaluate. *Id.* at 71. On December 27, 2017, Petitioner alerted NP Fritsch that her insurance had denied coverage for the MRI and that xrays needed to be ordered first. *Id.* at 70. Petitioner had xrays of her left upper arm on December 29, 2017 and an MRI on January 8, 2018, both of which were normal. *Id.* at 85-86, 88. Following her MRI, Petitioner requested a referral to an orthopedist. *Id.* at 68.

The next year, Ms. Miller presented to orthopedist, Dr. David Gay, on March 23, 2018, for an evaluation of her left shoulder. Ex. 5 at 54. Dr. Gay recorded that Petitioner now reported the date of onset as November 14, 2017, and the context of her injury as “received a flu shot.” *Id.* Dr. Gay found reduced range of motion and positive impingement signs and diagnosed impingement syndrome of the left shoulder. *Id.* at 56. Dr. Gay gave Petitioner a cortisone injection and noted “significant improvement with post-injection exam.” *Id.* Petitioner returned to Dr. Gay on May 7, 2018. *Id.* at 52. He noted improvement from the initial injection, performed a second cortisone injection, and referred Petitioner to physical therapy for six weeks. *Id.* at 53-54.

Petitioner began physical therapy on May 14, 2018. Ex. 1 at 78. On her intake form, Ms. Miller responded to the question “how and when the injury/disorder occurred” with “Nov. 14, 2017 from a flu shot.” *Id.* at 23. At her initial evaluation, she reported “left upper arm pain since a flu shot last November that became excruciating.” *Id.* at 78. She described pain with reaching and tightness at rest. *Id.* Upon examination, Petitioner exhibited “limited shoulder mobility and lateral shoulder pain with all active motions of the shoulder, limited strength and motor control.” *Id.* at 79.

Petitioner attended a total of 24 PT sessions and then returned to Dr. Gay for a follow up appointment on September 26, 2018. Ex. 1; Ex. 5 at 50. Dr. Gay noted that she had completed “12 weeks of PT with significant improvement.” *Id.* at 51. Petitioner still had pain with range of motion. *Id.* He explained that “there may be an additional 4-6 months of improvement” but recommended no additional treatment. *Id.* at 52.

There is nothing in the record as it currently stands to show Petitioner has since obtained further treatment of her left shoulder pain.

c. *Relevant Affidavit Testimony*

Ms. Miller's Declaration, filed at Exhibit 12, describes the onset of her left shoulder pain in detail. Specifically, she stated that she "told the pharmacist at the time of the vaccine that it hurt when he gave it to" her. Ex. 12 at ¶2. She remembered waking up "in the middle of the night in excruciating pain (10/10)" and being unable to "put any weight on [her] arm." *Id.* She explained that she saw her doctor "after 2 weeks had passed because the pain wouldn't let up." *Id.*

Ms. Miller described her pain as "severe" for the first six months after her vaccination, until she began physical therapy. *Id.* at ¶5. She described her limitations in "performing many activities for around 9-10 months." *Id.* at ¶4.

III. Findings of Fact

A. 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). The Federal Circuit has said that

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).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, 2005 WL 6117475, at *19.

The United States Court of Federal Claims has recognized, however, that “medical records may be incomplete or inaccurate.” *Camery v. Sec’y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later 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 & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff’d*, 746 F.3d 1335 (Fed. Cir. 2014).

Thus, medical records may be outweighed by testimony that is given later in time that is “consistent, clear, cogent, and compelling.” *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec’y of Health & Human 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 & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec’y of Health & Human 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 not only the medical records, testimony, but also 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 & Human 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). Indeed, as the Federal Circuit recently stated, although later oral testimony that conflicts with medical records is less reliable, it is appropriate for a special master to credit a petitioner’s lay testimony where it does not conflict with contemporaneous records. *Kirby v. Sec’y of Health & Human Servs.*, 997 F.3d 1378, 1382-84 (Fed. Cir. 2021).

B. Analysis

At issue is whether Petitioner's first symptom or manifestation of onset after vaccine administration occurred within 48 hours as set forth in the Vaccine Injury Table and the second QAI for a Table SIRVA. 42 C.F.R. § 100.3(a) XIV.B.; 42 C.F.R. § 100.3(c)(10)(ii) (required onset for pain listed in the QAI).

Respondent argues that Petitioner has failed to provide preponderant evidence that the onset of her pain occurred within 48 hours of her vaccination. Rule 4(c) Report at 5. Specifically, Respondent maintains that "although Petitioner claims that the onset of her symptoms was immediate, these claims were not corroborated by the contemporaneous medical records." *Id.* at 5, 6 (general references to pain "after" vaccination are insufficiently precise).

In so arguing, Respondent seems to embrace the view that the only way Petitioner can show she experienced symptoms within 48 hours of vaccination is with contemporaneous records that state the date of onset with specificity. However, the very terms of Vaccine Act allow that a "special master ... may find the first symptom ... of an injury ... occurred within the time period described in the Vaccine Injury Table even though the occurrence of such symptom ... *was not recorded*" in contemporaneous medical records. 42 U.S.C. § 300aa-13(b)(2) (emphasis added). Ultimately, resolving how to weigh the evidence on such matters falls within the purview of the special masters. 42 U.S.C. § 300aa-13.

In addition, the Program's standard of preponderance means that this kind of fact issue can be (and often is) resolved in a petitioner's favor *despite* a lack of specificity. Special masters weigh all items of evidence collectively – and although they may give some items more weight than others, it is the evidence in its totality that "moves the scale," as it were. Thus, several reasonable and reliable pieces of evidence supporting a temporal onset claim may satisfy preponderance even if no *single* item specifically records onset being reported *literally* within the timeframe specified by the Table. Also relevant is the fact that (in SPU's experience adjudicating SIRVA claims) injured petitioners often employ vague temporal language, based on their lack of awareness of the importance for Program purposes of specificity. This cannot reasonably be held against petitioners, any more than a delay in seeking treatment (based on the supposition that the shoulder pain will be transient) should be interpreted as weighing against a favorable finding.

Taking all of the above into account, there is more than sufficient evidence in this case to support a finding of 48-hour post-vaccination onset as "more likely than not." In multiple post-vaccination medical records, Petitioner consistently reported left shoulder pain in connection with her vaccination. See Ex. 1, 2, 5. Without fail, Petitioner attributed

her injury to the flu vaccine she received on November 14, 2017. And Petitioner's orthopedist and physical therapist noted the specific date in records on March 23, 2018, and May 14, 2018, respectively. Ex. 5 at 54; Ex. 1 at 78. Admittedly, the records from Petitioner's first two visits for her left shoulder pain (which occurred closest in time to vaccination) are more vague, using language like "L arm pain *after* flu vaccine 2 weeks ago" (Ex. 2 at 76), or "L arm pain that started *following* a flu injection" (*Id.* at 71). But this language does not, when considered against other records, undermine the determination that Table onset was met. No record has been offered in which an onset clearly *outside* the relevant timeframe was indicated.

In addition to the medical records, Petitioner provided affidavit testimony setting forth the immediate onset of pain at the time of vaccination, stating that she "told the pharmacist at the time of the vaccine that it hurt when he gave it to" her. Ex. 12 at ¶2. Petitioner went on to describe being awoken that same night in "excruciating pain (10/10)." *Id.* These witness statements provide enhancing, corroborative detail for the general notes recorded in the medical records. The Federal Circuit has held that it is appropriate to credit the lay testimony of a petitioner when said testimony does not *conflict* with the medical records. See *Kirby v. Sec'y of Health & Human Servs.*, 997 F.3d 1378, 1384 (Fed. Cir. 2021) (affirming special master's finding of severity based on petitioner's testimony in the absence of contemporaneous medical records).

Accordingly, I find there is preponderant evidence to establish the onset of Petitioner's pain occurred within 48 hours of vaccination.³

IV. Requirements for Table SIRVA

Because I have determined the onset of her left shoulder pain occurred within 48 hours of vaccination, Petitioner has fulfilled the second of the four QAI Table criteria. See 42 C.F.R. § 100.3(a)(XIV) (Table entry for SIRVA following influenza vaccine); 42 C.F.R. § 100.3(c)(10)(ii) (second QAI requirement). To establish that she suffered a Table SIRVA, Petitioner must satisfy the additional three QAI requirements. 42 C.F.R. § 100.3(c)(10)(i), (iii), (iv).

Respondent has not contested Petitioner's proof on the other QAI Table criteria. See Rule 4(c) Report. Further, the record in this case contains no indication that Petitioner suffered prior left shoulder issues or pain and reduced range of motion outside the left shoulder. See 42 C.F.R. § 100.3(c)(10)(i), (iii). Nor is there evidence of any other condition

³ I am aware of Petitioner's frustration that these kinds of objections have held up resolution of the claim. While I deem Respondent's position to be in good faith, and arising from facially-imprecise language from close-in-time records, Respondent should in future cases not permit this kind of objection to obstruct resolution of a claim that facially is otherwise likely to succeed as a Table claim.

or abnormality that would explain the left shoulder pain she experienced. See 42 C.F.R. § 100.3(c)(10)(iv).

Thus, Petitioner has satisfied all QAI criteria for a Table SIRVA.

V. Additional Requirements for Entitlement

Because Petitioner has satisfied the requirements of a Table SIRVA, she need not prove causation. Section 11(c)(1)(C). However, she must satisfy the other requirements of Section 11(c) regarding the vaccination received, the duration and severity of her injury, and the lack of other award or settlement. Section 11(c)(A), (B), and (D).

The vaccine record shows Petitioner received the flu vaccine in her left arm at a Walgreens Pharmacy in Florida. Ex. 4 at 5; see Section 11(c)(1)(A) (requiring receipt of a covered vaccine); Section 11(c)(1)(B)(i) (requiring administration within the United States or its territories). Additionally, Petitioner has stated that she has not filed any civil action or received any compensation for her vaccine-related injury, and there is no evidence to the contrary. Ex. 3 at ¶4; See Section 11(c)(1)(E) (lack of prior civil award).

Finally, the medical records show that more than six months after vaccination, Petitioner continued to suffer the residual effects of her SIRVA. See Section 11(c)(1)(D)(i) (statutory six-month requirement). Petitioner received her vaccination on November 14, 2017. Ex. 4 at 5. Thereafter, she received continuing treatment, with no significant gaps, through at least September 26, 2018, a period of just over ten months. Ex. 1, 2, 5. Thus, Petitioner has satisfied all requirements for entitlement under the Vaccine Act.

VI. Conclusion

Based on the entire record in this case, I find that Petitioner has provided preponderant evidence satisfying all requirements for a Table SIRVA. Petitioner is entitled to compensation in this case. A separate damages order will be issued.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Chief Special Master