

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 21-0376V

BONNIE GRACZYK,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: June 16, 2023

Jessica Olins, Maglio Christopher & Toale, PA, Washington, DC, for Petitioner.

Benjamin Patrick Warder, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT¹

On January 9, 2021, Bonnie Graczyk 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”) resulting from an influenza (“flu”) vaccine received in her left arm on November 19, 2019. Petition at 1, 3. Petitioner further alleges that the vaccine was administered in the United States, her vaccine related injuries have lasted more than six months, and neither Petitioner, nor any other party, has ever brought an action or received

¹ Because this Fact 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 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 (2018).

compensation in the form of an award or settlement for Petitioner's vaccine-related injuries. Petition at ¶¶ 6, 17, 20-21. The case was assigned to the Special Processing Unit of the Office of Special Masters (the "SPU").

For the reasons discussed below, I find that a preponderance of the evidence supports a finding that the onset of Petitioner's shoulder pain occurred within 48 hours, and that Petitioner has met the additional requirements to be entitled to compensation.

I. Relevant Procedural History

The case was activated and assigned to the SPU on April 23, 2021 (ECF No. 8). On September 15, 2021, Respondent filed a status report stating that he was amenable to a litigative risk settlement, and requested that Petitioner provide a demand (ECF No. 15). Petitioner served a demand on November 9, 2021 (ECF No. 19), and the parties commenced negotiations. However, on February 9, 2022, Petitioner reported that the parties had reached an impasse relating to the onset of Petitioner's symptoms, and Petitioner intended to file a motion for a fact finding on that issue (ECF No. 22).

On March 9, 2022, Petitioner filed a motion for a ruling on the record, requesting that I find that Petitioner experienced the onset of SIRVA symptoms within 48 hours of vaccination (ECF No. 24). Respondent filed a response in opposition on March 22, 2022 (ECF No. 26), and Petitioner replied on March 29, 2022 (ECF No. 27). In the reply, Petitioner noted that the only Table SIRVA requirement that Respondent had challenged was onset. Thus, Petitioner requested that I find not only that the onset requirement is satisfied, but also rule that Petitioner is entitled to compensation for a Table SIRVA. Respondent has not sought leave to file a sur-reply. The issues of the onset of Petitioner's shoulder pain and entitlement to compensation are 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 the 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. 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, the duration and severity of petitioner’s injury, and the lack of other award or settlement,³ 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 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 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:

³ In summary, a petitioner must establish receipt of 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; that residual effects of the injury continued for more than six months (or meet the severity requirement in other ways not applicable in this case); and no civil suit has been filed and no award or settlement has been collected for the injury. See Section 11(c)(1)(A)(B)(D)(E).

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) (2017).

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 relating to the onset of Petitioner's symptoms and entitlement to compensation.

1. Medical Records

On November 19, 2019, Petitioner received a flu vaccine in her left shoulder at a Publix Pharmacy in Hendersonville, North Carolina. Ex. 1 at 4. Two months later, on January 16, 2020, Petitioner was seen by her primary care physician ("PCP"), Dr. George Murphy, to follow up on unrelated health conditions. Ex. 2 at 15. The record noted that Petitioner reported that "at the site of her flu vaccine there is still a little tenderness after several months." *Id.* The examination section of the record states that her extremities were "normal, atraumatic, no cyanosis or edema." *Id.* at 18. The record is otherwise silent as to her shoulder.

Petitioner returned to her PCP a month later, on February 20, 2020. Ex. 2 at 7. She complained of pain in her left deltoid area, explaining that "the pain started when she got a flu shot back in November at Publix supermarket. It has continued on and off to this date." *Id.* Dr. Murphy suspected muscular damage or an inflammatory response from the vaccine, and gave Petitioner Mobic. *Id.* However, he warned her that "this may be a permanent thing." *Id.* On examination, he noted tenderness to palpation in the left deltoid area. *Id.* at 10.

On April 8, 2020, Petitioner was seen by orthopedist Dr. Edward Lilly for her left shoulder. Ex. 3 at 80. She reported having pain and stiffness in her left shoulder since her November 2019 flu shot. *Id.* at 82. She was having difficulty using her arm, and it had not improved. *Id.* On examination, her left shoulder active range of motion ("ROM") was 170 degrees in forward elevation and 75 degrees in external rotation. *Id.* Impingement signs were negative, and she had marked limitation of abduction, internal rotation, and external rotation. *Id.* She was assessed with adhesive capsulitis of the left shoulder, and an MRI was ordered. *Id.* at 82-83. On the patient history questionnaire completed for the orthopedist, Petitioner reported that she sought care for "pain in left arm from flu shot" and in response to a question about how long she had this problem she wrote "flu shot on Nov. 19, 2019." *Id.* at 86.

On the MRI screening form dated April 15, 2020, Petitioner reported that the reason for the MRI and/or symptoms was "pain in upper left arm from flu shot Nov. 19, 2019." Ex. 3 at 84.

Petitioner presented for a physical therapy (“PT”) evaluation on April 22, 2020. Ex. 3 at 73. She reported “onset of symptoms in her left shoulder started on 11/19/19 after she got her flu shot.” *Id.* at 75. The “Problems” section of the record lists “[f]ull thickness rotator cuff tear – Onset: 04/08/2020, Left.” *Id.* at 74.

Petitioner returned to Dr. Lilly on June 1, 2020 to follow up on a diagnosis of adhesive capsulitis and impingement of her left shoulder. Ex. 3 at 44. She was doing well with PT, and was close to 80 percent improved. *Id.*

2. Declarations

Petitioner submitted two declarations in support of her claim. Exs. 8 and 14. Ms. Graczyk avers that she felt soreness at the injection site immediately following the November 19, 2019 flu vaccination. Ex. 8 at ¶ 4. She expected the soreness to go away after a few days. *Id.* Her husband received his flu vaccine the same day, and his shoulder soreness resolved after a few days, but Petitioner’s shoulder remained sore. *Id.* at ¶ 5. Petitioner’s shoulder pain was severe enough to limit her range of motion and interfere with daily activities such as getting dressed, doing chores around the house, sleeping, and getting in and out of bed. *Id.* at ¶ 6. She called her PCP after the flu shot when the pain did not go away, and he told her it was normal and to be patient. *Id.* at ¶ 7. Following his advice, she waited until her previously scheduled January appointment to address her shoulder pain. *Id.*

Richard Graczyk, Petitioner’s husband, also submitted a declaration in support of her claim. Ex. 14. Mr. Graczyk averred that he and Petitioner received their flu shots while grocery shopping at Publix in November 2019. *Id.* at ¶ 2. He did not feel any shoulder pain after the shot, but on the car ride home Petitioner told him her left arm was painful. *Id.* at ¶ 3. Starting that day, he had to help with household chores and meal preparation. *Id.* at ¶ 4. That evening, she reported abnormal pain at the injection site. *Id.* at ¶ 5. Over the next several weeks, Petitioner complained of pain with movement in the evenings. *Id.* at ¶ 6. He continued to help her with getting dressed and getting in and out of bed due to her left arm pain. *Id.* at ¶ 7. Due to her continuing pain, he did all the driving, including to medical and PT appointments, as she did not feel safe driving with only her right arm. *Id.* at ¶ 8.

C. The Parties’ Arguments

Petitioner cites record evidence in support of her position that the onset of her shoulder pain occurred within 48 hours of vaccine administration. Petitioner’s Motion for

Ruling on the Record, filed Mar. 9, 2022 (ECF No. 24) (“Mot.”). Petitioner emphasizes that she reported shoulder pain from her flu shot to her PCP on January 16, 2020, and returned a month later reporting pain that started when she got her flu shot in November. *Id.* at *5-6. She saw an orthopedist in April 2020, reporting that pain and stiffness in her shoulder since her flu shot in November 2019. *Id.* at *6. When she presented for PT in April 2020, she again related the onset of her shoulder symptoms to her November 19, 2019 flu shot. *Id.* at *7.

Petitioner acknowledges a single contrary notation, found in a PT record, indicating onset of a rotator cuff tear on April 8, 2020. Mot. at *7. Petitioner asserts that this date, April 8, 2020, was the date of Petitioner’s orthopedic examination, rather than the date of onset of her symptoms. *Id.* at *8. Petitioner argues that other than this single incorrect notation, the record is devoid of evidence contradicting Petitioner’s assertion of onset immediately after vaccination on November 19, 2019. *Id.* Thus, in Petitioner’s view, a preponderance of the evidence supports a finding that onset was within 48 hours. *Id.* at *9.

Respondent asserts that Petitioner is not entitled to compensation. Response to Petitioner’s Motion, filed Mar. 22, 2022, at *2 (ECF No. 26) (“Opp.”). Respondent focuses heavily on the fact that the record of Petitioner’s January 16, 2020 appointment with Dr. Murphy barely mentions Petitioner’s shoulder pain. *Id.* at *7-9. Respondent takes issue with what he perceives as inconsistency between the “minor issues” recorded on January 16th and the more serious concerns recorded at the February 20, 2020 appointment and in Petitioner’s declaration. *Id.* From this, Respondent suggests that “it remains entirely unclear when petitioner started to have limited ROM in her left shoulder, or when she began to have difficulties sleeping and performing ADL [activities of daily living] because of pain in her left shoulder.” *Id.* at *9. On that basis, Respondent infers that Petitioner has not established that the onset of her *pain* began within 48 hours of vaccination. *Id.* (emphasis added).

Petitioner replies that Respondent incorrectly suggests that the medical records do not corroborate onset. Petitioner’s Reply, filed Mar. 29, 2022, at *1 (ECF No. 27) (“Reply”). Petitioner cites prior OSM onset rulings rejecting Respondent’s arguments about the level of proof required to establish that the onset of shoulder pain occurred within 48 hours. *Id.* at 2-8. Petitioner argues that Respondent “continues to ignore this Court’s clear direction, through its reasoned decisions, and ties up its own resources, those of DOJ, Petitioners’ counsel, as well as the Court’s, bringing losing legal arguments as to onset, as he has done in the instant case.” *Id.* at *3. Petitioner asserts, “[g]iven the sheer number of cases in which Respondent has made this argument, without success, the argument has now become specious.” *Id.* at *4. Petitioner states that, like many

SIRVA claimants, she took a “wait and see” approach, at her PCP’s guidance. *Id.* at *8. She experienced immediate pain, which became worse. *Id.*

Petitioner asserts that all of her medical records relate her pain to the flu vaccine, and her declarations corroborate the records. Reply at *9. Respondent has not cited evidence to the contrary. *Id.* Thus, Petitioner asserts that preponderant evidence establishes onset within 48 hours. *Id.* Because Respondent has not challenged any requirements other than onset, Petitioner requests that I find that she is entitled to compensation for a Table SIRVA. *Id.* at *10. Petitioner further requests that Respondent be instructed that his proffer should be “in line with the prior decision of this Court on pain and suffering in SIRVA cases.” *Id.*

D. Factual Finding Regarding QAI Criteria for Table SIRVA

1. Onset

Respondent appears to conflate the timing of the onset of Petitioner’s *pain* – the most relevant issue under the SIRVA QAI – with the timing of the onset of her *limited ROM and difficulties with daily activities* – which can inform the question of the onset of her pain, but are themselves required to begin immediately. The QAI do speak of limited ROM – but do not set forth a strict *timing* requirement for it, while the onset question in the Table and QAI speaks to the onset of Petitioner’s *pain*. And there is sufficient record evidence on that issue to deem this element satisfied.

Petitioner reported left shoulder pain from her flu vaccination two months after vaccination, at her January 16, 2020 appointment with Dr. Murphy. Dr. Murphy appears to have dismissed her reports of pain and not provided any treatment. When she returned a month later, he gave her a prescription, but warned that her pain may be permanent. Thus, it appears that he may not have taken her complaints seriously, or may have had doubts about how treatable her condition was.

Petitioner’s presentation for treatment, and treatment course, are fairly typical for a SIRVA case. She first reported shoulder pain from the flu vaccine two months after vaccination. Ex. 2 at 15. Over the course of her treatment, she repeatedly and consistently related her pain to her November 2019 flu vaccine. She reported that her pain “started when she got a flu shot back in November,” pain and stiffness since her November 2019 flu shot, “pain in upper left arm from flu shot Nov. 19, 2019,” “onset of symptoms in her left shoulder started on 11/19/19 after she got her flu shot.” Exs. 2 at 7; 3 at 75, 82, 84. The single notation suggesting a later onset appears within a record that also relates

onset to her November 2019 flu shot, and Respondent does not rely on that record in any event.

Respondent's objections ultimately seem to demand an absolute consistency within a petitioner's medical records that the Act does not require. Instead, the standard set forth in the Act is *preponderance of the evidence*. Section 13(a)(1). Inconsistency among medical records is thus relevant to the weighing of evidence to determine what the preponderance of the evidence supports – but inconsistency alone does not defeat a claim unless it preponderantly supports an alternative finding. Here, a preponderance of the evidence supports a finding that Petitioner's shoulder pain began within 48 hours of her flu vaccination.

2. Other SIRVA QAI Criteria

Respondent does not contest the remaining SIRVA QAI criteria, and I find that the record contains preponderant evidence that they are satisfied. Petitioner did not have a history of left arm pain or injury prior to her November 19, 2019 flu vaccination that would explain her symptoms after vaccination. Ex. 2 at 24-149; Opp. at *2. Her pain and reduced ROM were limited to her left shoulder, where the flu vaccine was administered, and no other condition or abnormality has been identified that would explain her post-vaccination symptoms. Ex. 2 at 7-23; Ex. 3 at 73-75; 80-86.

E. 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 4. She experienced the residual effects of her condition for more than six months. Ex. 3 at 44. She averred that she has not previously collected an award or settlement of a civil action for damages, and there are no civil actions pending. Ex. 8 at ¶ 12.

Conclusion

Based on my review of the record as a whole, I find that it is more likely than not that the onset of Petitioner's shoulder pain occurred immediately upon vaccination. I find that all other SIRVA Table requirements are met, as are other requirements for entitlement. Therefore, Petitioner's motion for a ruling on the record that she is entitled to compensation is **GRANTED**. **Petitioner is entitled to compensation.**

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran

Chief Special Master