In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 20-0845V

UNPUBLISHED

ANNETTE MOLINA, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: September 14, 2022 Special Processing Unit (SPU); Findings of Fact; Onset; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

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

Ryan Daniel Pyles, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT AND CONCLUSIONS OF LAW DISMISSING TABLE CLAIM[1]

On July 13, 2020, Annette Molina 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") from an influenza ("flu") vaccine she received on October 4, 2018. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters (the "SPU").

[1] Because this unpublished Fact Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in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 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 (2012).

For the reasons discussed below, Petitioner's Table SIRVA claim must be dismissed – primarily because the evidentiary record does not support the conclusion that her pain and reduced range of motion were limited to the vaccinated shoulder. This leaves a possibly meritorious causation-in-fact claim to be adjudicated, however – and hence dismissal of the Table claim will be accompanied by transfer of the case out of SPU for further proceedings.

I. Relevant Procedural History

A year after the case's assignment to SPU, Petitioner confirmed in July 2021 that she had sent a settlement demand to Respondent. ECF No. 22. On October 6, 2021, Respondent filed a status report stating that he was potentially open to engaging in settlement negotiations, but requesting an opportunity "to first report his formal position through a Rule 4(c) report." ECF No. 24. That same day, Petitioner filed a comprehensive Motion for Ruling on the Record ("Mot."), seeking a ruling on both entitlement and damages. ECF No. 25.

On November 9, 2021, Respondent filed a Rule 4(c) Report arguing that Petitioner had not established entitlement to compensation. ECF No. 28. Respondent specifically maintained that "the record does not support by preponderant evidence a finding that Petitioner's shoulder injury began specifically within forty-eight hours of vaccination." Rule 4 Report at 11. Respondent further argued that Petitioner's "symptoms were not limited to the shoulder in which the intramuscular vaccine was administered," and that Petitioner's diagnosis of calcific tendonitis is a condition that would explain her symptoms. *Id.* at 13.

On December 17, 2021, Respondent filed a Response to Petitioner's Motion for Ruling on the Record and Brief in Support of Damages ("Resp."). ECF No. 30. Petitioner filed a reply ("Repl.") on December 30, 2021. ECF No. 31.

The matter is now ripe for adjudication.

II. Medical History

Petitioner's pre-vaccination records reveal that she was in a motor vehicle accident in February 2015, after which she was treated for back pain. Ex. 4 at 8-14. Petitioner's records do not reveal any prior pain or dysfunction in either shoulder.

On October 4, 2018, Petitioner received a flu vaccine in her right deltoid. Ex. 1 at 3. Petitioner received the vaccine at the nursing home in Springfield, MA where she was employed as a nursing assistant. *Id.*; Ex. 2 at ¶9. Petitioner stated that she "immediately felt excruciating pain in [her] right shoulder" and that "in the moments following the vaccine, [her] right shoulder became increasingly stiff and painful." *Id.* at ¶9-10. She

further stated that she experienced weakness "within two days after receiving the vaccination." *Id.* at ¶11.

On December 4, 2018 (now two months after her vaccination), Petitioner sought treatment from her physiatrist for chronic lower back pain. Ex. 4 at 2-3. The record of that visit contains no reference to right shoulder pain, however. Then, by the end of December 2018, Petitioner recalls that her "range of motion was extremely limited." Ex. 2 at ¶12. She states that she reported her shoulder pain to a manager at work in the middle of January 2019 and that her employer requested that she see "one of their physicians" "for an evaluation." *Id.* at ¶13.

On February 6, 2019, four months after vaccination, Petitioner's right shoulder was evaluated by physician's assistant Jodi Maniscalco. Ex. 4 at 162. The record notes that Petitioner reported that her shoulder was "very sore after the injection," and that she reported the soreness to the nurse that administered the vaccine "the next week." *Id.* Petitioner reported that she spoke with a different nurse as work in November. *Id.* Petitioner reported pain of 7/10 to 9/10, worsening since December, that "will radiate to the right upper back" and "travels across back to the left shoulder as well." *Id.* Petitioner's shoulder exam was normal, with no tenderness to palpation, no edema, and full range of motion in all planes. *Id.* at 163. She was advised to follow up with her primary care physician ("PCP"). *Id.*

On March 19, 2019, Petitioner presented to her PCP "complaining of continuing pain in her right shoulder since she had flu immunization in October." Ex. 5 at 26. This record notes, however, that Petitioner "did not report the continued issues to the nursing home until several months later." *Id*. Petitioner reported pain which worsened with raising her arm and with internal and external rotation, as well as pain in her scapula. *Id.* On examination, there was full passive range of motion, but pain and crepitus with some motion, and full active range of motion. *Id.* at 28. An x-ray revealed calcification and Petitioner was diagnosed with calcific tendonitis. *Id.* at 29. Petitioner was referred to physical therapy and prescribed diclofenac. *Id.*

On July 17, 2019, Petitioner returned to her PCP to follow up on her right shoulder pain. Ex. 5 at 13. She had not attended physical therapy,[3] and had failed to follow through on scheduled appointments with her PCP and physiatrist. *Id*. Petitioner's exam showed full range of motion and strength. *Id.* A repeat x-ray showed increased calcification. *Id.* at 41. Petitioner was referred again to physical therapy and physiatry, and given a prescription for Mobic. *Id.* at 16.

[3] In April 2019, Petitioner made, but canceled, four physical therapy appointments. Ex. 9 at 12-15. There were no records of physical therapy treatment, although Petitioner referenced treatment for "less than a month" that she felt did not improve her symptoms in her affidavit. Ex. 2 at ¶17.

Petitioner reported to the emergency department four times in July and August of 2019, for issues unrelated to her shoulder pain. Ex. 3 at 8-10, 57, 77; Ex. 9 at 145. Then, on August 26, 2019, Petitioner presented to her physiatrist for her right shoulder pain. Ex. 7 at 19-20. She now reported that her "symptoms started in October 2018 after she had a flu shot," but that "she did not have symptoms immediately" and "developed soreness within a few days." *Id.* at 20. She reported her symptoms "became severe after a month." *Id.* Physician assistant, Joseph Chappell, diagnosed calcific tendonitis and recommended physical therapy. *Id.* at 24. PA Chappell discussed Petitioner's concern that she had a SIRVA injury and noted that Petitioner's "area of discomfort is in the lower aspect of the deltoid muscle" which "is likely referred pain from calcific tendonitis." *Id.* He noted that "it is difficult to say whether this actually occurred from an inappropriate injection which would have been higher," but that it was difficult to assess almost a year later. *Id.*

On August 28, 2019, Petitioner presented for an initial physical therapy evaluation. Ex. 8 at 8. She reported that she had "had a flu vaccination last October and [she] had pain in [her] shoulder which did not go away." *Id.* Petitioner stated that she was a PA student and did not have time previously to seek treatment. *Id.* Petitioner's exam was "consistent with the diagnosis of right calcifying tendinitis." *Id.* Petitioner did not return to physical therapy and was discharged on September 27, 2019. *Id*. at 11.

In September and October of 2019, Petitioner was seen in the emergency department four times, for more issues unrelated to her right shoulder pain. Ex. 9 at 195, 236, 257, 303. She then returned to her physiatrist on November 7, 2019. Ex. 7 at 8. She reported that she "underwent a course of physical therapy" with "very limited benefit." *Id*. She complained of continued pain that increased with any activity. *Id.* PA Chappell confirmed Petitioner's calcific tendinitis diagnosis and administered a corticosteroid injection. *Id.* at 13. Petitioner reported no significant improvement from the injection at her next appointment on December 18, 2019. Ex. 5 at 37. PA Chappell ordered an MRI and referred Petitioner to an orthopedist. *Id.* at 42.

From December 2019 through February 2020, Petitioner presented to the emergency room on four occasions. Ex. 9 at 455, 492, 513, 557. At one visit, on January 26, 2020, Petitioner was treated for right upper back pain, between her scapula and spine. *Id.* at 492. She was seen in the emergency department four more times for unrelated complaints between June and September 2020. Ex. 9 at 588, 778, 818, 965.

On September 28, 2020, Petitioner presented to an orthopedist, Dr. Noah Epstein, for the first time. Ex. 11 at 7. She reported that her pain started "3 years ago when she got an injection in her right deltoid, flu shot." *Id.* Dr. Epstein reviewed Petitioner's MRI and diagnosed calcific tendinitis. *Id.* at 8. He administered a subacromial steroid injection. *Id.* Petitioner followed up with Dr. Epstein on February 1, 2021, reporting that the injection "was helpful, but the pain has returned." *Id.* at 5. She reported "discomfort now but it has

not gotten to the point that she is not sleeping or cannot tolerate the discomfort." *Id.* The diagnosis remained calcific tendinitis and no further treatment was recommended at the time. *Id.* at 6.

III. Applicable Legal Standards

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 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). "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*, at *19. And the Federal Circuit recently "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).

The United States Court of Federal Claims has recognized 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).

The Court has also said that 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 the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 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).

IV. Finding of Fact

A. Onset

At issue first 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 the record does not support a finding of onset within 48 hours of vaccination because Petitioner did not seek treatment for her right shoulder pain until February 6, 2019, just over four months after her vaccination. Rule 4(c) Report at 11. Respondent further notes that, on December 4, 2018, two months earlier, Petitioner sought treatment for lower back pain, but that record said nothing about right shoulder pain – even though (since she was seeing a physiatrist) that presented a reasonable opportunity to mention such pain. *Id.* The absence of such evidence allowed for the conclusion that Petitioner's shoulder pain more likely began after the appointment. *Id.*

A treatment delay of four months is not by itself sufficient to compel a finding that onset did not occur within 48 hours of vaccine administration. *See Bergstrom v. Sec. of*

Health & Hum. Servs., No. 19-784V, 2020 WL 8373365 (Fed. Cl. Spec. Mstr. Dec. 4, 2020) (finding that onset occurred within 24 hours of vaccination, although the petitioner's first medical consult about her shoulder pain was nearly four months after vaccination). An intervening medical appointment with a record that is silent on shoulder or arm pain also does not inerringly rebut an onset showing consistent with the Table. *See Bishop v. Sec. of Health & Hum. Servs.*, No. 18-72V, 2019 WL 5718045 (Fed. Cl. Spec. Mstr. Sept. 20, 2019).

In viewing the record as a whole, I find Petitioner's explanation concerning the onset of her shoulder pain, and the absence of documentation of her pain at her December 4, 2018 medical records, to be plausible. In her affidavit, Petitioner states that she experienced excruciating pain immediately upon vaccine administration, and stiffness in the "moment following the vaccine." Ex. 2 at ¶9-10. She further stated that she experienced weakness "within two days after receiving the vaccination." *Id.* at ¶11. In her supplemental affidavit, Petitioner explained that the December 4, 2018 appointment was scheduled prior to her vaccination, and that her physiatrist's office is particular about addressing only one concern at each appointment. Ex. 10 at ¶5. She states that she did mention her right shoulder pain to her provider, but that he suggested she make another appointment to have her shoulder evaluated. *Id.* Petitioner went on to explain that her range of motion continued to worsen through the end of December 2018, and that she reported her pain to her manager at work, who advised her to seek treatment. *Id.* at 6-7.

Respondent argues that Petitioner's affidavit testimony alone cannot establish onset, particularly in light of the four-month delay in seeking treatment. Rule 4(c) Report at 12. However, *I am not solely relying on testimonial evidence*. For once Petitioner began treating her right shoulder pain, she consistently and repeatedly associated the onset of that pain with her flu vaccination, and such record evidence is thus corroborated by the witness testimony.

On February 6, 2019, for example, Petitioner reported that "she had an influenza vaccine on 10/4/2018 and that her shoulder was "very sore after" the flu vaccination." Ex. 4 at 162. She reported that she had informed the nurse that administered the vaccine that it was sore "the next week." *Id.* At a March 19, 2019 appointment with her PCP, Petitioner complained of "continuing pain in her right shoulder since she had flu immunization in October." Ex. 5 at 26. The record even notes that Petitioner admitted that she "did not report the continued issues to the nursing home until several months later." *Id*. In her first appointment with her physiatrist on August 26, 2019, Petitioner reported that her "symptoms started in October 2018 after she had a flu shot. Ex. 7 at 19. In her first orthopedist appointment on September 28, 2020, Petitioner reported that her pain started "3 years ago when she got an injection in her right deltoid, flu shot." Ex. 11 at 7. While these entries are still based upon information provided by Petitioner, they should be

afforded additional weight as they were uttered closer in the time to when she sought medical care for the alleged vaccine injury.[4]

Petitioner, who was employed as a nursing assistant, has repeatedly described immediate pain at the time of vaccination that worsened over time until she sought treatment. Once she sought treatment, Petitioner consistently reported that her pain began with her flu vaccination. Accordingly, I find there is preponderant evidence to establish the onset of Petitioner's pain occurred within 48 hours of vaccination.

B. *Injury Localized to Vaccinated Arm*

Also at issue is whether Petitioner's pain and limited range of motion were limited to the shoulder in which the intramuscular vaccine was administered as set forth in the Vaccine Injury Table and the third QAI for a Table SIRVA. 42 C.F.R. § 100.3(a) XIV.B.; 42 C.F.R. § 100.3(c)(10)(iii). Respondent argues that Petitioner's symptoms were not so limited. Rule 4(c) Report at 13. Here, the balance of evidence favors Respondent.

In addition to a history of chronic low back pain, Petitioner reported symptoms *beyond* her right shoulder throughout her medical records.[5] On February 6, 2019, for example, at her first appointment to evaluate her right shoulder pain, Petitioner reported pain that radiated "to the right upper back" and "across [her] back to the left shoulder as well." Ex. 4 at 162. On March 19, 2019, Petitioner reported pain "into the scapula." Ex. 5 at 26. On January 26, 2020, Petitioner was seen in the emergency department for right upper back pain, between her scapula and spine. Ex. 9 at 492. This evidence does not simply suggest pain *beginning* with the shoulder, but instead allows for the conclusion that pain was felt in other parts of the body.

Because the medical records reveal that Petitioner's pain and limited range of motion were not limited to her right shoulder, she cannot predominantly establish the third QAI for a Table SIRVA.

C. *Other Condition Present that Could Explain Symptoms*

A final issue in dispute is whether there is a condition or abnormality present that would explain Petitioner's symptoms. *See* 42 C.F.R. § 100.3(a) XIV.B.; 42 C.F.R. §

[4] The Federal Circuit has stated that "[m]edical records, in general, warrant consideration as trustworthy evidence . . . [as they] contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions." *Cucuras*, 993 F.2d at 1528 (emphasis added). Thus, the Circuit has instructed that greater weight should be accorded to this information even when the information is provided by Petitioner.

[5] Petitioner was seen by medical providers for a variety of conditions throughout her course of treatment. For brevity, only records where she sought treatment for her right shoulder pain are discussed herein.

100.3(c)(10)(iv). Respondent argues that Petitioner's "treating physicians have consistently diagnosed her with calcific tendinitis." Rule 4(c) Report at 13.

Petitioner's medical records reveal a repeated diagnosis of calcific tendinitis since her first x-ray ordered by her PCP on March 19, 2019. Ex. 5 at 29. The diagnosis was confirmed with a repeat x-ray on July 17, 2019, and with an MRI on September 28, 2020. Ex. 5 at 16, 41; Ex. 11 at 8. Petitioner's initial physical therapy evaluation revealed "signs and symptoms consistent with the diagnosis of right calcifying tendinitis." Ex. 8 at 8. Finally, Petitioner's physiatrist, physician assistant, Joseph Chappell, diagnosed calcific tendonitis, while noting Petitioner's concern that she had a SIRVA injury. Ex. 7 at 24. PA Chappell noted that Petitioner's "area of discomfort is in the lower aspect of the deltoid muscle" which "is likely referred pain from calcific tendonitis." *Id.* He further noted that "it is difficult to say whether this actually occurred from an inappropriate injection which would have been higher," but that it was difficult to assess almost a year later. *Id.*

The medical records reveal that Petitioner was diagnosed with a condition, calcific tendinitis, which was confirmed with imaging on three occasions, and which could explain her right shoulder symptoms. This puts into doubt her ability to predominantly establish the fourth QAI for a Table SIRVA (although such an argument could be rebutted with persuasive and reliable evidence).

V. Conclusion

Although I find Petitioner has preponderantly established that the onset of her shoulder pain occurred within 48 hours of vaccination, she cannot proceed in this action with a Table SIRVA claim because she has not predominantly established that her pain and limited range of motion were limited to the shoulder in which the vaccine was administered. In addition, even if the foregoing could be proven, Respondent has raised an alternative cause defense under one of the QAIs that at a minimum would invite expert input (and would be relevant even if the case proceeds as a non-Table claim). Accordingly, the matter shall be transferred to provide Petitioner the chance to prove that her generalized SIRVA-like injury was vaccine caused, and also to offer evidence regarding the alternative cause identified by Respondent.

Petitioner's Table SIRVA claim is dismissed, for the reasons set forth above and the case will be reassigned to a Special Master outside of the Special Processing Unit ("SPU").

IT IS SO ORDERED.

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