CORRECTED

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 20-1650V

JENNIFER LINDSEY,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: June 29, 2023

Leigh Finfer, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Colleen Clemons Hartley, U.S. Department of Justice, Washington, DC, for Respondent.

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

On November 23, 2020, Jennifer Lindsey 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"), as defined on the Vaccine Table Injury, after receiving the influenza ("flu") vaccine on October 23, 2018. Petition at 1, ¶¶ 12, 15.

[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).

For the reasons discussed below, a preponderance of the evidence supports the conclusion that the onset of Petitioner's left shoulder pain did *not* occur within 48 hours post-vaccination – meaning she cannot establish the onset required for her Table SIRVA claim. Additionally, there is evidence of another condition - calcific tendinosis - which would explain the symptoms Petitioner experienced. Therefore, the Table claim must be dismissed. A causation-in-fact or significant aggravation version of the claim can only go forward if Petitioner provides additional supporting evidence not yet offered in the case.

I. Relevant Procedural History

Along with the Petition, Ms. Lindsey filed the affidavit and medical records required by the Vaccine Act. Exhibits 1-13, filed Nov. 23, 2020, ECF No. 1; *see* Section 11(c). Thereafter, the case was activated and assigned to SPU. ECF No. 10.

On May 4, 2021, Respondent filed a status report identifying an issue regarding onset which "may require additional factual development." Respondent's Status Report at 2, ECF No. 14. Specifically, Respondent emphasized that Petitioner did not complain of her left shoulder pain until three months post-vaccination, and also questioned whether the pain could be due to an injury suffered during gynecological surgery performed on November 4, 2018, almost two weeks post-vaccination. *Id.* Petitioner was therefore ordered to file additional evidence and a motion for a factual ruling and briefing, if desired. ECF No. 15.

On August 31, 2021, Petitioner filed only a supplemental declaration[3] which, rather than clarifying the events of late 2018 and early 2019, added to the confusion surrounding the onset of Petitioner's left shoulder pain. Exhibit 14, ECF No. 17. Petitioner also filed a declaration[4] from her husband, supporting her assertions regarding onset and delay in treatment. Exhibit 15, filed Sept. 7, 2021, ECF No. 18. Her husband's affidavit did not address the confusion created by the timing of Petitioner's inquiry regarding causation.

On September 8, 2021, I issued an order directing Petitioner to file the medical records from her November 2018 surgery and any additional evidence needed to address the onset of her left shoulder pain, or to show cause why her Table claim should not be dismissed. ECF No. 19. In response, Petitioner filed additional medical records regarding her gynecologic issues and surgery, a response to the order to show cause, and another supplemental declaration addressing the cause of her left shoulder pain. Response, filed

[3] Petitioner's declaration was signed under penalty of perjury as required by 28 U.S.C.A. § 1746. Exhibit 14.

[4] The declaration from Petitioner's husband also was signed under penalty of perjury as required by 28 U.S.C.A. § 1746. Exhibit 15.

Oct. 26, 2021, ECF No. 20; Exhibit 16, Nov. 29, 2021, ECF No. 24; Exhibit 17, filed Dec. 29, 2021, ECF No. 26.

On December 16, 2021, Respondent filed a status report indicating "that he is in the process of completing his formal review of this matter and has identified critically missing records that are necessary to form a litigation position." ECF No. 25. He specifically requested "all records for evaluation of her alleged post-vaccination left shoulder pain prior to her visit to Bret Kean, M.D., an orthopedist, on February 28, 2019." *Id.* He observed that Petitioner was referred to Dr. Kean by PA Linnea Huson, but no records involving PA Huson were filed. Additionally, he requested the results of x-rays performed at Providence Heath and Services which appear outstanding. *Id.*

Several weeks thereafter, Petitioner filed a second declaration[5] providing further explanation regarding the onset of her pain. Exhibit 17, filed Dec. 29, 2021, ECF No. 26. In June 2022, she filed the medical records identified by Respondent. Exhibit 18, filed June 27, 2022, ECF No. 31. Thereafter, Respondent indicated a willingness to engage in settlement discussions. Status Report, filed July 26, 2022, ECF No. 33.

After two months, however, the parties reached an impasse in their settlement discussions. Status Report, filed Sept. 28, 2022, ECF No. 37. Respondent filed his Rule 4(c) Report, setting forth his objections to compensation on October 25, 2022. ECF No. 38. Specifically, he argues that the record supports a later onset of Petitioner's left shoulder pain – in November 2019 - and suggests a condition or abnormality – calcific tendinosis, that could explain Petitioner's symptoms. *Id.* at 8-10.

II. 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 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). "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 & Hum. Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

[5] Petitioner's second declaration was signed under penalty of perjury as required by 28 U.S.C.A. § 1746. Exhibit 17.

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. "Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, *4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). 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 & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has 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 & Hum. 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 v. Sec'y of Health & Hum. Servs*., 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such fact testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. 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 Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. 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).

Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV) (2017). 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).

III. Table SIRVA Claim

A. Issue

At issue is whether Petitioner's first symptom or manifestation of onset after vaccine administration (specifically pain) occurred within 48 hours as set forth in the Vaccine Injury Table and QAI for a Table SIRVA and whether there exists another condition which would explain Petitioner's symptoms. 42 C.F.R. § 100.3(a) XIV.B. (influenza vaccination); 42 C.F.R. § 100.3(c)(10)(ii) (required onset for pain listed in the QAI); 42 C.F.R. § 100.3(c)(10)(iv) (requirement that no other condition or abnormality exists that would explain a petitioner's symptoms).

B. Bases for Factual Findings

I make my findings regarding these issues after a complete review of the record to include all medical records, affidavits, additional evidence, and arguments by the parties. Specifically, I base the findings on the following evidence:

- Prior to vaccination, the medical records from Petitioner's primary care provider ("PCP"), show she experienced common conditions such as high cholesterol, high blood pressure, and obesity. *E.g.,* Exhibit 18 at 206-207, 216-219. Petitioner also suffered from left hip and groin pain and fibromyalgia[6] treated by twice daily doses of Gabapentin (1 tablet in the am and 2 tablets in the pm) and either naproxen or ibuprofen. *E.g., id.*

- In mid-2017, Petitioner was diagnosed with diabetes, controlled without long-term insulin use. Exhibit 18 at 173.

- On July 19, 2018, Petitioner was treated for postmenopausal bleeding. Exhibit 2 at 9. It was noted that she had a history of endometrial polyps. *Id.* at 12.

- An ultrasound performed on August 10, 2019, revealed the presence of another endometrial polyp. Exhibit 2 at 14. A biopsy was performed, and

[6] Fibromyalgia is "pain and stiffness in the muscles and joints that either is diffuse or has multiple trigger points." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY ("DORLAND'S") at 703 (32th ed. 2012).

surgical consult for a hysteroscopy and polypectomy with D & C[7] was recommended. *Id.* at 14, 18.

- On October 17th, Petitioner visited a psychologist to discuss anxiety related to her upcoming surgery and post-traumatic stress and insomnia related to events in her past. Exhibit 2 at 33-37.

- Petitioner received the flu vaccine alleged as causal at a PCP visit on October 23, 2018, when she was 57 years old. Exhibit 1; *see also* Exhibit 18 at 121-22. At this visit, her PCP reordered her Gabapentin, adjusting the dosage to "1 am, 1 mid day, and 3 tab in HS." *Id.* at 117.

- On October 31 and November 7, 2018, Petitioner returned to the psychologist for treatment of her anxiety, insomnia, and PTSD.[8] Exhibit 2 at 41-47. On November 7th, she also attended a pre-operative visit with her gynecologist. *Id.* at 47-53. Petitioner did not mention left shoulder pain at any of these appointments. *Id.* at 41-53. However, her ongoing fibromyalgia was listed as concern in the record from her November 7th pre-operative visit. *Id.* at 51.

- On November 12th, Petitioner returned to the psychologist for continued treatment of her anxiety and insomnia. Exhibit 2 at 54-56. It was noted that her surgery was scheduled for November 14th. *Id.* at 55.

- The same day, Petitioner discussed her possible sleep apnea during screening for the administration of general anesthesia during her surgery. Exhibit 16 at 1-3. Her fibromyalgia was list as a chronic problem at this appointment, but there is no suggestion she was suffering from left shoulder pain. *Id.*

- Petitioner's surgery progressed without complications on November 14th. Exhibit 16 at 3-144. There is no mention of left shoulder pain in these surgical records. *Id.* A list of active problems includes Petitioner's left hip and groin pain and medications needed for her fibromyalgia. *Id.* at 9-10.

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[7] An abbreviation for "dilation and curettage" (MEDICAL ABBREVIATIONS at 168 (16th ed. 2020), a D&C "is a surgical procedure in which the cervix (lower, narrow part of the uterus) is dilated (expanded) so that the uterine lining (endometrium) can be scraped with a curette (spoon-shaped instrument) to remove abnormal tissues." https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/dilation-and-curettage-d-and-c (last visited June 26, 2023).

[8] PTSD stands for post-traumatic stress disorder. MEDICAL ABBREVIATIONS at 494.

- On November 27th, Petitioner visited her dermatologist for an evaluation of skin lesions throughout her body. Exhibit 5 at 4-5. There is no mention of left shoulder pain in the medical record from this visit. Exhibit 5.

- Similarly, the medical record from Petitioner's post-surgical visit on November 27th does not contain any entry suggesting Petitioner was suffering from shoulder pain. Exhibit 2 at 57-61. Only slight cramping and Petitioner's ongoing fibromyalgia are mentioned. *Id.* at 57-58.

- The first mention of left shoulder pain is found in the record from a call Petitioner placed to her gynecologist on January 24, 2019. Exhibit 2 at 62. She asked about spotting and some occasional "ovulation pain and cramping" she was experiencing and "left arm pain after getting [a] flu shot in November, wondering if anything could have happened in surgery." *Id.* A second note regarding the call indicates Petitioner "ha[d] questions and concerns of pain in her left arm if its [sic] related to the surgery as well." *Id.*

- On February 4, 2019, Petitioner saw a physician's assistant at her PCP's clinic, complaining of upper left arm pain for three months that "[s]tarted after she got the flu shot last October." Exhibit 18 at 92. Pointing at her deltoid, she described the pain "like a knife stabbing into [her] arm . . . [s]ometimes just very achy." *Id.*

- Upon examination, Petitioner exhibited no "swelling, bruising, masses, or erythema, . . . ha[d] no pain when she flexes her bicep or tricep [sic], [and had] [n]o signs of impingement or rotator cuff derangement," but pain when her deltoid was engaged. Exhibit 18 at 93. The physician's assistant diagnosed Petitioner as having deltoid pain with an unclear etiology which was complicated by underlying fibromyalgia. *Id.* at 94. X-rays of Petitioner's left shoulder taken that same day revealed no evidence of fracture or dislocation, but "moderately advanced osteoarthritic changes." *Id.* at 82.

- Four days later, on February 8th, additional x-rays of Petitioner's left humerus were taken. Exhibit 18 at 71. They revealed degenerative changes and "[p]ossible tendinosis calcifications . . . near the rotator cuff insertion seen only on the oblique view." *Id.*

- On February 28th, Petitioner was seen by an orthopedist, complaining of upper left arm pain which began with a flu shot on October 23, 2018. Exhibit 3 at 6 (Petitioner's intake form); *see also id.* at 40 (a recitation of the medical history Petitioner provided). Adding that her pain "never stopped hurting and

continued to worsen," she described a stabbing pain into her arm, pain with movement, and pain at night. *Id.* at 6; *accord. id.* at 40 Petitioner provided a current list of medications, including the Gabapentin, Naproxen, Cymbalta, Ibuprofen, and Tylenol she was taking for her fibromyalgia. *Id.* at 6.

- After reviewing Petitioner's prior x-rays, the orthopedist diagnosed her with calcific tendonitis[9] of the left shoulder and administered a steroid injection. Exhibit 3 at 42-43. He also referred her to physical therapy ("PT"). Exhibit 4 at 10.

- At her first PT session on March 12, 2019, Petitioner was assessed as having "impingement of the left glenohumeral joint along with neural irritation and cervical restriction." Exhibit 4 at 14, 19. Treatment diagnoses of left shoulder pain and calcific tendinitis were noted in this record. *Id.*

- An MRI performed on March 14, 2019, revealed "tendinosis or degeneration involving the supraspinatus tendon, . . . no evidence for a rotator cuff tear, . . . [and findings] which may represent calcific tendinitis." Exhibit 3 at 45 (capitalization of all letters in the original). It was also noted "[t]here [wa]s a questionable abnormal signal . . . which may represent a labral tear." *Id.*

- At her next PT session five days later, it was noted that Petitioner's MRI showed an intact rotator cuff. Exhibit 4 at 22 (March 19th PT session).

- The next day, Petitioner reported improvement. Exhibit 4 at 23 (March 20th PT session). She exhibited full shoulder rotation and improved mobility at the cervical spine. It was noted that the March 14th MRI had shown "acrominum process degenerated changes." *Id.*

- Petitioner continued to show improvement during three additional PT sessions in late March and early April 2019. Exhibit 4 at 25-30.

- At her next orthopedic appointment on April 18th, described as follow-up of her left shoulder calcific tendinitis, Petitioner reported not much relief from her steroid injection or much improvement in her shoulder despite compliance with her PT and home exercise program. Exhibit 3 at 30. The

[9] Calcific tendinitis is "inflammation and calcification of the subacromial or subdeltoid bursa, resulting in pain, tenderness, and limitation of motion in the shoulder." DORLAND'S at 1881. It occurs more often in women between the ages of 40 to 60 years old. https://my.clevelandclinic.org/health/diseases/21638-calcific-tendonitis (last visited June 27, 2023).

orthopedist recommended continued observation and PT. Due to a side effect of the anti-inflammatory medication she was taking (nose bleeds), the orthopedist changed her prescription. *Id.*

- On May 22nd, Petitioner visited an urgent care facility after fall down some stairs, complaining of bilateral knee and lower and upper back pain. Exhibit 11 at 2. X-rays of her knees and back revealed only degenerative changes. *Id.* at 5-8. The treating physician ordered a walker and instructed Petitioner to stay on the ground floor as she recovered. *Id.* at 4.

- On June 24th, Petitioner returned to her orthopedist for follow-up regarding her left shoulder condition. Exhibit 3 at 24. Indicating that she was "tak[ing] a break from her home exercise program," Petitioner reported pain with overhead activity and reaching and "mild rest and night pain." *Id.* The orthopedist interpreted the March 14th MRI as showing "shoulder calcific tendinitis with subacromial and sub deltoid bursitis, . . . evidence of AC arthritis with a small amount of edema, . . . [and] no full thickness rotator cuff tear." *Id.* at 28.[10] The orthopedist administered a second steroid injection. *Id.* at 28-29.

- When seen again by the orthopedist on August 22nd, Petitioner reported no benefit from the second steroid injection she received on June 24th. Exhibit 3 at 19. Reporting pain with overhead activities, she was "equivocal about how client she ha[d] been with her home exercise program." *Id.* Recommending continued observation and more commitment to her home exercise program, the orthopedist indicated he "would consider a left shoulder diagnostic arthroscopy with rotator cuff debridement" if Petitioner's left shoulder condition did not improve. *Id.*

- On December 9, 2019, Petitioner returned to the orthopedist for treatment of her chronic right knee pain and left shoulder condition. Exhibit 3 at 12-13. Although Petitioner reported increased left shoulder pain, the orthopedist opted to continue with observation only. *Id.* at 12. For her right knee pain, he administered a steroid injection. *Id.* at 12, 17-18.

[10] Although there are several entries in the medical record (including this one) which refer to Petitioner's *right* rather than *left* shoulder, these incorrect descriptions appear to be due to simple error. *See* Exhibit 3 at 24, 28-29. The remaining entries in the record clearly reference *left* shoulder pain, and the referenced March 14th MRI was of Petitioner's left shoulder. *Id.* at 22-29 (June 24th visit), 45 (MRI results). Other than these apparently incorrect entries, there is no evidence indicating Petitioner was suffering from any right shoulder issues.

- The next orthopedic appointment Petitioner attended – on January 20, 2020, was for chronic pain and osteoarthritis in her right knee and obesity. Exhibit 3 at 8. There is no mention of left shoulder pain in this medical record. *Id.* at 8-11.

- In her affidavit, executed on November 10, 2020, Petitioner addressed only the basic requirements of her claim. Exhibit 13. However, she did not address the onset of her pain. *Id.*

- Petitioner provided additional detail in her first signed declaration, dated August 20, 2021. Exhibit 14. She attributed her delay in seeking treatment and questioning of whether her November 2018 surgery could have contributed to her condition to a lack of knowledge regarding vaccine causation, the busy holiday season, and anxiety linked to medical visits. *Id.* at ¶¶ 3, 5-6.

- In his signed declaration, Petitioner's husband echoed her claims of immediate and continuing left shoulder pain following vaccination. Exhibit 15 at ¶¶ 3, 5. He added that, to his knowledge, his wife had no history of prior left shoulder pain. *Id.* at ¶ 4.

- In her second signed declaration, Petitioner further discussed her inquiry about an aggravation of her left shoulder pain during her November surgery, arguing that it "does not negate the fact that [her] shoulder symptoms began after the flu vaccine." *Id.* at ¶ 5.

C. Pain Onset

During the month following vaccination, Petitioner attended multiple appointments without any mention of left shoulder pain. Instead, the records of these visits – many of which were focused on assessing Petitioner's condition and ongoing issues prior to and after her gynecologic surgery - contain references only to her fibromyalgia, anxiety, and possible sleep apnea. Exhibit 2 at 41-56; Exhibit 16.

Petitioner did not report left shoulder pain until a January 24, 2019 phone call to her PCP, three months post-vaccination and more than two months after her surgery. Exhibit 2 at 62. Although she partially linked her pain to the vaccination she received (mistakenly indicating vaccination occurred in November, rather than October), she also questioned whether her mid-November surgery could have had something to do with her pain. *Id.* This evidence supports a more gradual pain onset than Petitioner later claimed, more likely beginning in November 2018.

Until raised as an issue in this case, Petitioner did not provide any information or argument regarding the onset of her pain in her filings. She failed to address pain onset in her petition or affidavit. Petition; Exhibit 13 (affidavit).

The only evidence of the more immediate pain onset required for a Table SIRVA can be found in the medical record from an orthopedic visit on February 28, 2019, when Petitioner described left shoulder pain which continued after vaccination – worsening over time, and similar entries in her later provided response to my order to show cause and signed declarations from herself and her husband. Exhibit 3 at 6; Response at 5-7; Exhibit 14 at ¶ 4; Exhibit 15 at ¶ 3; Exhibit 17 at ¶¶ 3-5. Although these documents provide *some* evidence of a more immediate onset, they are not sufficient to counter the strong evidence of a more gradual, later onset – and that evidence predates the February 2019 record. Thus, I find Petitioner has failed to provide preponderant evidence of pain onset within 48 hours of vaccination.

D. Other Condition of Abnormality

Additionally, there is evidence revealing Petitioner suffered from another condition which would explain her symptoms. After reviewing x-rays taken in early February 2019, Petitioner's orthopedist attributed Petitioner's left shoulder pain to calcific tendinitis – a diagnosis repeated throughout her medical records thereafter. Exhibit 3 at 42. The MRI performed the following month, confirmed this diagnosis. *Id.* at 45. Despite the histories provided by Petitioner linking her left shoulder pain to the flu vaccine she received in late October 2018, none of her treating physicians opined that the vaccination was the cause of her pain.

The mere existence of an underlying, but previously asymptomatic, condition or abnormality (such as a rotator cuff tear, osteoarthritis, or other degenerative changes) does not prevent a petitioner from satisfying this Table criteria – especially when the timing and course of the injury is consistent with a Table SIRVA injury.[11] Rather, the

[11] *See Grossman v. Sec'y of Health & Hum. Servs.,* No. 18-0013V, 2022 WL 779666, at *17-18 (Fed. Cl. Spec. Mstr. Feb. 15, 2022) (involving degenerative changes shown on an MRI); *LaCourse-Burmeister v. Sec'y of Health & Hum. Servs.,* No. 20-0277V, 2022 WL 623991, at *7-8 (Fed. Cl. Spec. Mstr. Feb. 16, 2022) (involving tearing and tendinosis viewed on an MRI and not thought to be vaccine-related); *Youngmark v. Sec'y of Health & Hum. Servs.,* No. 17-1431V, 2021 WL 4892009, at *8-9 (Fed. Cl. Spec. Mstr. Sept. 29, 2021) (involving degenerative joint disease); *Lang v. Sec'y of Health & Hum. Servs.,* No. 17-0995V, 2020 WL 7873272, at *12-13 (Fed. Cl. Spec. Mstr. Dec. 11, 2020) (involving degenerative changes).

relevant inquiry is whether the condition or abnormality "wholly explains [a petitioner's] symptoms independent of vaccination." *Lang*, 2020 WL 7873272, at *13.

In this case, Petitioner's calcific tendinitis would explain the symptoms Petitioner experienced – including the more gradual onset of her pain and the exacerbation of her pain following surgery. Although not required, it actually better fits the facts and circumstances of this case.[12] Thus, I find on this record that Petitioner has failed to satisfy this fourth QAI criteria as well.

IV. Potential for Off-Table Claim

A petitioner's failure to establish a Table injury does not necessarily constitute the end of a case under all circumstances, because he or she might well be able to establish a non-Table claim for either causation-in-fact or significant aggravation. *See Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274 (Fed. Cir. 2005); *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1357 (Fed. Cir. 2013) (citing *Loving v. Sec'y of Health & Hum. Servs.*, 86 Fed. Cl. 135, 144 (2009)).

Here, however, any causation-in-fact or significant aggravation claim cannot proceed unless Petitioner can offer some proof of causation consistent with my finding regarding onset and a viable alternative cause. Additionally, she must establish a causal link and appropriate timeframe between the vaccination she received in October 2018 and left shoulder pain she complained of post-vaccination, as early as the next month.

Given the strong evidence from Petitioner's treating physicians – attributing her left shoulder pain to calcific tendinitis, coupled with the later and gradual onset of her pain - it is doubtful that Petitioner could prevail under an Off-Table claim. However, I will allow Petitioner the opportunity to obtain additional evidence of causation, if she so desires. And I believe an informal settlement, based upon a lower amount of compensation such as would be appropriate in a significant aggravation claim or litigative risk settlement, would constitute a proper resolution of this case. Therefore, I also will allow the parties time to continue their settlement discussions in light of my dismissal of Petitioner's Table claim, to determine if such an informal settlement can be reached.

[12] The condition or abnormality must qualify as an explanation for the symptoms a petitioner is experiencing, but need not be a better or more likely explanation. *Durham v. Sec'y of Health & Hum Servs.,* No. 17-1899V, 2023 WL 3196229, at *13-14 (Fed. Cl. Spec. Mstr. Apr. 7, 2023).

Conclusion

Petitioner has not established the onset of her left shoulder pain occurred within 48 hours of her receipt of the flu vaccine on October 23, 2018, and there exists another condition which would explain the symptoms Petitioner experienced. Accordingly, her Table SIRVA claim is DISMISSED.

Before I evaluate the merits of any off-Table claim, or decide that the case should be transferred out of SPU so expert opinions can be obtained, I will allow the parties an opportunity to continue their settlement discussions. Additionally, Petitioner may attempt to provide evidence to support a causation-in-fact or significant aggravation claim, such as a properly informed opinion of a treating physician. If Petitioner wishes to continue with her causation-in-fact claim, she will need to provide sufficient additional evidence to justify allowing the matter to go on.

That parties are hereby ORDERED to file a joint status report indicating whether they believe an informal resolution can be reached in this case and providing their preferred next step(s) in the case by Friday, August 14, 2023.

IT IS SO ORDERED.

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