

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 19-1463V

ELIZABETH LOUGHREN,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: September 6, 2023

Diana Lynn Stadelnikas, Maglio Christopher & Toale, PA, Sarasota, FL, for Petitioner.

Lynn Christina Schlie, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT¹

On September 23, 2019, Elizabeth Loughren 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 on October 26, 2016. Petition at 1-4. The case was assigned to the Special Processing Unit of the Office of Special Masters.

¹ Because this 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 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, I find that a preponderance of the evidence supports a finding that the onset of Petitioner's shoulder pain occurred within 48 hours of vaccination, that the residual effects of her condition continued for more than six months, and that Petitioner has satisfied the remaining requirements for entitlement.

I. Relevant Procedural History

On October 23, 2019, this case was activated (ECF No. 11). During the initial status conference on December 19, 2019, Respondent raised concerns about the statutory severity requirement, and Petitioner agreed to ascertain whether any additional medical records were available pertaining to this issue (ECF No. 14). On January 21, 2020, Petitioner confirmed that there were no additional medical records for 2017, the relevant time period (ECF No. 15).

On October 1, 2020, Respondent filed a status report requesting that Petitioner file worker's compensation records, if any claim was brought (ECF No. 20). Respondent also reiterated his concerns about severity, noting that Petitioner saw her primary care physician ("PCP") on March 14, 2017 (less than five months after vaccination), and there was no mention of shoulder pain. Respondent also stated that it may be necessary to retain experts to determine which, if any, of Petitioner's post-August 2017 shoulder symptoms or conditions are related to her SIRVA and which are from an August 2017 car accident.

On December 16, 2020, Petitioner filed Exhibits 7-9, including additional medical records and workers compensation records (ECF No. 21). On March 18, 2021, Respondent filed his Rule 4(c) Report opposing compensation (ECF No. 28). Following a status conference, Petitioner was directed to file additional records (ECF No. 29).

On November 19 and December 17, 2021, Petitioner filed Exhibits 10-17, containing additional medical records and declarations (ECF Nos. 34, 35). On February 1, 2022, Respondent stated that review of the additional evidence had not altered his position (ECF No. 38). On March 3, 2022, a status conference was held, during which the question of the severity requirement was again raised (ECF No. 39). The parties were directed to brief entitlement, and Petitioner was directed to file additional evidence (ECF No. 39).

On June 15, 2022, Petitioner filed a motion for a finding of fact, with a supporting memorandum, along with Exhibit 18, a letter from her PCP (ECF Nos. 43-45). Respondent responded on August 15, 2022 (ECF No. 46), and petitioner filed additional medical records and replied on September 6, 2022 (ECF Nos. 48, 49). The matter of Petitioner's entitlement to compensation is now 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 his 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 and the lack of other award or settlement,³ a petitioner must establish that 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 she received. Section 11(c)(1)(C). The Vaccine Act further includes a "severity requirement," pursuant to which a petitioner demonstrate that they:

- (i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the

³ In summary, a petitioner must establish that he received 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 and has not filed a civil suit or collected an award or settlement for her injury. Section 11(c)(1)(A)(B)(E).

vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention.

Section 11(c)(1)(D).

“[T]he fact that a Petitioner has been discharged from medical care does not necessarily indicate that there are no remaining or residual effects from her alleged injury.” *Morine v. Sec’y of Health & Human Servs.*, No. 17-1013, 2019 WL 978825, at *4 (Fed. Cl. Spec. Mstr. Jan. 23, 2019); *see also Herren v. Sec’y of Health & Human Servs.*, No. 13-1000V, 2014 WL 3889070, at *3 (Fed. Cl. Spec. Mstr. July 18, 2014) (“a discharge from medical care does not necessarily indicate there are no residual effects”). *See also Peebles v. Sec’y of Health & Human Servs.*, No. 20-0634V, 2022 WL 2387749 (Fed. Cl. Spec. Mstr. May 26, 2022) (finding severity requirement met where Petitioner sought care for four months, followed by fifteen month gap); *Silvestri v. Sec’y of Health & Human Servs.*, No. 19-1045V, 2021 WL 4205313 (Fed. Cl. Spec. Mstr. Aug. 16, 2021) (finding severity requirement satisfied where Petitioner did not seek additional treatment after the five month mark); *Schafer v. Sec’y of Health & Human Servs.*, No. 16-0593V, 2019 WL 5849524 (Fed. Cl. Spec. Mstr. Aug. 28, 2019) (finding severity requirement met where Petitioner’s last treatment was at five months and nine days after vaccination).

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:

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).

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

Although I have reviewed the entire record, this ruling contains only an overview of facts relating to the onset of Petitioner's symptoms, the severity requirement, and Petitioner's entitlement to compensation.

1. Medical Records

Petitioner received a flu vaccine in her left arm on October 26, 2016. Ex. 1 at 1. The vaccine was administered by the employee health division of Petitioner's employer, Bassett Medical Center, where she worked as a nurse manager. *Id.*; Ex. 9 at 37.

Nearly two months later, on December 19, 2016, Petitioner was seen by orthopedist Dr. Paul Klawitter. Ex. 2 at 5. She reported left shoulder pain that had been bothering her for about two months "since she received a vaccination in the shoulder." *Id.* The pain increased with certain movements like reaching across her body or overhead, and was worse at night. *Id.* She had been using over-the-counter medication and ice, without much relief. *Id.* On examination, her left shoulder range of motion was painful and she had positive Hawkins impingement signs. *Id.* at 7. Dr. Klawitter diagnosed Petitioner with left shoulder impingement and rotator cuff strain, and administered a steroid injection. *Id.* at 8. He recommended that she start with home physical therapy, and stated if she

was not improving in four to six weeks, he would consider formal physical therapy (“PT”) and/or a shoulder ultrasound or MRI. *Id.* at 8-9.

Two months later, on February 14, 2017, Petitioner was seen by her PCP Dr. Jennifer O’Reilly, and she reported left shoulder pain since October 2016. Ex. 2 at 10. Petitioner reported that on October 26th she had received her flu vaccine at work, and it was given high on her shoulder. *Id.* She had immediate shoulder pain, which was worsening. *Id.* She had tried ice and motrin, which took the edge off. *Id.* The steroid injection given by Dr. Klawitter “worked for a short period of time.” *Id.* She rated her pain as eight out of ten at worst, and stated that the pain was “significantly limiting her activities” and she was not able to lift her arm. *Id.* On examination, she exhibited decreased range of motion, tenderness, swelling, pain, and decreased strength in her left shoulder. *Id.* at 12. Dr. O’Reilly assessed her with a left shoulder injury and adverse effect of vaccine, noting that her shoulder pain was due to SIRVA. *Id.* at 13.

On March 14, 2017, Petitioner returned to Dr. O’Reilly for low back pain, leg pain, and menstrual problems. Ex. 2 at 14. She reported that she was doing a home exercise program daily with no improvement, explaining that there was no local PT available through her insurance company. *Id.* She reported limping due to a bad right knee. *Id.* This record otherwise does not mention left arm or shoulder pain, and does not document any shoulder examination. *Id.* at 14-16.

Five months later, on August 11, 2017, Petitioner was seen in her PCP’s office by nurse practitioner (“NP”) Hannah Doscher following a car accident experienced a day earlier. Ex. 2 at 17. Petitioner reported that she was hit from behind while stopped at a stop sign. *Id.* She did not experience immediate pain, but by the prior evening her neck and shoulders started feeling very stiff. *Id.* at 18. She reported that she now had pain at the base of her scalp, her posterior neck, and in between her shoulder blades. *Id.* She was diagnosed with a neck strain and given home exercises to do. *Id.* at 20-21.

Three days later (August 14), Petitioner saw Dr. O’Reilly. Ex. 2 at 21. She again reported that she was rear ended by another car on August 10th while driving between work locations. *Id.* Within hours of the accident, her neck and shoulders began to feel extremely stiff, and since then she had decreased range of motion in her neck that was worsening. *Id.* She reported “severe left shoulder pain since the accident” and that she “[f]elt a pop in the shoulder when gripping the wheel on impact.” *Id.* Her shoulder was swollen and felt weak, with her shoulder pain at nine out of ten at worst. *Id.* Her shoulder pain woke her at night, and was excruciating if she tried to lift her arm at all. *Id.* She reported pain at the base of her scalp, posterior neck, and between her shoulder blades, as well as in her left shoulder and upper back. *Id.* at 21-22. On examination, she had left shoulder pain with any passive movement, and the exam was limited due to pain. *Id.* at 24. The pain was located over the anterior shoulder and acromioclavicular joint. *Id.* She had significantly limited flexion and extension of her neck. *Id.* Dr. O’Reilly ordered a

shoulder MRI and prescribed Flexeril and Vicodin. *Id.* at 25. Dr. O'Reilly was concerned about the severity of Petitioner's left shoulder pain and weakness, noting that her acromioclavicular joint was under the seatbelt when the belt locked, and that forward motion against an arm braced against the wheel and against a locked seatbelt could cause AC joint separation, a rotator cuff tear, or a clavicle injury. *Id.*

Petitioner returned to Dr. O'Reilly three days later, on August 17th. Ex. 2 at 26. She was still experiencing neck pain at the base of her skull and chronic headaches. *Id.* She had been taking a muscle relaxer regularly, but was only able to take hydrocodone twice. *Id.* She rated her pain as six out of ten when medicated, and nine out of ten when the medicine wore off. *Id.* Her range of motion was improving but still limited. *Id.* Her shoulder pain had not improved at all, and her shoulder remained weak. *Id.* Dr. O'Reilly indicated Petitioner should stay off work for four more days, and that it was not safe for her to drive long distances. *Id.* at 29.

On August 20, 2017, Petitioner underwent a left shoulder MRI. Ex. 2 at 79-80. The MRI revealed minimal fluid in the subdeltoid bursa that could reflect some mild bursitis, but no rotator cuff tear or significant tendinopathy. *Id.* at 80.

On September 5, 2017, Petitioner returned to Dr. O'Reilly. Ex. 2 at 30. She continued to complain of neck and left shoulder pain. *Id.* Her neck pain was improving, but her shoulder pain was getting progressively worse. *Id.* Petitioner rated it as ten out of ten at worst. *Id.* Any motion, especially lifting the arm, aggravated the pain. *Id.* Her range of motion was worsening, and the pain was keeping her up at night. *Id.* On examination, Dr. O'Reilly noted Petitioner's left shoulder range of motion as significantly decreased, with pain and decreased strength. *Id.* at 33. Dr. O'Reilly referred Petitioner to an orthopedist and encouraged gentle range of motion exercises to prevent adhesive capsulitis from worsening. *Id.*⁴

On September 20, 2017, Petitioner reported to physician assistant ("PA") Stefanie Cassano. Ex. 2 at 34. The record indicates that she presented with "[l]eft shoulder problem since MVA 8-10-17." *Id.* She reported a pain level of at two out of ten at rest, and nine out of ten with movement. *Id.* She had two injections without benefit. *Id.* The record explains that Petitioner was "rear ended in August and suffered bad shoulder pain and decreased range of motion ("ROM"). PCP gave her a cortisone injection 2 weeks ago with no relief." *Id.* On examination, her ROM was limited by pain and she had positive Hawkins impingement results. *Id.* at 36. She was assessed with left shoulder pain and adhesive capsulitis of her left shoulder, and referred for physical therapy. *Id.* at 36-37.

⁴ It appears that Petitioner may have received a steroid injection at this visit. See Ex. 2 at 33 (treatment plan stating "[s]ee injection note"); Ex. 2 at 34 (PCP gave her a cortisone injection 2 weeks ago").

Petitioner continued to seek care for shoulder pain related to her car accident for the rest of 2017 and 2018, ultimately undergoing shoulder surgery on October 8, 2018. See Exs. 2 at 37-57; 14 at 8-21. She did post-operative PT starting on the day of her surgery, October 8, 2018, and continuing through March 19, 2019. Ex. 14 at 24-102. She continued to treat her left shoulder injury from her car accident through August 2020. Exs. 2 at 60-73; 5 at 3-26; 7 at 7-53; 8 at 4-11, 18-21. She subsequently sought care for *right* shoulder problems between November 2020 and April 2021. Exs. 10 at 9-51; 11 at 10-22; 12 at 5-7; 13 at 7.

2. Worker's Compensation Records

Petitioner filed a worker's compensation claim on February 24, 2017. Ex. 9 at 36-37. The form reports an injury occurring on October 26, 2016, when she received an immunization too high on her arm. *Id.* at 36. She alleged that she was now unable to lift her left arm to the side or over her head, and unable to hold weighted items with her left arm. *Id.* She had notified her employer of the injury on February 13, 2017, but had not missed work due to her injury. *Id.* at 37. She also indicated that Jamie Neis, RN and Denise Delvecchio, LPN had seen her injury happen. *Id.*

The records include a form titled "Doctor's Initial Report" dated March 9, 2017, and signed by Dr. Klawitter. Ex. 9 at 2-5. The injury date is recorded as October 26, 2016 and diagnoses were impingement syndrome of left shoulder and strain of muscle/tendon of the rotator cuff of the left shoulder. *Id.* at 2. The injury happened when she received a flu vaccine injection in her left shoulder. *Id.* at 3. An examination was done on December 19, 2016. *Id.* Dr. Klawitter opined that the incident the patient described was the medical cause of the injury. *Id.* at 4. He also agreed that Petitioner's complaints were consistent with her injury history, and that her history was consistent with his objective findings. *Id.* He assigned a temporary impairment rating of 15%. *Id.* He documented a plan of care consisting of a home exercise program and over the counter anti-inflammatory medications, and indicated that further educational materials were given. *Id.* He indicated that no diagnostic tests or referrals were needed, and that Ms. Loughren should return as needed. *Id.* at 5.

A form titled "Doctor's Progress Report" was included in the worker's compensation file. Ex. 9 at 11. It documents an examination by Dr. O'Reilly on February 14, 2017. Dr. O'Reilly noted diagnoses of unspecified injury of left shoulder and upper arm, and adverse effect of vaccines and biological substances. *Id.* Dr. O'Reilly indicated that Petitioner needed a left shoulder MRI. *Id.* at 12. She indicated that in her opinion the incident that Ms. Loughren described was the medical cause of the injury, and that Petitioner's complaints were consistent with the injury and the history was consistent with the objective findings. *Id.* She assigned a temporary impairment rating of ten percent. *Id.* She indicated that Petitioner exhibited decreased ROM in her left shoulder and left shoulder pain due to SIRVA. *Id.* Dr. O'Reilly added that Petitioner could work with

limitations including no lifting over ten pounds, no overhead activities, and no reaching. *Id.*

Dr. O'Reilly submitted a pre-approval request for a left shoulder MRI and physical therapy on February 23, 2017. Ex. 9 at 16-18. The form does not indicate that any action was taken on these requests.

It appears that the worker's compensation claim was denied on March 27, 2017. Ex. 9 at 48. The form indicates the denial was due to "No Causal Relationship (No Medical Evidence of Injury)." *Id.* It further states that there was a question whether the accident arose in and out of the course and scope of employment, and noted the claim was untimely filed. *Id.*

3. Affidavit and Declarations

Petitioner filed an affidavit and three declarations in support of her claim. Exs. 4, 15, 16, 17. Petitioner states that she received the October 26, 2016 flu shot at an employee flu clinic. Ex. 15 at ¶ 1. It caused immediate pain down her left arm, and that two other nurses present commented that it looked to have been administered high on her arm. *Id.* She went to Dr. O'Reilly's office to show her what had happened and was instructed to keep an eye on it. *Id.* at ¶ 2. Two weeks later it was still painful and restricting her ability to move her arm to the side. *Id.* at ¶ 3. She again went to Dr. O'Reilly, who told her it was important to keep using her arm as much as possible so that she did not develop frozen shoulder. *Id.* She also reported the injury to her operational manager and clinical director. *Id.*

As time went on her arm worsened, and moving it out to the side was "nearly impossible at times." *Id.* at ¶ 4. Dr. O'Reilly thought she had SIRVA that may have caused a frozen shoulder, and explained that this involves a process of freezing and thawing. *Id.* at ¶ 6. Dr. O'Reilly said that her understanding was that this process was not lessened by physical therapy or injections, and the best course was to keep using it as much as possible, and do some daily exercises. *Id.* Petitioner continued to self treat with a warm shower, exercise, and ice, and tried to use her arm as normally as possible. *Id.* at ¶ 7.

In December 2016, she was working in a different medical clinic. Ex. 15 at ¶ 8. The nursing manager said she was tired of watching Ms. Loughren struggle, and that the orthopedist, Dr. Klawitter, had an opening. *Id.* Petitioner then saw Dr. Klawitter, who told her there were mixed reviews on injections and physical therapy, but that she needed to do something to function better. *Id.* He gave her an injection and said that physical therapy wouldn't hurt, but he was not sure it would help either. *Id.* Dr. Klawitter told her he would not be able to follow up with her because he was leaving the organization. *Id.*

Petitioner continued to struggle on a daily basis but felt nothing was going to change her course, so she used her arm as much as possible, took ibuprofen, and pushed through. Ex. 15 at ¶ 9. On multiple occasions she spoke with Dr. O'Reilly, who continued

to encourage her to use her arm as much as possible.⁵ *Id.* at ¶ 10. The injection from Dr. Klawitter did not help, and “by March my arm didn’t move at all.” *Id.* The pain was located in the outside of her arm where the deltoid muscle is, which hurt even at rest, and the remainder of her arm, armpit, and trapezius hurt with any movement. *Id.* at ¶ 11. She continued to live with the frozen shoulder, doing her exercises as much as possible and praying. *Id.* at ¶ 12. She was on the schedule to “officially” be seen by Dr. O’Reilly on multiple occasions, but gave up the appointments for people who were sick, explaining that “we were extremely low on appointments.” *Id.*

After the car accident in August of 2017, her shoulder hurt in a different area, in the front of the arm where the joint meets the collar bone. Ex. 15 at ¶ 13. At that point, she could not move her shoulder or neck to do the exercises Dr. O’Reilly had given her. *Id.* She stated that her shoulder “hasn’t moved properly since October 26, 2016.” *Id.* at ¶ 14. While the new shoulder and neck pain from the car accident “didn’t help,” the problem began with the flu vaccine injection. *Id.*

Ramona Jackson submitted a declaration in support of Petitioner. Ex. 16. Her signature indicates that she is a registered nurse and has additional degrees. *Id.* She averred that on October 28, 2016 she witnessed Ms. Loughren “in a considerable amount of pain in her left shoulder.” *Id.* at ¶ 1. While working together, Ms. Jackson noticed that “it was very apparent she had difficulty using her arm and stated that moving it out to the side is unbearable.” *Id.* at ¶ 2.

Jamie Neis Potter submitted a declaration on Petitioner’s behalf. Ex. 17. Ms. Neis Potter explained that she did not observe the October 2016 flu vaccine being administered,⁶ but did see the mark, or hole, at the injection site afterwards. *Id.* at ¶ 1. She averred that the “injection site was noticeably, clearly above the deltoid muscle where intramuscular injections are typically administered and was too high a site for IM [intramuscular] injection.” *Id.* She added, “Elizabeth has complained of pain at the site every day since this occurred. She has also experienced decreased range of motion to the affected shoulder.” *Id.* at ¶ 2. Ms. Potter recalled also witnessing Ms. Loughren’s “inability to raise [the] affected arm and complaining of pain.” *Id.* at ¶ 3

4. Letter of Petitioner’s PCP, Dr. Jennifer O’Reilly

Petitioner’s PCP, Dr. O’Reilly, submitted a letter dated June 14, 2022 relating to Petitioner’s injuries. Ex. 18. Dr. O’Reilly reported that she had seen Ms. Loughren on

⁵ In her memorandum in support of the motion for a ruling on the record, Petitioner explained that she worked as a registered nurse at Bassett Medical Center with and alongside her PCP, Dr. O’Reilly. Petitioner’s Memorandum, filed June 15, 2022, at *4 (ECF No. 45).

⁶ Jamie Neis was listed on the worker’s compensation form as someone who had seen the injury happen. Ex. 9 at 37. Thus, there appears to be some tension between Petitioner’s recollection of the vaccination and Ms. Neis Potter’s.

February 14, 2017 for shoulder pain that began after her flu vaccine was given high in the shoulder into the shoulder joint. *Id.* at 1. Ms. Loughren had immediate pain. *Id.* She treated with ice and motrin, with mild relief. *Id.* She had received a steroid injection from an orthopedist in December 2016, and the relief from that lasted “a few weeks at most.” *Id.* She did home exercises, but continued to experience a sharp stabbing pain, mainly with ROM, at a maximum of eight out of ten. *Id.* The pain was significantly limiting her activities. *Id.* Dr. O’Reilly’s examination showed that Petitioner had a frozen shoulder, and that Petitioner’s symptoms and onset after vaccination into the joint were consistent with SIRVA. *Id.* Because no local PT services were available with her insurance, she continued home exercises. *Id.*

Dr. O’Reilly ordered an MRI, which was cancelled by radiology on March 8, 2017 due to scheduling conflicts. Ex. 18 at 1. Dr. O’Reilly explained that she noted Petitioner “on a daily basis to have symptoms of frozen shoulder – arm remained flexed at elbow and slightly extended at shoulder, she was unable to reach forward or abduct at the shoulder past 80 degrees, and she performed all tasks with her right arm.” *Id.* Her coworkers referred to her as “T Rex” due to her inability to extend or abduct at the shoulder. *Id.* Importantly, Dr. O’Reilly adds, “[t]hese symptoms continued until her follow-up appointment in August.” *Id.* (emphasis added).

Dr. O’Reilly also recounted the medical treatment associated with the August 10, 2017 car accident, and stated that at that time “[s]he [Ms. Loughren] had not regained function in her shoulder and had continued to have a frozen shoulder since the initial injury from the vaccine in 9/2016.”⁷ Ex. 18 at 2. Dr. O’Reilly adds that Ms. Loughren “was noted at work by this provider to have continued shoulder symptoms up to the accident.” *Id.*

C. The Parties’ Arguments

Petitioner argues that her left shoulder pain began immediately after vaccination, citing Exs. 2 at 5, 10; 9 at 2-4; 15 at 1-2; 16, 17, 18. Petitioner’s Memorandum, filed June 15, 2022, at *9 (ECF No.45) (“Mem.”). Petitioner argues that her first medical visit, nearly two months after vaccination, “is not inconsistent with finding the onset of immediate pain.” *Id.* at *13.

Concerning the severity requirement, Petitioner asserts that when viewed as a whole, the medical record supports a finding that the sequelae of Petitioner’s vaccine-related injury lasted longer than six months. Mem. at *13. The residual effects of her injury continued between February and August 2017, citing in support the letter submitted by her treating physician, Dr. O’Reilly, Exhibit 18. *Id.* Petitioner acknowledges that her

⁷ I interpret “9/2016” as referring to the October 26, 2016 flu vaccination, with Dr. O’Reilly mistakenly recalling the month it was administered.

shoulder injury “was complicated by the motor vehicle accident, but this injury does not negate or contradict the symptomatology from the SIRVA injury.” *Id.*

In support of her arguments, Petitioner argues that “the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance.” Mem. at *7 (*citing Murphy v. Sec’y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff’d* 968 F.2d 1226 (Fed. Cir. 1992), *cert. denied*, 113 S. Ct. 263 (1992)). Petitioner argues that the Federal Circuit reaffirmed this principle recently in *Kirby*, 997 F.3d 1383. Petitioner also asserts that the Vaccine Act “does not require that a petitioner suffer consistent symptoms throughout the six-month period post-vaccination,” citing a recent decision finding that a temporary lack of symptoms did not preclude a petitioner from meeting the severity requirement. Mem. at *9 (*citing Begay v. Sec’y of Health & Human Servs.*, No. 20-0494V, 2021 WL 4165028 (Fed. Cl. Aug. 12, 2021)).

Respondent argues that there is insufficient evidence that Petitioner’s SIRVA-related symptoms persisted for more than six months. Respondent’s Response to Petitioner’s Motion, filed Aug. 15, 2022, at *12 (ECF No. 46) (“Resp.”). Respondent emphasizes that the last record documenting ongoing SIRVA symptoms was her February 14, 2017 appointment with Dr. O’Reilly. *Id.* Petitioner did not raise any left shoulder problems at her March 14, 2017 visit. *Id.* Petitioner has not explained the discrepancy between the March 14, 2017 record’s silence on shoulder pain and her declaration stating that by March 2017 her arm “did not move at all.” *Id.*

Respondent notes that the declarations from Ms. Jackson and Ms. Potter are lacking in detail as to the duration of Petitioner’s shoulder pain. Resp. at *13. Respondent adds that Ms. Potter’s statement that Petitioner complained of pain “every day” since her vaccination in 2016 “is confusing considering the records reflect that petitioner moved to Florida in 2020.” *Id.* at n.3.

Respondent further argues that Dr. O’Reilly’s June 2022 letter was prepared more than five years after the March 2017 visit, and is further signed but unsworn. Resp. at *13 (deeming the letter “remarkably lacking in detail, likely because the letter was authored five years later”). Dr. O’Reilly does not explain the March 14, 2017 visit, and offers no further explanation or insight on whether Petitioner’s shoulder ailments after her August 2017 accident were in any way related to her SIRVA. *Id.* at *14. While Dr. O’Reilly states that Petitioner had not regained function in her shoulder and had continued to have a frozen shoulder since the flu vaccine, Respondent argues that because “the letter was prepared five years later for purposes of litigation and . . . is not supported by the contemporaneous medical records,” Dr. O’Reilly’s unsworn statement should be given less evidentiary weight. *Id.*

Respondent further argues that Petitioner’s shoulder pain following her August 2017 car accident is not related to her vaccination. Resp. at *14. After the car accident,

Petitioner's pain was different in nature, and presented in conjunction with other new complaints. *Id.* Respondent contends that Petitioner's arthroscopic surgery and manipulation under anesthesia were due to injuries from her car accident, and adds that this procedure does not satisfy the severity requirement because it was done on an outpatient basis. *Id.* at *18 n.4.

Respondent concludes that the medical records also do not establish that Petitioner suffered SIRVA as defined by the Table. Resp. at *18-19. And Petitioner did not report any shoulder related pain to a healthcare provider until December 19, 2016, 54 days after vaccination, and thus the records do not support a finding that the onset of her pain was within 48 hours of vaccination. *Id.* at *19.

In reply, Petitioner reiterates that in her view, the absence of references to sequela is not the same as records negating the condition. Petitioner's Reply, filed Sept. 9, 2022, at *1 (ECF No. 49) ("Reply"). *Kirby* recognized that "petitioners may simply stop talking about long-standing injuries to their doctors, either because they believe that nothing else can be done for them or because the visit is focused on a different condition." Reply at *3. The fact that a petitioner has been discharged from medical care "does not necessarily indicate that there are no remaining or residual effects from his or her alleged injury." *Id.* at *4 (citing *Herren v. Sec'y of Health & Human Servs.*, No. 13-1000V, 2014 WL 3889070, at *3 (Fed. Cl. Spec. Mstr. July 18, 2014)).

Petitioner also argues that her treating physician and employer provided a personal statement regarding her observations of Petitioner. Reply at *2. Petitioner states that Dr. O'Reilly has nothing to gain from providing this statement, and was in a direct and relevant position to make these observations. *Id.*

Petitioner acknowledges, however, that her shoulder pain following her August 2017 car accident was different from that beforehand. Reply at *2. Petitioner suggests that to the extent that any sequelae are not related to her SIRVA, this would be resolved in the damages phase. *Id.* at *5.

Finally, concerning onset, Petitioner argues that "one cannot reasonably expect that treating physicians would include precise onset information relevant only to this legal proceeding – that the onset occurred specifically within 48 hours of vaccination." Reply at *5 (citing *Goldman v. Sec'y of Health & Human Servs.*, No. 16-1523V, 2020 WL 6882186, at *15-16 (Fed. Cl. Nov. 2, 2020)). Petitioner cites *Niemi v. Sec'y of Health & Human Servs.*, No. 19-1535V, 2021 WL 4146940, at *4 (Fed. Cl. Spec. Mstr. Aug. 10, 2021), as "[a]nother example of Respondent's unreasonable litigative positions." Reply at *6. In *Niemi*, I stated that the Vaccine Act "clearly does *not* require that symptoms be recorded within a specific timeframe to be preponderantly established. Rather, it requires only that onset *occurs* in the relevant timeframe." *Niemi*, 2021 WL 4146940 at *4.

D. Factual Finding Regarding QAI Criteria for Table SIRVA

1. Onset

A preponderance of record evidence supports the conclusion that onset of Petitioner's shoulder pain more likely than not occurred within 48 hours of vaccination. The record establishes that when Petitioner was first seen by Dr. Klawitter just under two months after vaccination, she reported that her shoulder pain had been bothering her for about two months *since* her vaccination. Ex. 2 at 5. She then saw her PCP two months later, and again reported *immediate* shoulder pain after a flu vaccine given high on her shoulder. Ex. 2 at 10. Dr. O'Reilly assessed her with a shoulder injury and adverse effect of a vaccine and noted that her shoulder pain was due to SIRVA. *Id.* at 13. The fact that these instances did not occur more contemporaneously with vaccination does not undermine their consistency, or provide a basis to find that the reported onset is not likely accurate.

These records are consistent with Petitioner's declaration stating that she had "immediate pain" after vaccination. Ex. 15 at ¶ 1. In addition, Ms. Jackson declared that she witnessed Petitioner in left shoulder pain on October 28, 2016 (two days after vaccination), while Ms. Neis Potter stated that Petitioner had complained of pain daily since vaccination. Exs. 16 at ¶ 1; 17 at ¶ 2.

2. Other SIRVA QAI Criteria

The remaining SIRVA criteria are not contested, and are also satisfied by a preponderance of the evidence. Petitioner did not have either a history of pain, inflammation, or dysfunction of her left shoulder, or any other condition or abnormality, that would explain her condition after vaccination. *See generally* Ex. 2. Petitioner's pain and reduced ROM were limited to the shoulder in which the vaccine was administered. *Id.*

E. Severity Requirement

The record also supports – albeit closely – the conclusion that the residual effects of her condition continued for more than six months.

Petitioner first sought care nearly two months after vaccination, and then again sought care two months later, four months after vaccination. At the five month mark, she saw her PCP and did not report any left shoulder problems. This treatment history alone underscores that this was overall a mild SIRVA.

The record of subsequent treatment is thin, but two pieces of evidence tip the scale *slightly* in Petitioner's favor. First, the worker's compensation record indicates that Dr. O'Reilly sought approval for a left shoulder MRI and PT in late February 2017, four months after vaccination. Ex. 9 at 16-18. Second, Dr. O'Reilly's letter confirms, based on the doctor's personal observations, that Ms. Loughren's left shoulder symptoms continued

through the time of her August 2017 car accident, and in this interval she had not regained function in her shoulder from the vaccine injury. Ex. 18 at 1-2. Together, these records demonstrate that at the four month mark, Petitioner was still symptomatic enough to make additional diagnostic testing and treatment appropriate. Because Petitioner worked in a clinic with Dr. O'Reilly (a physician), Dr. O'Reilly was in a unique position to observe the condition and function of Petitioner's shoulder on a regular basis, and thus to provide information on Petitioner's condition.

I acknowledge that Dr. O'Reilly's letter was dated five years after the events in question and is not sworn. For these reasons, it is entitled to somewhat less weight than it otherwise would be. However, it is corroborated by the worker's compensation records and other evidence.

Petitioner's assertion that by March 2017 her arm "didn't move at all" (Ex. 15 at ¶ 10) is somewhat incongruous with lack of any mention of shoulder pain in the March 14, 2017 appointment record (Ex. 2 at 14). However, Petitioner correctly points out that intermittent relief from symptoms does not preclude a finding that the severity requirement is met.

Overall, this record allows the conclusion that Petitioner's SIRVA-associated symptoms persisted more than six months post-vaccination, despite the trailing off of active treatment at the four to five-month mark. However, although the record contains ample evidence of subsequent treatment associated with her August 2017 car accident, I do *not* find that pain and other symptoms she experienced thereafter can be attributed to the SIRVA. While the claim does not founder on severity, it is also plainly not a particularly "severe" SIRVA – and damages sought must reflect this. I am highly unlikely to find on this record that Petitioner's post-accident treatment bears at all on damages, and therefore Petitioner must take this into account in making any settlement demand.

F. 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 1. She averred that she has not previously collected an award or settlement of a civil action for damages for her vaccine-related injury. Ex. 4 at ¶ 4.

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 within 48 hours of vaccination and that the residual effects of her condition continued for at least six months. 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**.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Chief Special Master