In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 20-873V
Filed: October 16, 2023

ELAINE MONTANA,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Master Horner

Ronald Craig Homer, Conway, Homer, P.C., Boston, MA, for petitioner.
Matthew Murphy, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT[1]

On January 12, 2021, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10, *et seq.* (2012),[2] alleging that she suffered the Table Injury of Shoulder Injury Related to Vaccine Administration ("SIRVA") in her left shoulder following an influenza ("flu") vaccination that she received on November 21, 2017. (ECF No. 1.) For the reasons set forth below, I conclude that petitioner is entitled to compensation for her alleged Table Injury.

I. Applicable Statutory Scheme

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In

[1] Because this document 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 document 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] Within this decision, all citations to § 300aa will be the relevant sections of the Vaccine Act at 42 U.S.C. § 300aa-10, *et seq.*

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general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. § 300aa-11(c). Finally – and the key question in most cases under the Program – the petitioner must also establish a causal link between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination, which is also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. *See* § 300aa-13(a)(1); § 300 aa-11(c)(1)(C)(i); § 300aa-14(a).

As relevant here, the Vaccine Injury Table lists a SIRVA as a compensable injury if it occurs within 48 hours of vaccine administration. *See* § 300aa-14(a), *amended by* 42 CFR § 100.3. Table Injury cases are guided by statutory "Qualifications and aids in interpretation" ("QAIs"), which provide more detailed explanation of what should be considered when determining whether a petitioner has actually suffered an injury listed on the Vaccine Injury Table. 42 CFR § 100.3(c). To be considered a "Table SIRVA," petitioner must show that her injury fits within the following definition:

> 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 . . . . 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 CFR § 100.3(c)(10).

Vaccine Program petitioners must establish their claim by a "preponderance of the evidence." § 300aa-13(a). That is, a petitioner must present evidence sufficient to show "that the existence of a fact is more probable than its nonexistence." *Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). However, a petitioner may not receive a Vaccine Program award based solely on her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. *See* § 300aa-13(a)(1). Once a petitioner has established their *prima facie* case, the burden then shifts to respondent to prove, also by preponderant evidence, that the alleged injury was caused by a factor unrelated to vaccination. *Althen v. Sec'y of Health & Human Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005); § 300aa-13(a)(1)(B).

II. Procedural History

This case was initially assigned to the Special Processing Unit ("SPU") on August 21, 2020. (ECF No. 14.) Petitioner filed her medical records between July of 2020 and May of 2021. (ECF Nos. 6-8, 16, 23; Exs. 1-24, 28-38.) During that time, she also filed affidavits by herself and Mark Maugans, with whom she has lived for over twenty years. (ECF No. 9; Exs. 25-27.) While the case was in the SPU, the parties attempted settlement, but were unable to resolve the case. Respondent filed his Rule 4 Report on August 2, 2022. (ECF No. 39.) Respondent primarily challenged petitioner's Table Injury claim of SIRVA on the basis of timing of onset. He also indicated that an alternative cause-in-fact claim was unsupported. (*Id*. at 9-13.)

The case was reassigned to the undersigned on January 9, 2023. (ECF Nos. 44.) After the case was reassigned, I instructed the parties to advise as to any further steps they wished to take to develop the record. Thereafter, petitioner filed additional evidence, consisting of witness statements and several letters, marked as Exhibits 39-44. (ECF Nos. 46-49.) Petitioner then filed a motion for a ruling on the written record on April 10, 2023. (ECF No. 51.) The motion primarily addressed onset of her condition; however, because she contended onset was the only issue raised in respondent's Rule 4 Report, petitioner also requested a finding that she is entitled to compensation for SIRVA. (*Id*. at 3, n.3.) Respondent filed a response to the motion on June 22, 2023. (ECF No. 53.) Respondent confirmed that he does not oppose a ruling on the written record; however, he cross-moves for a ruling dismissing the petition. (*Id*. at 1.) Petitioner filed a reply on July 11, 2023. (ECF No. 54.)

In light of the above, I have determined that the parties have had a full and fair opportunity to present their cases and that, given the parties' assent, it is appropriate to resolve entitlement on the existing record. *See* Vaccine Rule 8(d); Vaccine Rule 3(b)(2); *see also Kreizenbeck v. Sec'y of Health & Human Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020) (noting that "special masters must determine that the record is comprehensive and fully developed before ruling on the record"). Accordingly, this matter is now ripe for resolution.

III. Factual History

a. As Reflected in the Medical Records

Petitioner's prior medical history includes the following conditions: breast cancer, a benign tumor of the right bronchus and lung, chronic obstructive pulmonary disease ("COPD"), injury to the brachial plexus of her right shoulder, right shoulder rotator cuff tear, a left foot and ankle fracture, empyema, asthma, gastroesophageal reflux disease ("GERD"), lymphedema, and trigger finger of the left thumb. (*See* Exs. 2-7, 10, 13-15, 18, 20-22, 31, 35.) On November 21, 2017, petitioner received the subject flu vaccine at her annual wellness visit. (Exs. 1, p. 1; 10, p. 28.)

On November 30, 2017, petitioner saw Dr. Madhu Chaudhry for an oncology follow up appointment. (Exs. 2, p. 9; 20, p. 38.) During this visit, she did not report any shoulder pain. Her musculoskeletal physical exam was limited to noting "[n]o inflammation or deformity of the joints" with extremities further noted as "[w]arm, well-perfused, no lower extremity edema." (Ex. 2, p. 11.) On the same day, petitioner saw Dr. Neri M. Cohen, a cardiovascular and thoracic surgeon, for a follow up regarding her carcinoid tumor. (Exs. 4, p. 47; 35, p. 278.) She reportedly denied having any pain symptoms broadly. (Ex. 4, p. 48.) Petitioner's physical exam noted that she could not raise her arm beyond 180 degrees; however, the record does not specify which arm. (*Id*. at 51.)

On December 27, 2017, petitioner saw Dr. Paul J. Meissner, Jr., a podiatrist, for a vasospastic episode where all her toes were cyanotic and cold to the touch. (Ex. 9, p. 5.) She was diagnosed with vasospastic disease, and Dr. Meissner recommended applying 20% urea cream and taking aspirin to improve blood flow. (*Id.* at 6.) Petitioner, again, did not mention any shoulder pain at this appointment. No physical exam was recorded beyond noting xerosis of her skin and a corn on her toe. (*Id*. at 5.) On January 10, 2018, petitioner had a follow up appointment for her asthma with Dr. Marie D. Chatham, a pulmonologist. (Exs. 3, p. 20; 35, p. 274.) She again did not mention any shoulder pain. Her physical exam was limited to noting that her extremities were "warm without clubbing, cyanosis, or edema." (Ex. 3, p. 23.)

Petitioner's medical records show that she first mentioned her left shoulder pain during an appointment with PA-C Ana Beard and Edward George McFarland, M.D., on February 16, 2018. (Ex. 5, p. 73-75.) During this appointment, PA-C Beard noted that petitioner reported she began having pain and stiffness in her left shoulder following her flu shot.[3] (*Id.* at 73.) During this appointment petitioner reported that "[s]he had the usual soreness for a couple of days, but then the pain persisted and became much more severe. Her arm started to feel weak and she was not able to do simple daily activities." (*Id.*) (This history also states that petitioner stopped working due to her shoulder pain; however, petitioner has filed other evidence refuting that notation.) PA-C

[3] In the medical records, PA-C Beard's notes incorrectly report that petitioner received the flu vaccine in October, not November. (Ex. 5, p. 73.) This error appears to have originated from petitioner's own handwritten intake form. (*Id*. at 77.)

Beard recommended an updated MRI of both shoulders, physical therapy, and a "Medrol Dosepak." (*Id.* at 74.) In light of her prior history of right shoulder dysfunction, she was assed as having "bilateral shoulder pain," despite specifically having presented for care for left shoulder pain that was identified as a "new problem." (*Id*. at 73-74.)

On February 22, 2018, petitioner had an MRI of her right shoulder without contrast. (Ex. 5, p. 88.) The MRI showed evidence of a partial tear. (*Id.*) On this same day, petitioner also had an MRI of her left shoulder without contrast. (*Id.* at 90.) This MRI showed "evidence of a small focal insertional tear involving the supraspinatus tendon" and a "partial tear involving the infraspinatus tendon." (*Id.* at 90-91.) On February 26, 2018, PA-C Beard discussed the results of petitioner's MRI. (*Id.* at 129.) She reported to petitioner that petitioner did not have a tear in her right shoulder but did have a small full thickness tear in her left shoulder. (*Id.*)

On that same day, petitioner saw Nicole M. Blake, PT, to begin physical therapy for her left shoulder. (Ex. 21, p. 3.) Petitioner reported increased pain with doing her hair, carrying things, and getting dressed. (*Id.*) She also reported more than four disturbances a night due to her increased pain. (*Id.*) Petitioner reported her pain was 1/10 at this appointment and 8/10 at its worst. (*Id.*) Petitioner was able to reach above her head but had increased pain when reaching around her back. (*Id.*) PT Blake notes that petitioner reported pain and stiffness in her left shoulder following her November 2017 flu shot. (*Id.*) She continued physical therapy through October of 2018, showing improvement. (*Id.* at 12-121.)

On April 2, 2018, petitioner saw James P. Higgins, M.D., for trigger thumb in her right hand and chronic carpal tunnel syndrome in her left hand. (Ex. 6, p. 12.) Dr. Higgins gave her a cortisone shot. (*Id.*) Petitioner saw PA-C Beard for a follow up on her bilateral shoulder pain on April 13, 2018. (Ex. 5, pp. 96, 138.) It was noted that petitioner was improving and continued physical therapy was recommended. (*Id.* at 97, 138.) Neither surgery nor any therapeutic injection was considered necessary at that time. (*Id.* at 97.)

On April 19, 2018, petitioner saw CRNP Megan Wood for a pre-operative appointment before an endoscopic carpal tunnel release procedure on her left arm to relieve some of her carpal tunnel symptoms. (Ex. 35, p. 261.) Petitioner reported "'frozen shoulder' of the left side due to vaccine she received in Nov[ember] 2017." (*Id.*) Petitioner noted that she had been improving slowly with physical therapy. (*Id.*)

Petitioner saw Dr. Higgins on May 7, 2018. (Ex. 6, p. 10.) During this appointment, she complained of pain in the ulnar boarder of her right wrist. (*Id.*) Dr. Higgins concluded this is a sign of carpal tunnel syndrome. (*Id.*) After discussing various treatment options, petitioner decided to proceed with a nerve conduction study. (*Id.*) On May 15, 2018, petitioner saw Lynn Staggs, M.D., at the referral of Dr. Higgins for an electrodiagnostic consultation. (*Id.* at 13.) Dr. Staggs confirmed Dr. Higgins' diagnosis of carpal tunnel syndrome and found "no evidence of left acute cervical radiculopathy, nor ulnar compression." (*Id.* at 15.)

On July 20, 2018, petitioner saw PA-C Beard to discuss a complete tear of her rotator cuff in her left shoulder. (Ex. 5, p. 179.) PA-C Beard recommended petitioner continue physical therapy and return for a repeat MRI in three months. (*Id.*)

On September 11, 2018, petitioner had an initial evaluation with CRNP David Kitchen at the Greater Baltimore Lymphedema Center. (Ex. 35, p. 234-41.) CRNP Kitchen noted that petitioner was diagnosed with SIRVA in her left shoulder following her flu shot in 2017. (*Id.* at 235.) He noted that petitioner had recently experienced decreased range of motion in her left arm. (*Id.*) Petitioner described that 10 days earlier she began experiencing swelling in her left chest and arm. (*Id.*) CRNP Kitchen diagnosed petitioner with cellulitis of the chest wall and lymphedema of her left upper extremity, and he recommended that petitioner would benefit from decongestive therapy and told petitioner to wear compression garments as instructed. (*Id.* at 240-41.) Petitioner began occupational therapy with OT Michelle R. Frazier for her lymphedema on September 13, 2018. (*Id.* at 227-35.) It was noted that petitioner had a moderate amount of soft swelling in her chest and left breast. (*Id.* at 230.) OT Frazier recommended that petitioner continue occupational therapy two times a week for 12 weeks. (*Id.* at 232.)

Thereafter, petitioner continued both her physical therapy and her occupational therapy throughout September and into October. On September 17, 2018, petitioner had both physical therapy for her arm and occupational therapy for her lymphedema. (Exs. 21, p. 106; 35, p. 223.) During her physical therapy appointment, it was noted that petitioner presented "with mild loss of motion and increase in shoulder stiffness following cellulitis/lymphedema" and a further one to two more sessions was recommended to improve symptoms. (Ex. 21, p. 109.) Petitioner was ultimately discharged from physical therapy on October 16, 2018. (*Id.* at 115-19.) The focus of petitioner's occupational therapy with OT Frazier was drainage and compression garments. (Ex. 35, pp. 225-26.)

On October 26, 2018, petitioner received an MRI of her left shoulder, which revealed no evidence of a rotator cuff tear but did reveal mild osteoarthritis. (Exs. 19, pp. 7-8; 24, pp. 16-17.) PA-C Beard noted the rotator cuff tear had not changed, but "a little bit more" arthritis was present. (Ex. 28, p. 67.) Surgery was still not indicated. On January 9, 2019, petitioner saw PA-C Beard for a further evaluation of her left shoulder. (Ex. 28, p. 40.) She noted that petitioner was using a "non gradient lymphedema pump" called LymphoPress to treat her lymphedema. (*Id.*) Petitioner reported that since she started using the pump, she has experienced a flare of her left rotator cuff symptoms. (*Id.*) On January 11, 2019, petitioner followed up with CRNP Kitchen. (Ex. 35, p. 155.) Petitioner reported that using the pump caused her "severe, sometimes excruciating, pain, especially on [her] wrist, where [she has] carpal tunnel, and worse, on [her] injured shoulder." (*Id.* at 156.) CRNP Kitchen instructed patient to stop using the pump and switched her to a Flexitouch pump. (*Id.* at 163.)

After reporting the exacerbation of her shoulder pain, petitioner went back to physical therapy on January 28, 2019. (Ex. 21, p. 122.) Petitioner went to physical therapy again on January 30, February 6, February 13, February 18, and February 25, 2019. (*Id.* at 129-43.) On February 26, 2019, petitioner saw CRNP Kitchen for a follow up. (Ex. 35, 135.) Petitioner reported that she had been using her compression clothing more frequently. (*Id.* at 137.) In addition, petitioner was fitted for her Flexitouch pump. (*Id.* at 138.) Petitioner continued to attend physical therapy for her shoulder once a week throughout the month of March. (Ex. 21, p. 144-57.) She was discharged on April 8, 2019. (*Id.* at 160-63.)

Petitioner had a follow up appointment with CRNP Kitchen on July 2, 2019. (Ex. 35, p. 114.) She reported that her lymphedema is "well controlled." (*Id.* at 119.) She was instructed to continue wearing compression garments and using the Flexitouch pump. (*Id.*) On July 18, 2019, petitioner saw PA-C Beard for chronic pain in both shoulders. (Ex. 24, p. 21.) An x-ray of both shoulders showed no fracture or dislocation of either shoulder, but moderate osteoarthrosis in both shoulders. (*Id.* at 26; Ex. 28, p. 9.)

Petitioner saw PA-C Beard on September 30, 2020, for a follow up evaluation of her chronic bilateral shoulder pain. (Ex. 37, p. 145.) She reported at this time that her right shoulder was worse. (*Id.*) On October 10, 2020, petitioner underwent an MRI that showed a small tear in her right shoulder and bicep muscle. (Ex. 32, p. 2; Ex. 37, pp. 114, 134.) Petitioner attempted to treat these tears through physical therapy throughout October 2020 until January 2021. (Ex. 38, pp. 14-72.) On January 19, 2021, petitioner saw Phillip Stetler, D.O., and Dr. MacFarland who recommended surgery to repair these right shoulder tears. (Ex. 37, p. 46-48.)

b. As Reflected in the Affidavits

i. Elaine Montana

Petitioner submitted two affidavits. (ECF Nos. 9-1, 47 (Exs. 25, 40).) Petitioner worked as a nurse in geriatric and rehab units, usually with patients suffering from dementia, for 40 years. (Ex. 25, ¶ 4.) She notes that this work required "intense physical exertion, balance and upper body strength i.e., heavy lifting and transferring of patients and supplies, using both arms to lift, upper body mobility and agility, and reaching overhead and balancing while squatting." (*Id.*)

In her first affidavit, petitioner started by describing some of her medical history. (Ex. 25.) She describes herself as "in relatively good health" from November 2014 to November 2017. (*Id.* ¶ 1.) She states that she "stayed active, fit, and able to perform [her] job responsibilities through aerobic and weight training exercise, by swimming and by doing the physical labor needed to maintain [her] home." (*Id.* ¶ 4.) She describes how she had a prior history of brachial plexus in her right shoulder and developed frozen shoulder on her right side after a surgery in 2013. (*Id.* ¶ 1.) She notes that, before this incident, she always had full use of her left hand and arm, and that she

became more dependent on her left arm after she developed frozen shoulder on her right side. (*Id.*) Her frozen shoulder began to improve in 2015. (*Id.*)

Since 2017, petitioner describes seeing various physicians, including her primary care physician; an oncologist for stage one breast cancer; a surgeon to remove a benign growth in her lung; a pulmonologist, an allergist, and an otolaryngologist for asthma, allergies, and reactive upper airway issues; an orthopedic specialists for a stress fracture in her left foot and for trigger thumb; a gynecologist; and a podiatrist. (*Id.* ¶ 2.) She notes that she was involved in a car accident in 2012 but had since resumed all normal activities. (*Id.*) She states that she has always "attended the necessary preventative and follow up care visits and [has] complied with prescribed self-care." (*Id.* ¶ 3.)

Petitioner reports that she received a flu vaccine in her left arm at her annual checkup on November 21, 2017. (*Id.* ¶ 5.) She describes a "mild soreness at the injection site" following her vaccination. (*Id.*) "In the days following the injection, [she] noticed the mild soreness had progressed." (*Id.* ¶ 6.) She states that this soreness became a more "noticeable pain" and began to "spread over [her] entire left arm and radiate down from [her] left shoulder." (*Id.*) By December, petitioner began to avoid raising her left arm due to the pain. (*Id.*)

During this time, petitioner reports that she had resigned from her job on November 8, 2017, and she was not actively lifting patients or performing any other activities that may injure her shoulder. (*Id.*) She continued to exercise during this time, but she had to switch up her routine in late December 2017 to accommodate her pain. (*Id.*) She also began waking up in the middle of the night due to the pain. (*Id.*) Petitioner initially assumed that she had pulled a muscle and that the pain would eventually subside, so she did not mention it during any of her follow up appointments through 2017-2018. (*Id.* ¶¶ 6-7.)

By January 2018, petitioner started to become aware that something was wrong. (*Id.* ¶ 7.) Her pain became more and more intolerable as 2018 continued. (*Id.* ¶ 8.) She was unable to raise her left arm without excruciating pain. (*Id.*) Simple tasks like reaching to get something from a cabinet, getting dressed, styling her hair, or lifting anything became nearly impossible. (*Id.*) She describes one incident where she was unable to screw in a light bulb because it was too painful and her arm was too weak. (*Id.*) After this, petitioner "called her shoulder physician and took the next available appointment." (*Id.*)

On February 16, 2018, petitioner notes that she saw Dr. McFarland, her shoulder physician, and PA-C Beard. (*Id.* ¶ 9.) At this appointment, petitioner notes she was diagnosed with a shoulder injury due to the flu vaccine. (*Id.*) She underwent an MRI that revealed rotator cuff tears and inflammation in her left shoulder. (*Id.*) She states that she started physical therapy and was prescribed a Medrol dose pack. (*Id.*)

Since her diagnosis, petitioner has continued to have regular appointments with her physical therapist and her orthopedic surgeon. (*Id.* ¶ 11.) In August 2018,

petitioner notes that she was diagnosed with cellulitis of her left breast as a result of lymphedema. (*Id.*) "[L]ymphedema is a condition triggered by an injury to the affected side." (*Id.*) She states that her doctor "felt [her] left shoulder injury likely triggered the lymphedema," rather than her breast surgery, because her breast surgery was four years earlier and without complications. (*Id.*) This condition requires lifelong treatment with compression garments and "other treatment modalities." (*Id.*) Petitioner states that the lymphedema led to increased inflammation in her left shoulder and required additional physical therapy. (*Id.*)

In her second affidavit, petitioner clarifies that she received her flu vaccine on November 21, 2017, not in October 2017 as "erroneously recorded in the progress note" from her initial appointment regarding her left shoulder pain. (Ex. 40, ¶ 1.) She states that her left shoulder pain did not exist at the time of her resignation on November 8, 2017, and therefore, it was not the reason for her resignation. (*Id.* ¶ 2.) She further clarifies that she "did not resign because [she] was having problems lifting patients." (*Id.*) Instead, she claims that she resigned due to "concerns [she] had about changes that came with new management after [her] facility was purchased by another company." (*Id.*) Her reasons for resigning were recorded in her November 30, 2017, visit with her lung surgeon. (*Id.*) She attempted to rescind this resignation and claims she would not have attempted to do this if she was experiencing pain. (*Id.* ¶ 3.)

Petitioner also clarifies why she did not discuss her shoulder pain in subsequent doctors' appointments between November 2017 and February 2018. (*Id.* ¶ 7.) She states that she "did not, and would not even now, mention a pain in her shoulder and arm during a routine follow up assessment for other conditions." (*Id.*) She attributes this to her time as a nurse and states that she only discusses the conditions that prompted her to see that specific doctor, not other conditions. (*Id.*) She states that "[t]hese appointments were only to discuss serious conditions that had been, and could still be, potentially life-threatening." (*Id.*) She claims, "As a medical professional, when I see each doctor, I am narrowly focused on the specialized area they are treating." (*Id.*)

ii. Mark Maugans

Mark Maugans also submitted an affidavit in this case. (ECF No. 9-3; Ex. 27.) Mr. Maugans has lived with petitioner for the past 22 years. (Ex. 27, ¶ 1.) He states that petitioner has always "led an active, healthy life, and has been passionate about both health and fitness." (*Id.*) He describes how petitioner "worked a physically demanding job" and "has always been responsible for maintaining [their] home and large property." (*Id.*)

Mr. Maugans describes how petitioner told him she was going for her annual checkup and planned to receive her annual flu shot at the end of November 2017. (*Id.* ¶ 2.) Mr. Maugans describes how petitioner mentioned soreness in her left shoulder where she had received the shot in the week following her appointment. (*Id.*) He notes that she "talked about her pain routinely and how it began shortly following the flu shot." (*Id.*) He recalls her "saying that the pain was becoming stronger" and that "both her left

shoulder and left arm hurt" between late November 2017 and early December 2017. (*Id.*)

Mr. Maugans states that petitioner continued to talk about the pain in her left shoulder and arm throughout the rest of December 2017 and January 2018. (*Id.* ¶ 3.) He notes that she was having trouble sleeping due to the pain and required him to help more around the house. (*Id.*) Mr. Maugans describes one incident where petitioner "had been trying to change a light bulb," however, she "was so weak and was in so much pain [that] she could not lift the bulb, even to her shoulder level." (*Id.*) He states that after two months of this pain, petitioner "decided to seek medical treatment." (*Id.* ¶ 4.)

Mr. Maugans reports that, since petitioner's "first visit with her orthopedic physician for her left shoulder pain, [he has] watched her diligently perform her recommended therapies." (*Id.* ¶ 5.) However, he notes that "[h]er pain continues to this day, and she now has to contemplate surgery as part of her recovery process." (*Id.*)

iii. Rhonda Torian

Rhonda Torian, petitioner's co-worker, also submitted an affidavit in this case. (ECF No. 49; Ex. 44.) Ms. Torian worked with petitioner at CommuniCare Healthcare Center, which was previously known as Golden Living. (Ex. 44, ¶ 1.) She states that, when they worked together, petitioner's job required her to lift and transfer patients and reach overhead. (*Id.*) She noted that petitioner "performed all of the physical work required by her job without any difficulty." (*Id.*)

Ms. Torian states that when Golden Living was bought by CommuniCare, "many changes followed." (*Id.* ¶ 2.) She notes that there were changes in "pay, work hours, staffing, policies, and the types of patients" accepted by the facility. (*Id.*) She describes how a lot of people, including petitioner, resigned and the company eventually had to hire temporary workers. (*Id.*) Ms. Torian opines that petitioner's "resignation had nothing to do with her physical abilities" and suggests that petitioner "resigned because she felt a lot of changes were compromising safety, and the quality and continuity of care." (*Id.*) She explains that petitioner did not talk about her problems with her left shoulder until after she had resigned. (*Id.* ¶ 3.)

IV. Discussion

For the reasons discussed below, I conclude that petitioner has met her *prima facie* burden of proof with respect to each of the four QAI criteria for establishing a Table Injury of SIRVA. I further conclude that respondent has not met his burden of proof with respect to whether petitioner's condition was caused by any factor unrelated to vaccination. Accordingly, petitioner is entitled to compensation for a Table SIRVA.

a. Petitioner's *Prima Facie* Showing of a Table SIRVA

i. No history of pain, inflammation or dysfunction of the affected shoulder

The first SIRVA criterion requires "[n]o 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." 42 CFR § 100.3(c)(10)(i). Petitioner argues in her motion that she has satisfied this requirement. (ECF No. 51, p. 24.) Respondent has not raised any argument to the contrary. (ECF No. 53.)

In his Rule 4 Report, respondent argued that a notation in petitioner's medical records associating her shoulder pain to her employment necessarily placed onset prior to the date of vaccination. (ECF No. 39, p. 10 (citing Ex. 5, p. 73).) Petitioner later filed additional evidence clarifying the circumstances of her resignation as well as a letter from her physician indicating the notation at issue was made in error. (Exs. 39-44.) Thereafter, respondent did not raise this argument in his response to the instant motion for a ruling on the written record. (ECF No. 53.) Without further explanation, the argument that petitioner had preexisting left shoulder pain cannot be harmonized with respondent's argument in response to the instant motion (made relative to SIRVA criterion ii as discussed below) that her November 30, 2017 oncology record demonstrates an absence of shoulder pain. In any event, I find the evidence subsequently filed by petitioner (Exhibits 39-44) sufficient to refute that she resigned from her job due to left shoulder pain predating the vaccination at issue.

Based on my review of the record as a whole, although petitioner had other prior medical concerns, including longstanding limitations in her opposite shoulder, I find petitioner has satisfied this requirement by preponderant evidence.

ii. Pain occurs within 48 hours of vaccination

The second SIRVA criterion requires that the "[p]ain occurs within the specified time-frame," *i.e.*, within 48 hours of vaccination. 42 CFR § 100.3(c)(10)(ii); 42 CFR § 100.3(a). This is the primary issue addressed by the parties. Based on my review of the record as a whole, I find that, for the reasons discussed below, petitioner has satisfied this requirement by preponderant evidence.

The Vaccine Act instructs that a special master may find the time period for the first symptom or manifestation of onset required for a Table Injury is satisfied "even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." § 300aa-13(b)(2). However, consistent with petitioner's burden of proof overall, that finding must be supported by preponderant evidence. *Id*. A special master must consider the medical record as a whole and is not bound by any particular diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, cause, and aggravation of petitioner's injury or illness that is contained in a medical record. § 300aa-13(b)(1). However, the Federal Circuit has held that contemporaneous medical records are

ordinarily to be given significant weight due to the fact that "[t]he 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). Nonetheless, there is no presumption that medical records are complete and accurate. *Kirby v. Sec'y of Health & Human Servs*., 997 F.3d 1378, 1383 (Fed. Cir. 2021).

There is no dispute that when petitioner first sought care for her left shoulder pain, she specifically attributed her pain to her flu vaccine. (ECF No. 53, p. 2.) Moreover, respondent does not dispute that petitioner suffered left shoulder pain "at some point" after her vaccination. (*Id*. at 10.) However, respondent disputes that there is preponderant evidence that petitioner suffered shoulder pain within 48 hours of vaccination. (*Id*. at 9-10.) Respondent stresses that petitioner did not seek treatment for her shoulder pain until nearly three months after vaccination. (*Id*. at 9.) Therefore, he contends that there are no objective findings from any physician confirming shoulder pain within days of vaccination. (*Id*. at 10.) Respondent suggests this is particularly concerning because petitioner had other medical appointments in the interim (especially a November 30 oncology encounter and a January 10 pulmonology encounter) where her shoulder pain was not documented. (*Id*. at 9.) Respondent stresses petitioner's November 30 oncology encounter, which occurred approximately a week post-vaccination, and which documented an absence of joint inflammation or arthritis. (*Id*. (citing Ex. 2, pp. 9-10).) Respondent suggests that this musculoskeletal exam was of particular importance to the oncologist given petitioner's left-side lumpectomy and lymph node removal. Moreover, the oncologist documented petitioner's left shoulder complaints in later records. (*Id*. (citing Ex. 2, pp. 13, 17).)

Standing alone, the fact that petitioner waited more than three months to seek treatment is not significant. *See, e.g.*, *Lang v. Sec'y of Health & Human Servs.*, No. 17-995V, 2020 WL 7873272, at *10 (Fed. Cl. Spec. Mstr. Dec. 11, 2020) (explaining that "prior decisions by myself and other Special Masters have found that postponing treatment for a limited number of months is not *per se* dispositive of whether onset of shoulder pain occurred within the specified time period for a SIRVA"); *Smallwood v. Sec'y of Health & Human Servs.*, No. 18-0291V, 2020 WL 2954958, at *10 (Fed. Cl. Spec. Mstr. Apr. 29, 2020) (explaining that it is common for SIRVA petitioners to delay treatment "thinking his/her injury will resolve on its own"). Moreover, when petitioner did present for care of her shoulder condition, the history she provided not only attributed her injury to her vaccination, but also specifically confirmed onset within 48 hours of vaccination. (Ex. 5, p. 73.) Although the record misstates the month of vaccination, the recorded history indicates that "her left shoulder problem *started with* a flu shot . . . . She had the usual soreness for a couple of days, but *then the pain persisted* and became much more severe." (*Id*. (emphasis added).) Thereafter, her subsequent records are consistent with this history, though generally less specific. (*See, e.g.*, Ex. 21, pp. 3-4 (noting pain "following getting a flu shot"); Ex. 35, p. 261 (noting frozen shoulder "due to vaccine she received in Nov 2017").) Thus, onset occurring within 48

hours of vaccination is supported by the relevant *treatment* records. *Cucuras*, 993 F.3d at 1528 ("With proper treatment hanging in the balance, accuracy has an extra premium.")

As respondent contends, petitioner's medical records as a whole include more contemporaneous encounters that require further scrutiny given that they may tend to cast doubt on the accuracy of the onset reported in the later treatment records. Respondent goes too far, however, in asserting that these records carry a "presumptive accuracy." (ECF No. 53, p. 10; *but see Kirby*, 997 F.3d at 1383 ("We reject as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions.").) Ultimately, I conclude that these encounters, though closer in time to the vaccination, do not indicate that the shoulder treatment records are inaccurate with respect to onset. Neither of the encounters highlighted by respondent was with a primary care provider or a relevant specialist. Instead, they related to specific ongoing concerns relative to oncology and pulmonology respectively. (Exs. 2, pp. 9-12; 3, pp. 20-25.) Neither record includes any in depth assessment of petitioner's musculoskeletal condition.

Respondent is unpersuasive in contending that a musculoskeletal exam was "of particular importance to [petitioner's] oncologist." (ECF No. 53, p. 9.) Although respondent is correct that petitioner's alleged SIRVA is on the same side as her lumpectomy and lymph node removal, respondent has not explained why this would prompt the oncologist to be monitoring for left shoulder musculoskeletal dysfunction specifically. Respondent notes that a later oncology exam of September 6, 2018, did document "left upper arm swelling." (*Id.* (quoting Ex. 2, p. 17).) However, that was documented in relation to the lymphatic system. Although the Review of Systems notes a denial of joint pain and inflammation generally, the musculoskeletal physical exam is limited to noting "[n]o inflammation or deformity of the joints," with no indication of what joints were examined and in what manner. (Ex. 2, pp. 17-19.) This lack of attention or detail is not consistent with that exam being of "particular importance." *Accord Kirby*, 997 F.3d at 1383 (explaining that a notation of "No Present – Dizziness" does not necessarily evidence a complete neurologic exam). Dr. Cohen's examination of the same date did include some reference to reduced range of motion. (Ex. 4, p. 51.)

More importantly, review of the complete medical records suggests that the oncologist's recordkeeping with respect to petitioner's musculoskeletal complaints was not reliable. Respondent stresses that the oncologist did later record as of July 9, 2018, that petitioner had been "undergoing physical therapy on her bilateral rotator cuff tears." (ECF No. 53, p. 9 (quoting Ex. 2, p. 13).) However, despite recording that petitioner was actively treating bilateral shoulder symptoms, the oncologist still recorded a musculoskeletal Review of Systems and Physical Examination that was identical to the November 30, 2017 encounter record. (*Compare* Ex. 2, pp. 9-11, *with* Ex. 2, pp. 13, 15.) The same assessments are repeated a third time at the September 6, 2018 encounter despite again noting the ongoing treatment of bilateral shoulder symptoms and also separately observing left arm lymphatic swelling. (Ex. 2, pp. 16-19.) Thus, given that these negative assessments for shoulder pain were included by the

oncologist verbatim at encounters where he otherwise separately confirmed ongoing shoulder symptoms, they do not reliably evidence the absence of shoulder symptoms during the earlier November 30, 2017 encounter.

iii. Pain and reduced range of motion are limited to the affected shoulder

The third SIRVA criterion requires that the "[p]ain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered." 42 CFR § 100.3(c)(10)(iii). Petitioner asserts that there is no evidence that she had complaints beyond her affected shoulder. (ECF No. 51, p. 37-39.) Respondent argues, however, that petitioner's bilateral shoulder pain is evidence that her pain was not limited to her left shoulder (ECF No. 53, p. 11; *see also* ECF No. 39, p. 11 (citing Exs. 2, p. 13; 5, pp. 73, 86, 179; 20, p. 21; 28, p. 48).) Petitioner counters that "[t]o suggest petitioner's left shoulder vaccine injury involves some aspect of a bilateral process is a misrepresentation of the plain reading of petitioner's medical records." (ECF No. 54, p. 6.)

Although respondent is correct that some of petitioner's medical records indicate that she presented with "bilateral" shoulder pain, the medical records do explicitly distinguish the etiology and history of the pain she experienced in each shoulder. (*See, e.g.*, Exs. 5, p. 179 (noting that petitioner presented "for follow up evaluation of her bilateral shoulder pain, left worse than right" with "a history of a plexopathy on the right side from birth" and "left shoulder pain [that] started with a flu shot"); 28, p. 48 (assessing "a history of brachial plexus injury from birth on the right side and a partial-thickness rotator cuff tear on the left").) There is no readily apparent reason to doubt that a person with a preexisting right shoulder complaint could subsequently suffer an unrelated left shoulder injury. Moreover, there is no indication from the medical records that any of petitioner's treating physicians considered her right and left shoulder pain to be a part of the same condition. Nor has respondent provided any medical opinion or other explanation indicating why two separate shoulder complaints in opposite shoulders would be suspicious for a unifying etiology given the facts of this case.

Accordingly, based on my review of the record as a whole, I find petitioner has satisfied this requirement by preponderant evidence. *Accord Grossman v. Sec'y of Health & Human Servs.*, No. 18-00013V, 2022 WL 779666, at *15 (Fed. Cl. Spec. Mstr. Feb. 15, 2022) (explaining that SIRVA QAI criterion iii looks for "patterns of pain or reduced range of motion indicative of a contributing etiology beyond the confines of a musculoskeletal injury to the affected shoulder").

iv. No other condition or abnormality is present that would explain the patient's symptoms

Finally, the fourth SIRVA criterion requires that "[n]o 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 CFR § 100.3(c)(10)(iv). Petitioner argues that she has satisfied this criterion based on her medical history and medical records. (ECF No. 51, p. 39.) Respondent has not raised any argument to the contrary. Based on my review of the record as a whole, although petitioner had other medical concerns, I find petitioner has satisfied this requirement by preponderant evidence.

b. Factor Unrelated

Once petitioner has satisfied her own *prima facie* burden, respondent has the opportunity to demonstrate, also by a preponderance of the evidence, that petitioner's injury was nonetheless caused by a factor unrelated to vaccination. § 300aa-13(a)(2); § 300aa-13(a)(1)(B); *Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs.*, 717 F.3d 1363, 1367 (Fed. Cir. 2013). In this case, respondent has not raised any such argument.

V. Conclusion

For all the reasons discussed above, after weighing the evidence of record within the context of this program, I find by preponderant evidence that petitioner suffered a Table Injury of SIRVA resulting from her November 21, 2017 flu vaccination. A separate damages order will be issued.

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master