In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 21-680V
Filed: May 5, 2025

ISABEL DEL VECCHIO,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Master Horner

Renee J. Gentry, The Law Office of Renee J. Gentry, Washington, D.C., for petitioner.
Mary E. Holmes, 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, *et seq.* (2012) ("Vaccine Act"),[2] alleging that she suffered a left shoulder injury as a result of an influenza ("flu") vaccination she received on February 17, 2018. (ECF No. 1.) For the reasons set forth below, I conclude that petitioner is entitled to compensation.

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 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;

[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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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. 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 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. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

As relevant here, the Vaccine Injury Table lists Shoulder Injury Related to Vaccine Administration ("SIRVA") as a compensable injury if it occurs within ≤48 hours of administration of a flu vaccine. § 300aa-14(a), *amended by* 42 C.F.R. § 100.3. Table Injury cases are guided by a statutory "Qualifications and aids in interpretation" ("QAI"), which provides more detailed explanation of what should be considered when determining whether a petitioner has actually suffered an injury listed on the Vaccine Injury Table. § 300aa-14(a). To be considered a Table SIRVA petitioner must show that his/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, and any other neuropathy).

42 CFR § 100.3(c)(10).

Alternatively, if no injury falling within the Table can be shown, a petitioner could still demonstrate entitlement to an award by instead showing that the vaccine recipient's injury or death was caused-in-fact by the vaccination in question. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(ii). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321-22 (Fed. Cir. 2010) (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). To successfully demonstrate causation-in-fact, petitioner bears a burden to show: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. § 300aa-13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2 (alternation in original); *see also Snowbank Enters., Inc. v. United States*, 6 Cl. Ct. 476, 486 (1984) (explaining that mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). 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. § 300aa-13(a)(1).

Cases in the Vaccine Program are assigned to special masters who are responsible for "conducting all proceedings, including taking such evidence as may be appropriate, making the requisite findings of fact and conclusions of law, preparing a decision, and determining the amount of compensation, if any, to be awarded." Vaccine Rule 3(b)(1). Special masters must ensure each party has had a "full and fair opportunity" to develop the record. Vaccine Rule 3(b)(2). However, special masters are empowered to determine the format for taking evidence based on the circumstances of each case. Vaccine Rule 8(a); Vaccine Rule 8(d). Special masters are not bound by common law or statutory rules of evidence but must consider all relevant and reliable evidence in keeping with fundamental fairness to both parties. Vaccine Rule 8(b)(1). The special master is required to consider "all [] relevant medical and scientific evidence

contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." § 300aa-13(b)(1)(A). The special master is required to consider all the relevant evidence of record, draw plausible inferences, and articulate a rational basis for the decision. *Winkler v. Sec'y of Health & Human Servs.*, 88 F.4th 958, 963 (Fed. Cir. 2023) (citing *Hines ex rel. Sevier v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991)).

II. Procedural History

Petitioner filed medical records and other evidence marked as Exhibits 1-25 over several months and then filed her Statement of Completion in May of 2021. (ECF Nos. 7-8, 10-12, 15-19, 23.) Based on the allegations in the petition, this case was initially assigned to the Chief Special Master as part of the Special Processing Unit ("SPU"), which is intended to expedite cases having a high likelihood of informal resolution. (ECF Nos. 21-22.) Respondent completed his medical review in February of 2023, and the parties thereafter explored settlement, though they were unable to informally resolve the case. (ECF Nos. 37, 43.) In the meantime, petitioner filed updated medical records marked as Exhibits 26-27. (ECF Nos. 33, 41.)

Respondent filed his Rule 4 Report in September of 2023, and the case was reassigned to the undersigned the following month. (ECF Nos. 45-47.) In his report, respondent argued that petitioner cannot meet the requirements for a Table Injury of SIRVA because her clinical presentation is not compatible with any of the four QAI criteria. Specifically, respondent argued that petitioner did not have any reduced range of motion in her shoulder, but instead had pre-existing cervicalgia inclusive of left shoulder pain that predated her vaccination. (ECF No. 45, pp. 5-6.) Regarding causation-in-fact, respondent argued that, without an expert medical opinion, petitioner's medical records were inadequate to satisfy the *Althen* test. (*Id*. at 6.)

Shortly after reassignment, I issued a Rule 5 Order. (ECF No. 49.) Within the order, I explained that my initial review suggested that there could be issues that potentially confound a Table SIRVA claim, but stressed that petitioner's treating orthopedist had specifically opined that petitioner suffered chemical bursitis secondary to her vaccination. (*Id*. at 3 (discussing Ex. 12, pp. 6, 11).) Although I expressed doubt that petitioner would meet the specific SIRVA requirements, I concluded there was a high likelihood petitioner would prevail. (*Id*.) I indicated that it might be reasonable for petitioner to seek to rely on her orthopedist's opinion to support a cause-in-fact claim based on the existing record, but cautioned that a more detailed expert opinion would likely be needed if respondent opted to file an expert report of his own. (*Id*.)

Thereafter, both parties confirmed that the case is ripe for adjudication without having filed any expert reports. (ECF Nos. 53, 54.) Petitioner filed an affidavit by chiropractor Tyler Page and updated medical records marked as Exhibits 28-29,

respectively. (ECF Nos. 51, 55.) Petitioner then filed a motion for a ruling on the written record, which is fully briefed. (ECF Nos. 56-58.)

In light of the above, I have determined that the parties have had a full and fair opportunity to present their cases and that 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").

III. Factual History

Prior to the vaccination at issue, petitioner had a history of neck pain that she associated with shoulder pain and which may have been related to a motor vehicle accident in 2015. (Ex. 2, pp. 5, 9; Ex. 20, p. 2; Exs. 28-29.) Prior to vaccination, she was last seen for neck pain on October 19, 2016. (Ex. 2, p. 9.) Petitioner received the vaccination at issue on February 17, 2018. (Ex. 4, p. 4.) Although the administration record confirms an intramuscular injection into the deltoid, it does not specify whether the site of injection was the right or left deltoid. (*Id.*)

On March 1, 2018, petitioner presented to her primary care provider, where she was seen by Physician Assistant ("PA") Grodzki, with a chief complaint of "Left Arm Pain." (Ex. 2, p. 21.) PA Grodzki recorded:

> Patient reports that 2 weeks ago she received a flu vaccine, administered by a pharmacist at Hannaford[']s in Maine. The vaccine was administered into her left arm. Patient has not received a vaccine since she was a child so she does not know if the vaccine administration felt like a typical vaccine administration. Patient reports that she had left arm pain the day she received the vaccine, but the next day that pain was accompanied by left sided neck pain and upper back/shoulder pain. Patient is continuing to endorse left arm, neck, and upper back/shoulder pain, although it has been improving. The pain is constant 4/10 pain, although it is slightly less painful in the morning and slightly more painful at night. Patient has been taking ibuprofen, using heat/ice, and applying icy-hot to area, all of which provide temporary [relief]. The pain is worse when patient is turning pages or driving with her left hand. Patient also reports severe clavicle pain a few days after receiving the vaccine, and that clavicle pain has now resolved. She also endorses mild weakness to the left arm. Patient denies any ecchymosis, erythema, or swelling after incident throughout now. Patient also denies any recent exercise or trauma to area. She denies any fevers, chills, paresthesia, loss of sensation, nausea, vomiting, headaches, palpitations, trouble breathing, or losing control of bowel or bladder.

(*Id.*) On physical exam, petitioner had full strength in all major muscle groups, as well as full range of motion of her neck, arm, and back muscles. However, she endorsed

mild pain with external rotation of the shoulder. (*Id.* at 23.) PA Grodzki felt that a SIRVA was "[p]ossible," but at only two-weeks post-vaccination, she would not rule out normal post-vaccination pain. (*Id.* at 24.) Petitioner was advised to rest and to continue using over-the-counter treatments. (*Id.*)

Petitioner returned to the same provider on April 19, 2018, with a continued complaint of arm pain following her flu shot. (Ex. 2, p. 27.) She reported pain that was

> dull, aching 4/10, increases to 10/10 with movement. She also notes pain in the right upper back, and isn't sure if the pain is radiating to the other side. Patient also notes that she had some paresthesias into her pinky last week that was intermittent and only lasted 1-2 days, then resolved. . . . Patient notes that she worked out a few weeks ago and the next day she had very limited range of motion, was unable to extend her left arm. This lasted about a week and was eventually relieved with gradual stretching.

(*Id.*) On physical exam, petitioner again had full range of motion in her neck, arm, and back muscles. However, she had mild pain with lateral extension of her neck, a positive lag sign with internal rotation, and mild pain with external rotation of the shoulder. (*Id.* at 28.) PA Grodzki continued to suspect a SIRVA and recommended either an MRI or a specialist referral. (*Id.* at 29.) Petitioner opted for the MRI, which showed "[t]race amount of fluid in the subacromial/subdeltoid bursa suggesting possible bursitis" and no rotator cuff or labral tears. (*Id.* at 29, 35.) When petitioner returned for review of her MRI, she reported that her pain had not changed from her prior appointment, but noted that "the pain radiates to the other side." (*Id.* at 33.) She denied any further numbness or tingling, but it was noted that she "continues to have limited range of motion and decreased strength in that extremity." (*Id.*) PA Grodzki's impression then changed to bursitis. Petitioner declined a steroid injection, and an orthopedic or physical therapy referral was therefore recommended. (*Id.* at 35.)

Petitioner had a consultation with an orthopedist, Dr. Anbari, on August 6, 2018, at which she described her left shoulder pain as occurring within 24 hours of her prior flu vaccination. (Ex. 12, p. 11.) She also noted some numbness in the ulnar nerve of her hand. (*Id*.) On physical exam, petitioner had "quite a bit of discomfort in the anterior aspect of the shoulder," scapular winging, discomfort with rotator cuff testing, and positive impingement signs. (*Id*.) The orthopedist also recorded that "[s]he has full range of motion, strength and stability to the opposite shoulder with no issues coming from the neck." (Ex. 12, p.11.) Upon review of petitioner's MRI, the orthopedist interpreted the study as showing "significant" subacromial bursitis and no rotator cuff tears. (*Id*.) The orthopedist's impression was that petitioner "examines as if she has chemical bursitis secondary to her injection." (*Id*.) He diagnosed "[l]eft shoulder chemical bursitis status post flu shot" and recommended a course of physical therapy. (*Id*.)

Petitioner then presented for a physical therapy evaluation on August 13, 2018. (Ex. 3, p. 5.) The "reason for referral" states that petitioner "presents with left shoulder

pain, decreased active range of motion, hypertonicity and tenderness of shoulder complex muscles, and decreased rotator cuff activation resulting from subacromial bursitis following a flu shot in February." (*Id*.) It was noted that the "entire shoulder complex" is sore and that the pain radiates down into the bicep with occasional numbness or tingling down the arm to the pinky finger. (*Id*.) In pertinent part, the objective examination found reduced strength of the left shoulder with internal and external rotation, as well as reduced active range of motion with flexion, abduction, and external rotation. (*Id*. at 6.) Petitioner continued her physical therapy into October of 2018. (Ex. 3.)

Petitioner returned to the orthopedist on September 17, 2018, seeing PA Farrington. (Ex. 12, p. 10.) It was noted that her range of motion had improved with physical therapy, but that she still had pain. Because she wanted to avoid either surgery or a steroid injection, she was prescribed a Medrol Dosepak. She was advised to continue physical therapy and return in six weeks. (*Id.*) She returned on October 29, 2018, seeing Dr. Anbari again. (*Id.* at 9.) Physical therapy was reportedly doing "a really good job" with petitioner's motion, but she felt she had developed clicking with internal and external rotation, which she attributed to a thick bursa. (*Id*.) Petitioner's physical exam that day produced numbness down her arm, which Dr. Anbari believed "is contributing a lot to her symptoms." (*Id.*) Physical exam confirmed the clicking petitioner had reported and it was noted that her humeral head was "sitting forward quite a bit," but there was no sign of instability. (*Id.*) Petitioner had developed weakness as compared to her opposite shoulder. Dr. Anbari recommended continued physical therapy, with added attention on strengthening, and she was to follow up in three months. (*Id.*) Her diagnosis remained chemical bursitis status post flu shot injection. (*Id.*)

Petitioner saw Dr. Anbari again on January 28, 2019. (Ex. 12, p. 8.) She was reportedly feeling better, but with continuing discomfort in her left shoulder. (*Id*.) On physical exam, she had full range of motion of the shoulder, but with popping and clicking, as well as discomfort with flexion and extension and scapular winging. (*Id*.) Dr. Anbari recommended continued physical therapy and instructed petitioner to follow up as needed. (*Id*.) Her diagnosis remained chemical bursitis. (*Id*.)

Petitioner returned to Dr. Anbari about four months later, on May 30, 2019. (Ex. 12, p. 6.) Petitioner reported that

> [s]he has been having a really hard time with her shoulder. Despite everything she has done for it, it really does not seem to be making any difference. Today she is describing a lot of pain which has been going on for two weeks now and going from the neck down to her shoulder in addition to everything she has been dealing with before. She has had it before but not to this extent.

(*Id.*) On physical exam, petitioner had decreased range of motion in all directions and "a lot of discomfort with rotator cuff testing." (*Id.*) Additionally, "[h]er neck has

discomfort with rotation of neck especially towards the left side with positive Spurling sign." (*Id.*) Dr. Anbari recommended x-rays of the neck to check for cervical spine abnormalities, but opined that "I think this may be a separate entity." (*Id.*) He noted that it might be contributing to some of her shoulder symptoms, "although I doubt it because the pain she had was immediately after her flu shot that she had to the shoulder." (*Id.*) Regarding the shoulder, Dr. Anbari concluded that petitioner had failed conservative treatment and recommended an arthroscopic bursectomy and subacromial decompression. Regarding the neck, however, he advised waiting to see whether it improved. (*Id*.) Petitioner now had separate diagnoses of persistent chemical bursitis, as well as cervical radiculitis. (*Id*.) Petitioner re-raised her neck pain with her primary care provider a few days later, but it was noted that her orthopedist had scheduled further follow up. (Ex. 2, pp. 57-59.)

About a month later, on June 19, 2019, petitioner saw a rehabilitation specialist, Dr. Abella, on referral from Dr. Anbari, for her neck issue. (Ex. 12, p. 4.) Petitioner reported that "about three weeks ago she awoke with a stiff neck, unable to move. No obvious precipitating event." (*Id.*) She indicated that her symptoms had subsided with Advil and heat, and it was further noted that her symptoms "do not refer into the upper extremity, although she does have some chronic left shoulder pain." (*Id.*) On physical exam, petitioner's cervical range of motion included "a pulling sensation" with forward flexion, but she had no pain, and her range of motion was otherwise within functional limits. (*Id.*) She had normal strength and intact light touch sensation in both upper extremities. Review of petitioner's x-rays showed disc space narrowing with endplate spurring at C5-6, but with no spondylolisthesis. (*Id.* at 5.) Petitioner was assessed as having a resolved exacerbation of neck pain associated with her C5-6 disc degeneration. (*Id.*) However, petitioner subsequently began seeing a chiropractor in mid-July 2015, reporting that she had aggravated her neck pain after shoveling hay. (Ex. 15, p. 4.) She reported that her neck pain was radiating into her left upper extremity. (*Id.*)

More recent records show that petitioner returned for a revaluation in March of 2023, at which time she was evaluated by PA Farrington. (Ex. 27, p. 6.) It was noted that petitioner "was injured in 2019 with a vaccine injury from a flu shot" and that she had been suffering "significant bursitis and impingement." (*Id.*) Petitioner felt she was able to do most things, but felt she still had some limitations in the shoulder. On physical exam, she had full range of motion of both the shoulder and cervical spine and with no signs of impingement. (*Id*.) However, petitioner complained "about a lot of scapular pain, and pain that radiates down to her elbow and into her hand, with numbness of her pinky." (*Id*.) PA Farrington recommended further follow up after a new MRI of the shoulder, but no further orthopedic records have been filed.

IV. Analysis

a. Site of Vaccination

A threshold question is whether petitioner actually received the vaccination at issue in the shoulder affected by her alleged SIRVA. Respondent has repeatedly noted that petitioner's vaccine administration record does not confirm into which shoulder petitioner's vaccine was injected. (ECF No. 57, p. 2; ECF No. 45, p. 2.) However, respondent has never explicitly argued that the evidence does not preponderate in favor of a finding that it was administered in her left shoulder. (ECF No. 57, pp. 5-10; ECF No. 45, p. 5.) Petitioner's vaccine administration record does confirm she received an intramuscular injection into her deltoid. (Ex. 4, p. 4.) Moreover, when petitioner sought treatment for her condition, she consistently attributed her injury to her flu vaccination, which she reported as having been administered in her left shoulder. (*E.g.*, Ex. 2, p. 21.) This is some evidence as to the injection site. *See, e.g., Hanna v. Sec'y of Health & Human Servs*., No. 18-1455V, 2021 WL 3486248, at *9 (Fed. Cl. Spec. Mstr. July 15, 2021) (collecting prior cases for the proposition that subsequent treatment records are probative evidence regarding the site of injection). By contrast, petitioner stresses that "[t]here is not a single notation in the record" that contradicts a left shoulder administration. (ECF No. 56, p. 10.)

Accordingly, considering the record as a whole, there is preponderant evidence that petitioner received the February 17, 2018 flu vaccination at issue intramuscularly into her left shoulder.

b. Table SIRVA QAI Criterion (i) - No History of Pain, Inflammation or Dysfunction of the Affected Shoulder.

Petitioner acknowledges that she had prior neck issues inclusive of complaints of shoulder pain, but contends that her treating physicians distinguished her alleged SIRVA as a separate condition. (ECF No. 56, p. 12.) Thus, petitioner contends that her prior condition is not incompatible with a Table SIRVA. (*Id*.) Respondent argues, however, that "[p]etitioner's history of cervicalgia also prevents her from meeting the QAI due to '[an]other condition or abnormality' under 42 C.F.R. § 100.3(c)(10)(iv) and, in conjunction with her imaging studies confirming a C5-C6 spine injury, indicates a pre-existing 'inflammation or dysfunction' that would explain her post vaccination diagnostic findings under 42 C.F.R. § 100.3(c)(10)(i)." (ECF No. 45, p. 6; ECF No. 57, p. 9.)

The first SIRVA criterion states that there must be "[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 C.F.R. § 100.3(c)(10)(i) (emphasis added). Here, respondent cites preexisting pain and dysfunction having an etiology related to the spine rather than "of the affected shoulder." And, while petitioner's history of neck pain and dysfunction may be related to the C5-C6 degeneration evidenced on her x-rays, petitioner's post-vaccination shoulder symptoms

were diagnosed as bursitis that was also confirmed by diagnostic study, *i.e.*, MR imaging that showed fluid in the subacromial space. (Ex. 2, p. 35.) Respondent has neither pointed to any evidence suggesting that petitioner's bursitis pre-dated the vaccination at issue nor sought to explain how the cervical spine dysfunction he cites could explain a diagnostic study finding bursal fluid in the subacromial space. Instead, petitioner's treating physicians correlated her diagnosed buritis to her reports of post-vaccination shoulder pain. (Ex. 12, p. 11; Ex. 2, pp. 29, 35.)

Accordingly, considering the record as a whole, there is preponderant evidence that petitioner was free of any history of pain, inflammation, or dysfunction of the affected shoulder prior to the vaccination at issue that would explain her diagnosed bursitis.

c. Table SIRVA QAI Criterion (ii) - Pain Occurs Within 48 Hours of Vaccination.

Respondent argues that petitioner cannot establish that she experienced onset of shoulder pain within 48 hours of vaccination "because her initial accounts of neck and shoulder pain predate her vaccination." (ECF No. 57, p. 8.) Specifically,

> Petitioner's records indicate that she experienced neck and associated shoulder pain intermittently since a 2015 motor vehicle accident. Ex. 2 at 64; Ex. 20 at 3. At an urgent care visit in 2016, petitioner was diagnosed with cervicalgia and treated for neck and shoulder pain, which she reported as worse on the left side. Ex. 20 at 2-3. She also reported muscle spasms in her neck and shoulders to her PCP prior to the vaccination in October 2016. Ex. 2 at 9.

(*Id.*)

Respondent's argument is not persuasive. Petitioner contends that her prior neck complaints reflected "at most generalized neck pain," which is not diagnostic of cervicalgia and is distinct from her post-vaccination complaints. (ECF No. 58, p. 3 (emphasis omitted).) But, in any event, respondent acknowledges that petitioner's prior reports of neck pain affecting her shoulder were only "intermittent" and the most recent medical record he cites is from October 2016, about a year and a half prior to the vaccination in question. There is no evidence of record indicating that petitioner had been symptomatic during that period. Moreover, when petitioner sought treatment for her alleged SIRVA, she consistently reported a distinct onset of post-vaccination shoulder pain beginning within 48 hours of vaccination. (*E.g.*, Ex. 12, p. 11; Ex. 2, p. 21.) Petitioner's treating physicians correlated her presentation of post-vaccination pain to bursitis that was confirmed by MRI. (Ex. 2, pp. 29, 35; Ex. 12, p. 11.) Thus, the contemporaneous clinical judgment of petitioner's treating physicians is contrary to respondent's assertion that petitioner's post-vaccination presentation of shoulder pain was a continuation of her prior neck complaints.

Accordingly, considering the record as a whole, there is preponderant evidence that petitioner experienced onset of left shoulder pain within 48 hours of the vaccination at issue.

d. Table SIRVA QAI Criterion (iii) – Presence of Reduced Range of Motion.

Respondent raises two concerns with respect to the third SIRVA criterion. First, he contends that this criterion requires that there be reduced range of motion, which he asserts is absent in this case. (ECF No. 57, pp. 6-7.) Second, he argues that petitioner had symptoms beyond the confines of her affected shoulder. (*Id*. at 7-8.) Because respondent's second argument rises or falls in connection with his arguments under the fourth criterion, it will be addressed separately in the following section.

Although reduced range of motion is a requirement, *see Bolick v. Sec'y of Health & Human Servs*., No. 20-893V, 2023 WL 8187307, at *6-8 (Fed. Cl. Spec. Mstr. Oct. 19, 2023), respondent does not account for the complete history of petitioner's alleged SIRVA. Respondent cites petitioner's initial presentation to her primary care provider as demonstrating full range of motion on physical exam, as well as an April 19, 2018 notation (ECF No. 57, p. 6 (discussing Ex. 2, pp. 23, 27)), in which petitioner provided a history to her primary care provider indicating that "[p]atient notes that she worked out a few weeks ago and the next day she had very limited range of motion, was unable to extend her arm. This lasted about a week and was eventually relieved with gradual stretching" (Ex. 2, p. 27). Respondent asserts that petitioner has not provided any "objective findings" that she suffered reduced range of motion. (ECF No. 57, pp. 6-7.) However, petitioner persuasively counters that her reduced range of motion was objectively confirmed during her physical therapy evaluation. (ECF No. 56, p. 13 (discussing Ex. 3, p. 6).)

Although petitioner's primary care provider did not detect reduced range of motion upon examination, he is not a shoulder specialist and he did not document what maneuvers he tested. By contrast, both petitioner's orthopedist and physical therapist documented reduced range of motion and the physical therapist documented the examination in detail.[3] (Ex. 12, pp. 10-11; Ex. 3, p. 6.) The history petitioner provided

[3] Petitioner's initial orthopedic encounter is ambiguous with respect to any explicit documentation of reduced range of motion. (Ex. 12, p. 11.) However, respondent interprets the initial orthopedic encounter as indicating that petitioner had full range of motion of the left shoulder. (ECF No. 57, p. 3 (discussing Ex. 12, p. 11).) Upon close inspection, this is not how I read this record. After identifying several ways in which petitioner was experiencing discomfort in the left shoulder, the orthopedist states that "[s]he has full range of motion, strength and stability *to the opposite shoulder* with no issues coming from the neck." (Ex. 12, p. 11 (emphasis added).) While "to the opposite shoulder" is not entirely clear, the same orthopedic practice documented at petitioner's next encounter (this time she was seen by a PA) that, following physical therapy, "[h]er range of motion has improved but she still has pain." (*Id*. at 10.) Given that petitioner's physical therapy evaluation documented reduced range of motion and given that the orthopedic practice subsequently documented an improvement in range of motion, it is unlikely that petitioner's August 6, 2018 encounter record actually documented full range of motion of the left shoulder. Instead, I read the notation at issue as documenting full range of motion in the right shoulder.

on April 19, 2018, does cloud the issue a bit; however, that history describes "very limited" range of motion consisting of an inability to extend the arm. (Ex. 2, p. 27.) It is not clear that this notation speaks to the entire course of her reduced range of motion (as opposed to an exacerbation) or that this would account for all the planes of reduced range of motion recorded by the physical therapist. (Ex. 3, p. 6.)

Accordingly, considering the record as a whole, there is preponderant evidence that petitioner suffered reduced range of motion of the shoulder affected by her alleged SIRVA.

e. Table SIRVA QAI Criteria (iii) and (iv) – Pain and Reduced Range of Motion are Limited to the Affected Shoulder and No Other Condition or Abnormality is Present that Would Explain the Symptoms.

Finally, respondent argues relative to the fourth SIRVA criterion that petitioner suffered "preexisting cervicalgia associated with shoulder pain that would explain her post vaccination symptoms" and further argued that "petitioner continued to report neck pain after her vaccination, including at her initial presentation after receiving the vaccine." (ECF No. 57, p. 9.) Relatedly, he argues relative to the third criterion that petitioner's complaints were not "primarily" related to her shoulder and that she "consistently reported pain outside her shoulder," including her neck, back, and down her arm to her pinky finger. (*Id*. at 7-8.) Petitioner disagrees, contending that the symptoms she reported beyond the confines of the shoulder were incidental in that there is no evidence her symptoms were of a spinal etiology and her treating physicians were able to distinguish her alleged SIRVA from her other complaints. Accordingly, she contends she has satisfied the third and fourth criteria. (ECF No. 56, pp. 13-14; ECF No. 58, pp. 1-5.)

The third SIRVA criterion requires that the petitioner's "[p]ain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered." 42 C.F.R. § 100.3(c)(10)(iii). Radiating pain does not *per se* prevent petitioner from demonstrating a Table SIRVA where the petitioner's condition is otherwise diagnosed and treated as a shoulder condition. *E.g.*, *Werning v. Sec'y of Health & Human Servs.*, No. 18-0267V, 2020 WL 5051154, at *10 (Fed. Cl. Spec. Mstr. July 27, 2020). Instead, "the gravamen of this requirement is to guard against compensating claims involving patterns of pain or reduced range of motion indicative of a contributing etiology beyond the confines of a musculoskeletal injury to the affected shoulder." *Grossmann v. Sec'y of Health & Human Servs*., No. 18-00013V, 2022 WL 779666, at *15 (Fed. Cl. Spec. Mstr. Feb. 15, 2022). Thus, for example, petitioners having symptoms radiating down the arm and to the hand have been found to have met the Table requirements for SIRVA where "[t]he evidence supporting a SIRVA can be distinguished from other incidental complaints of pain and neurological symptoms." *Kahler v. Sec'y of Health & Human Servs*., No. 19-1938V, 2024 WL 1928451, at *8 (Fed. Cl. Spec. Mstr. Mar. 27, 2024). By contrast, a prior petitioner was found not to have met the third SIRVA criterion where she had pain and sensory symptoms stemming from her neck to her hand that were "prominent" symptoms and "were

contemplated by her treating physicians in attempting to arrive at a unifying diagnosis." *Durham v. Sec'y of Health & Human Servs*., No. 17-1899V, 2023 WL 3196229, at *12 (Fed. Cl. Spec. Mstr. May 2, 2023).

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 C.F.R. § 100.3(c)(10)(iv). This element of petitioner's showing "requires consideration of a petitioner's medical condition as a whole." *Record v. Sec'y of Health & Human Servs*., No. 21-1312V, 2025 WL 868957, at *6 (Fed. Cl. Feb. 26, 2025). However, while the "other condition or abnormality" at issue must qualify as an explanation for the petitioner's symptoms, it "need not be a better or more likely explanation." *French v. Sec'y of Health & Human Servs*., No. 20-0862V, 2023 WL 7128178, at *6 (Fed. Cl. Spec. Mstr. Sept. 27, 2023). Indeed, a petitioner may fail to meet the fourth SIRVA criterion even where there is clinical evidence of an alternative condition that falls short of a definitive diagnosis. *Durham*, 2023 WL 3196229, at *14 (noting that the regulation cites "clinical evidence of" various conditions).

In this case, petitioner did have a prior history of neck pain, which respondent acknowledged to be "intermittent," and she often reported symptoms as part of her post-vaccination history that were not strictly limited to her shoulder. For example, when she first presented to her primary care provider, she reported that her shoulder pain radiated to her neck, arm, and back, and even reported transient clavicle pain. (Ex. 2, pp. 21, 27.) She also reported "intermittent" parasthesia and numbness down her arm into her hand. (*Id.* at 27, 33; Ex. 3, p. 5; Ex. 12, pp. 9, 11.) However, the core complaint at each of petitioner's encounters was with regard to her shoulder. Moreover, petitioner's orthopedist specifically confirmed shoulder impingement upon physical exam and also concluded based on examination that she had "no issues coming from the neck." (Ex. 12, p. 11.) The orthopedist diagnosed petitioner's initial post-vaccination presentation as bursitis, which was confirmed by MR imaging. (*Id.*; Ex. 2, p. 35.) It was not until May of 2019, well over a year after the initial onset of petitioner's post-vaccination shoulder pain, that petitioner otherwise reported a distinct onset of neck pain arising at that time. (Ex. 12, p. 6.) Although that presentation was diagnosed by petitioner's orthopedist as cervical radiculitis, he was explicit in concluding that this was a new and separate condition. (*Id*.)

This case represents a close call with respect to the third and fourth SIRVA criteria. Other petitioners have been found not to have met the Table requirements for SIRVA due to suspicion of a cervical radiculopathy even where there was otherwise enough evidence of a shoulder injury to demonstrate causation-in-fact. *Colbert v. Sec'y of Health & Human Servs.*, No. 18-166V, 2022 WL 2232210, at *16-17 (Fed. Cl. Spec. Mstr. May 27, 2022) (finding, especially in light of positive EMG/NCS findings, that "it does not appear that petitioner's clinical presentation can be definitively parsed between her various overlapping diagnoses"); *Layne v. Sec'y of Health & Human Servs.*, No. 18-57V, 2022 WL 3225437, at *16-17 (Fed. Cl. Spec. Mstr. July 12, 2022) (finding that, although petitioner's neurologic conditions would not wholly explain her condition, she

carried a diagnosis of cervical radiculopathy supported by objective evidence that contributed to her overall presentation). However, this case is distinguishable. Although petitioner did have a prior history of neck complaints, and did present subjective complaints beyond the shoulder, very little evidence exists during the post-vaccination period to support a cervical complaint. (*E.g.* Ex. 12, p. 11 (initial orthopedic examination confirming "no issues coming from the neck.") The x-ray imaging respondent cites as evidencing degenerative disc disease as a source of symptoms was not completed until May of 2019, after petitioner had reported a distinct and acute onset of neck pain separate from her preceding chronic presentation. (Ex. 12, p. 6 (May 2019 encounter noting new onset of neck pain), pp. 4-5 (June 2019 encounter noting C5-6 disc degeneration on cervical spine x-ray and that her neck "symptoms do not refer into the upper extremity").) Additionally, petitioner's orthopedist was very clear in distinguishing petitioner's neck and shoulder issues throughout the course of her treatment. (*See, e.g.*, *id.* at 6 (noting, after providing a diagnosis of cervical radiculitis for petitioner's neck pain, that "I think this may be a separate entity, may have been a silent entity and may have contributed some too her symptoms in her shoulder although I doubt it because the pain she had was immediately after her flu shot that she had to the shoulder"); at 11 (noting "no issues coming from the neck" and diagnosing "chemical bursitis secondary to her injection.")

Accordingly, considering the record as a whole, there is preponderant evidence that petitioner suffered a shoulder injury with pain and reduced range of motion limited to the affected shoulder and that no other condition or abnormality is present that would explain the symptoms of that shoulder injury.[4]

f. Factor Unrelated to Vaccination

Once petitioner has met her prima facie burden of proof, the burden shifts to respondent to demonstrate that petitioner's injury was caused by factor(s) unrelated to vaccination. § 300aa-13(a)(1)(B); *Deribeaux v. Sec'y of Health & Human Servs.*, 717 F.3d 1363, 1367 (Fed. Cir. 2013). Respondent has not raised any such argument in this case apart from his argument under the fourth SIRVA criterion that petitioner's condition is due to cervicalgia. (ECF No. 57.) Respondent's argument with respect to cervicalgia fails under respondent's shifted burden of proof for the same reasons as discussed above. In particular, even if respondent were persuasive in attributing some subset of petitioner's symptoms to cervicalgia, he has not explained how cervicalgia would explain petitioner's documented bursitis.

[4] Because this represents a close case under the specific Table criteria for SIRVA, I additionally note that, even if petitioner had not met the Table criteria, a successful cause-in-fact claim would be highly likely based on Dr. Anbari's medical opinion as petitioner's treating orthopedist that she suffered bursitis secondary to vaccination. (Ex. 12, p. 11.) Respondent agreed as a factor in creating the SIRVA concept that "scientific evidence convincingly supports a causal relationship between an injection-related event and deltoid bursitis." Proposed Rulemaking, 2015 WL 4538923, at *45135-36; *Morris v. Sec'y of Health & Human Servs*., No. 19-1570V, 2023 WL 5092691, at *6 (Fed. Cl. Spec. Mstr. July 11, 2023) (quoting *L.J. v. Sec'y of Health & Human Servs.*, No. 17-59V, 2021 WL 6845593, at *14 (Fed. Cl. Spec. Mstr. Dec. 2, 2021) for the proposition that "the very decision to add a claim [to the Vaccine Injury Table] reflects Respondent's determination that valid science supports revising the Table.")

V. Conclusion

After weighing the evidence of record, I find by preponderant evidence that petitioner suffered a Table Injury of SIRVA resulting from the flu vaccination she received on February 17, 2018. Accordingly, petitioner is entitled to compensation for her SIRVA. A separate damages order will be issued.

IT IS SO ORDERED.

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