In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 18-00013V
Filed: February 15, 2022
PUBLISHED

SUSAN GROSSMANN, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Special Master Horner Shoulder Injury Related to Vaccine Administration ("SIRVA"); Influenza ("Flu") Vaccine; Table Injury; Ruling on the Record

Leah VaSahnja Durant, Law Offices of Leah V. Durant, PLLC, Washington, DC, for petitioner.
Sarah Duncan, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT[1]

On January 2, 2018, petitioner, Susan Grossman, filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012),[2] alleging that her receipt of an influenza vaccination on October 21, 2016, caused a left shoulder injury. (ECF No. 1.) For the reasons set forth below, I conclude that petitioner is entitled to an award of 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,

[1] Because this decision contains a reasoned explanation for the special master's action in this case, it will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. *See* 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the decision 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 the special master, upon review, agrees that the identified material fits within this definition, it will be redacted from public access.

[2] All references to "§ 300aa" below refer to the relevant section of the Vaccine Act at 42 U.S.C. § 300aa-10-34.

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

As relevant here, the Vaccine Injury Table lists a Shoulder Injury Related to Vaccine Administration or "SIRVA" as a compensable injury if it occurs within 48 hours of administration of an influenza vaccine. § 300aa-14(a) as amended by 42 CFR § 100.3. Table Injury cases are guided by statutory "Qualifications and aids in interpretation" ("QAIs"), 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. 42 CFR § 100.3(c). To be considered a "Table SIRVA," petitioner must show that his injury fits within the following description:

> 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).

Alternatively, if no injury falling within the Table can be shown, the petitioner may still demonstrate entitlement to an award by 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). To so demonstrate, 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 (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). In particular, a petitioner must show by preponderant evidence: (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 in order to prove causation-in-fact. *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 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*, 592 at 1322 n.2. Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). However, a petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1).

II. Procedural History

This case was originally assigned to the Special Processing Unit ("SPU"). (ECF No. 1.) Petitioner filed medical records between January 16, 2018, and July 30, 2019. (ECF Nos. 7-8, 13, 31, 41, 45.) Respondent initially requested that his Rule 4(c) report remain suspended while the parties pursued settlement negotiations. (ECF No. 23.) However, the parties were unable to informally resolve the case and respondent filed his Rule 4(c) report recommending against compensation on October 15, 2019. (ECF No. 49.)

On April 2, 2020, petitioner filed an expert report authored by orthopedist Clifford J. Colwell, Jr., M.D. (ECF No. 53.) This case was then reassigned from the Special Processing Unit to Special Master Roth on May 11, 2020. (ECF No. 57.) On June 9, 2020, respondent filed a responsive expert report from Paul Cagle, M.D. (ECF No. 58.) Thereafter, petitioner substituted a different expert (Uma Srikumaran, M.D.) and both parties filed additional expert reports on October 8 and December 7, 2020. (ECF Nos.

61, 65.) On January 21, 2021, petitioner filed a supplemental report from Uma Srikumaran, M.D. (ECF No. 66.)

This case was reassigned to my docket on January 29, 2021. (ECF No. 68.) On March 23, 2021, respondent filed a second supplemental expert report from Dr. Cagle. (ECF No. 70.) The parties subsequently determined that the record was complete. (ECF No. 71.) On June 2, 2021, petitioner filed a motion for a ruling on the record. (ECF No. 73.) Respondent filed his response on July 2, 2021. (ECF No. 74.) Petitioner filed her reply on July 19, 2021. (ECF No. 75.)

I have determined that the parties have had a full and fair opportunity to present their cases and that it is appropriate to resolve this issue without a hearing. *See* Vaccine Rule 8(d); Vaccine Rule 3(b)(2); *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 is significant for hyperlipidemia, obesity, vestibular neuronitis, Lyme disease, temporomandibular joint dysfunction, varicose veins, degenerative disc disease, right hip bursitis and osteoarthritis.[3] (Ex. 2, pp. 36-37; Ex. 3, *passim*; Ex. 4, pp. 131-93; Ex. 11, pp. 1-5; Ex. 12, *passim*.) Respondent agrees, however, that "[p]etitioner did not have a history of left shoulder pain or injury." (ECF No. 74, p. 4.)

On October 21, 2016, petitioner received an influenza vaccination at Rite Aid Pharmacy in the left deltoid. (Ex. 1, p. 1.) On November 7, 2016, petitioner called her primary care physician Kenneth Lubansky, M.D., reporting that she received a flu shot in her left arm and "[t]he pharmacist hit a nerve, she has extreme pain in left arm all across her left side and left upper back, she took an Aspacreme patch with lidocaine and nothing will relieve it." (Ex. 8, p. 1.)

On November 15, 2016, petitioner presented to orthopedic surgeon Robert DeFalco, D.O., complaining of "left shoulder pain." (Ex. 2, p. 1.) Petitioner stated that "she has had pain for the past 3 weeks…after getting the flu shot." (*Id.*) She complained of "superior & posterior pain shoulder that radiates up into neck & down arm." (*Id.*) Petitioner further reported "numbness & tingling in left arm & hand." (*Id.*) Dr. DeFalco reviewed petitioner's left shoulder x-rays which were noted to be negative.

[3] Petitioner's physical therapy records further indicate that petitioner underwent an L4 L5 discectomy in 1992 and 1995. (Ex. 4, p. 189; *see also* Ex. 11, p. 1 ("diskectomies in the lower lumbar spine in 1993 and 1998"))

(*Id.* at 1, 11.) Petitioner described pain that was aggravated with range of motion. (*Id.* at 1.) Upon physical examination, "[t]enderness over the left tip of the acromion and subacromial bursa" was noted. (Ex. 2, p. 2.) Petitioner's "left forward flexion [wa]s 180 degrees with pain in the impingement zone." (*Id.*) Hawkins-Kennedy and Neer impingement tests were positive on the left; though "no tenderness of the left posterior surface, left parascapular area or left trapezius" was reported. (*Id.*) Petitioner had full range of motion in her neck with no pain. (*Id.*) She was given a steroid injection into the left shoulder subacromial space. (*Id.*) Dr. DeFalco's assessment was "Bursitis of left shoulder" and petitioner was ordered to start physical therapy and return in three to four weeks. (Ex. 2, p. 2.)

On November 18, 2016, petitioner presented to Skylands Medical Group Sports and Physical Therapy where she was seen by Ann Riesenman, P.T., reporting pain in the lateral left shoulder at the time of the exam, with a pain rating of 3/10. (Ex. 4, p. 127, 129.) Petitioner had an incoming diagnosis of "adhesive capsulitis of left shoulder" and "impingement syndrome of left shoulder." (Ex. 4, p. 130.) Petitioner's range of motion was 70 degrees external rotation with associated pain and "tenderness & multiple trigger points" with positive impingement signs. (Ex. 4, pp. 128.) Petitioner's assessment included decreased shoulder range of motion with associated pain. (Ex. 4, p. 129.)[4]

On December 9, 2016, petitioner presented to Kevin White, D.O., complaining of right hip pain beginning on December 5, 2016. (Ex. 2, p. 12.) Petitioner "pivoted with her right foot and she felt a sharp stabbing pain in her right hip which radiates down into her groin." (*Id.*) X-rays of petitioner's hip revealed no fractures, no dislocations, and mild degenerative joint disease. (*Id.* at 13.) Petitioner was diagnosed with right hip osteoarthritis. (*Id.*) This record contained no mention of petitioner's shoulder, arm, or neck pain. (*See id.*)

On December 19, 2016, petitioner returned to Ann Riesenman for physical therapy for continued left shoulder pain. (Ex. 4, p. 111-12.) Petitioner noted that the "pain is less intense into the [left] upper arm but most of the day present in the [left] cervical region – upper trap." (Ex. 4, p. 111.) At the time of exam, petitioner reported 4/10 pain in the lateral left shoulder. (*Id.*) Petitioner's range of motion for left abduction was 165 degrees and "painful" and left external rotation was 70 degrees and "painful." (*Id.* at 112.) Petitioner's continued diagnoses were cervicalgia, adhesive capsulitis of the left shoulder, and impingement of the left shoulder. (*Id.* at 114.) Petitioner returned for physical therapy again on January 30, March 8, and April 24, 2017. (Ex. 4, pp. 2-6; 57-61; 82-86.) Petitioner had continued diagnoses of cervicalgia, adhesive capsulitis of the left shoulder, and impingement of the left shoulder. (Ex. 4, pp. 6, 61, 86.) On April 24, 2017 petitioner reported, "I am frustrated, for I feel like I am no longer improving."

[4] Between November 18, 2016, and April 24, 2017, petitioner attended twenty-eight physical therapy sessions as Skylands Medical Group and Sports Physical Therapy. (Ex. 4, pp. 1-130.)

(Ex. 4, p. 2.) Petitioner reported "shoulder/Elbow pain and stiffness with reaching, lifting" however, "I am consistent with the [home exercise program] that helps a lot, and overall I would say I made a 70% improvement." (*Id.*) At this time petitioner "requested discharge due to not wanting to exhaust her insurance benefits." (Ex. 4, p. 5.)

On May 5, 2017 petitioner returned to Dr. DeFalco for continued "left shoulder pain." (Ex. 2, p. 19.) Petitioner reported "feeling about the same, compared to last visit." (*Id.*) She described "deep and dull throbbing pain" at a 7/10, and Dr. DeFalco noted that "pain is superior that radiates down to elbow." (*Id.*) Upon physical examination, Dr. DeFalco observed "[left] shoulder – full [range of motion] and strength [with] no impingement sign." (*Id.* at 20.) Petitioner was given a steroid injection in the left shoulder subacromial space. (*Id.*) She was diagnosed with left shoulder bursitis. (*Id.*) Dr. DeFalco further noted that he "would like to see [petitioner] for her shoulder next week. I believe her pain is coming from her cervical spine. Overall, motion and strength in the [left] shoulder are good[.]" (*Id.*) Dr. DeFalco ordered an MRI of the cervical spine and instructed petitioner to follow up with Dr. Salari. (*Id.*)

On June 2, 2017 petitioner presented to orthopedic surgeon Benham Salari, D.O., for "neck pain / left arm." (Ex. 2, p. 29.) Petitioner presented with "complaint of neck & left arm pain that started in October 2016 following a Flu shot. Patient with left sided [cervical spine] pain that extends to left shoulder & elbow." (*Id.*) She also reported upper arm spasms, left arm weakness and rated her pain at 5-10/10, "aggravated by everything, mostly sleeping." (*Id.*) Upon physical examination Dr. Salari noted "bilateral upper and lower extremities have good range of motion and no significant deformities." (*Id.* at 30.) The cervical spine MRI performed on May 9, 2017, revealed mild degenerative changes of the cervical spine; small right paracentral disc protrusions at C5-C6 and C6-C7; and no significant spinal canal or neural foraminal stenosis at any level. (*Id.* at 27-28, 30.) Dr. Salari's assessment was left shoulder bursitis. (*Id.* at 31.) Dr. Salari ordered a left shoulder MRI to assess for rotator cuff pathology. (*Id.*) He further noted that "MRI findings do not suggest cervical spine pathology or cervical spine radiculopathy." (*Id.*)

On July 12, 2017, petitioner underwent an MRI of the left shoulder. (Ex. 2, pp. 41-42.) The MRI revealed minimal lateral humeral joint effusion, degenerative marrow changes to the acromioclavicular joints, increased linear signal along the thickened supraspinatus tendon "probably representing tendinopathy." (*Id.* at 41.) It further revealed mild interstitial tears, though the infraspinatus, subscapularis and teres minor tendons were intact, "no definite labral tear" was identified, there was moderate AC joint arthropathy and laterally sloping acromial process "which does demonstrate mild mass effect on the superior surface of the proximal supraspinatus tendon." (*Id.*) Accordingly, the radiologist's impression indicated supraspinatus tendinopathy with mild interstitial tears; moderate AC joint arthropathy; and mild impingement with lateral sloping

acromial process demonstrating a mild mass effect on the superior surface of the proximal supraspinatus tendon. (*Id*.)

On August 1, 2017 petitioner returned to Dr. DeFalco for continued left shoulder pain. (Ex. 2, p. 43.) Dr. DeFalco noted petitioner's "[p]ain is superior that radiates down arm" and "rated as 3/10 in severity right now and 8/10 in severity at its worst." (*Id.*) Upon physical examination, he noted "[t]enderness over the left tip of the acromion and subacromial bursa." (*Id.* at 44.) Petitioner demonstrated full forward elevation, full external rotation, full internal rotation, and left forward flexion was noted at 180 degrees with pain in the impingement zone. (*Id.*) Hawkins-Kennedy and Neer impingement tests were positive on the left. (*Id.*) Dr. DeFalco noted that the left shoulder MRI showed rotator cuff tendonitis, and no tears of the rotator cuff. (*Id.*) Petitioner was assessed with left shoulder bursitis. (*Id.*) Dr. DeFalco further noted that petitioner "has had pain for 9 mo[nths] – difficulty sleeping every night – has had PT and HEP / nsaids without any improvement [in] l[eft] shoulder." (Ex. 2, p. 44.) Dr. DeFalco concluded "at this point would suggest arthroscopy l[eft] shoulder – subacromial decompression." (*Id.*)

On August 14, 2017 Dr. DeFalco made a preoperative diagnosis of "impingement syndrome, left shoulder" and "Labral tear, anterior-posterior superior labral complex." (Ex. 6, p. 85.) During surgery, Dr. DeFalco noted that there were no degenerative changes in the joint itself, though he observed a "labral tear in the anterior-posterior superior labral complex and a debridement was performed." (*Id.* at 86.) The rotator cuff and glenohumeral ligament were intact. (*Id.*) Dr. DeFalco further noted that the subacromial space had "thick bursitis" where a "bursectomy was performed." (*Id.*) He also observed "a rather large anterolateral spur" and thus a "subacromial decompression was performed." (*Id.*) No complications were noted. (*Id.*)

On August 24, 2017, petitioner presented to Diane Niestepski, PA-C, for her first post-operative appointment.[5] (Ex. 2, p. 50-52.) Petitioner complained of "constant achy pain of left shoulder rated as a 3/10." (*Id.* at 50.) The sutures were removed, a cortisone injection to the subacromial space was performed, range of motion was initiated, and physical therapy was recommended. (*Id.*) Petitioner's diagnoses included superior glenoid labrum lesion of the left shoulder, subsequent encounter; bursitis of the left shoulder; and impingement syndrome of the left shoulder. (*Id.* at 51.) On September 19, 2017, petitioner returned for another follow-up appointment with Dr. DeFalco. (*Id.* at 53-55.) Dr. DeFalco noted that petitioner was "feeling better compared to last visit." (*Id.* at 53.) He documented left forward flexion at 180 degrees with pain in the impingement zone; full left external and internal rotation at 90 degrees abduction. (*Id.* at 54.) Petitioner's Hawkins-Kennedy and Neer impingement tests were positive on the left. (*Id.*) Petitioner's diagnoses remained the same as her previous visit and Dr.

[5] Between August 28, 2017, and December 13, 2017, petitioner attended 27 physical therapy sessions at Skyland Sports and Physical Therapy. (Ex. 4, pp. 194-225; Ex. 7.)

DeFalco instructed her to follow-up in four weeks. (*Id.*) On December 12, 2017, petitioner presented to Dr. DeFalco, again noting that she was "feeling better compared to last visit." (Ex. 2, p. 72.) She reported soreness at 3/10 in severity in the office and 4/10 severity at its worst. (*Id.*) Dr. DeFalco noted that petitioner's "shoulder looks pretty good."[6] (*Id.* at 74.) Upon physical examination, he documented full forward flexion bilaterally and full left external and internal rotation at 90 degrees abduction bilaterally. (*Id.* at 73.) No signs of impingement pain were documented. (*See id.*)

Ten months later, on October 30, 2018, petitioner presented for a follow-up appointment with Dr. DeFalco. (Ex. 15, pp. 1-2.) Petitioner complained of "superior shoulder pain & lateral left elbow pain" that was aggravated "by reaching, lifting, carrying, laying on left side." (*Id.*) Her pain was "alleviated by Oxycodone that she just weaned off, heat ice[.]" (*Id.*) Petitioner requested a prescription for aquatic physical therapy for the left shoulder. (*Id.*) Petitioner reported her left shoulder pain was a 3/10. (*Id.*) Her physical exam revealed tenderness over the left tip of the acromion and subacromial bursa; left forward flexion at 180 degrees with pain in the impingement zone; and Hawkins-Kennedy and Neer impingement tests were positive on the left. (*Id.* at 2.) Petitioner was diagnosed with left shoulder bursitis. (*Id.*)

Between October 9, 2018, and December 27, 2018, petitioner attended nine aquatic therapy sessions for treatment on her left shoulder. (Ex. 17, pp. 1-15.) Subsequently, between April 18, and May 1, 2019, petitioner attended four aquatic therapy sessions, during which time she reported shoulder pain. (Ex. 17, pp. 16-34.) On May 31, 2019, petitioner presented to her physical therapist who recommended that she return to the orthopedist for tenderness along the rotator cuff, hesitance to use the left shoulder, and functional limitations. (Ex. 17, p. 38.)

On July 16, 2019, petitioner presented to Dr. DeFalco for a follow-up for left shoulder pain. (Ex. 18, pp. 1-2.) Dr. DeFalco noted that "[p]ain is superior & down into armpit," reported "as sharp pain" at 2/10 severity at rest and 7/10 severity at its worst. (*Id.*) Upon physical examination, petitioner's Hawkins-Kennedy and Neer impingement tests were positive on the left. (*Id.* at 2.) Petitioner was assessed with left shoulder bursitis. (*Id.*) Dr. DeFalco ordered petitioner to continue physical therapy, icing, and home exercises. (*Id.*) He offered petitioner a left shoulder injection, but petitioner declined. (Ex. 18, p. 2.)

b. As reflected in petitioner's affidavit

Petitioner filed her affidavit on February 27, 2018. (ECF No. 10.) Petitioner states that she presented to Rite-Aid Pharmacy for a flu vaccine. (Ex. 9, p. 1.) After

[6] Dr. DeFalco also noted that petitioner was "scheduled for spine surgery next week." (Ex. 2, p. 74; *see also* Ex. 2, p. 68 (petitioner "is intending to have large multilevel spinal fusion surgery in the next few weeks" (dated 11/30/2017)); Ex. 16, p. 1 ("lumbar decompression and fusion 12/20/1017").)

receiving the vaccine, "immediately [she] felt an odd sensation traveling down [her] arm to [her] elbow." (*Id.*) Petitioner was not concerned and "thought it was the fluid from the vaccine." (*Id.*) By the time she arrived home, petitioner avers that "the pain had increased and gave [her] an intense headache." (*Id.*) She speculated that this could be "symptoms of the flu injection that would likely resolve on its own." (*Id.*)

Five days later, on October 26, 2016, petitioner contacted the Rite-Aid pharmacy to discuss her symptoms. (Ex. 9, p. 1.) By this time, petitioner describes her symptoms of "deep throbbing pain" in her left arm that "immobilized [her] arm." (*Id.*) She avers that the range of motion in her neck and head were impacted, she had difficulty sleeping, and experienced frequent headaches. (*Id.*) Petitioner states that her primary care physician, Kenneth Lubansky, recommended that she see an orthopedic doctor. (*Id.*) On November 15, 2016, petitioner presented to Dr. Robert DeFalco at the Orthopedic Institute of New Jersey. (*Id.*) Petitioner states that Dr. DeFalco took x-rays, gave her a cortisone injection and medication, and prescribed physical therapy. (*Id.*)

Petitioner avers that she began physical therapy at the Skylands Medical Group on November 17, 2016. (Ex. 9, p. 1.) Her physical therapy continued through December 13, 2017. (*Id.*) Petitioner states that during this time she was under the care of Dr. DeFalco who attempted a conservative approach involving physical therapy, MRI, medication, and cortisone injections. (*Id.*) After these conservative treatments failed, petitioner states that it was decided that surgery was the best course of action. (*Id.*) Subsequently Dr. DeFalco performed surgery on petitioner's left shoulder on August 14, 2017. (*Id.*)

Petitioner states completing basic daily functions have become very difficult, including grooming, dressing, cleaning, lifting, shopping, and driving. (Ex. 9, p. 2.) According to petitioner, travel, hobbies, and other social activities are no longer possible. (*Id.*) She further states that her work managing the bath showroom division at Hamburg Supply has been affected by her pain. (*Id.*) Petitioner avers that her job requires pulling and packing orders and carrying and showing product samples. (*Id.*) She further avers that although co-workers assisted her with helping customers, she lost commissions, she used all of her personal and vacation time when she was unable to work due to her pain, and she was concerned about losing her job. (*Id.*) Lastly, petitioner states that this event caused her to suffer exhaustion, frustration, weight gain and depression; and she has suffered significant financial hardships related to her medical expenses. (*Id.*)

IV. Summary of Expert Opinions

a. Petitioner's Initial Expert Clifford Cowell, Jr., M.D.

Initially, petitioner presented an expert opinion by orthopedist Clifford Cowell Jr., M.D.[7] Dr. Cowell opines that petitioner meets the requirements for a SIRVA injury. (Ex. 19, p. 1.) Specifically, Dr. Cowell opines that there was no indication that petitioner had any previous history of pain, inflammation, or dysfunction of the affected shoulder prior to her flu vaccination. (*Id.*) Furthermore, he stresses that petitioner's symptoms began immediately following the injection. (*Id.*) Dr. Cowell emphasizes that "all of [petitioner's] medical records that discuss the issue of onset…consistently indicate that her pain occurred within the specific time frame outlined in the SIRVA requirements." (*Id.* at 2.)

Dr. Cowell explains that it is "extremely common" for patients with shoulder injuries to report pain in the neck and arm. (Ex. 19, p. 2.) For support Dr. Cowell cites Gorski and Schwartz, who reported on thirty-four patients with neck pain who met the criteria for shoulder impingement syndrome. (*Id.* (citing Jerrold M. Gorski & Lawrence H. Schwartz, *Shoulder Impingement Presenting as Neck Pain,* 85(A) J. OF BONE & JOINT SURGERY 635 (2003) (Ex. 22).) In that study, Dr. Cowell explains, thirty of thirty-four patients had immediate relief of neck pain and the remaining four reported substantial relief three weeks later. (Ex. 19, p. 2.) Dr. Cowell highlights the authors' conclusion that, in some patients, neck pain may be caused by shoulder impingement. (*Id.*) Shoulder bursitis, Dr. Cowell notes, "doesn't discriminate between neck and shoulders, which means pain may occur in either area." (*Id.* (citing Anne Asher, *Common Causes of Neck and Shoulder Pain,* VERYWELLHEALTH, https://www.verywellhealth.com/common-causes-of-neck-and-shoulder-pain-4126559 (last updated Nov. 22, 2019) (Ex. 23).)

Three weeks after vaccination, Dr. Cowell observes that petitioner reported tenderness over the left tip of the acromion and subacromial bursa, petitioner had left forward flexion at 180 degrees with pain in the impingement zone, and her Hawkins-Kennedy and Neer tests were positive on the left—all findings consistent with SIRVA. (Ex. 19, p. 2.) Petitioner's incoming diagnoses listed in her physical therapy records include "Adhesive capsulitis of left shoulder" and "Impingement syndrome of left

[7] Dr. Cowell serves as the medical director of the Shiley Center for Orthopaedic Research and Education at Scripps Clinic where he acts as the Donald and Darlene Shiley Chair in Orthopaedic Research. (Ex. 19, p. 1.) He is also a clinical professor in the Department of Orthopaedics and Rehabilitation at the University of California, San Diego, School of Medicine, and an adjunct clinical professor at the Department of Basic Science and Clinical Research at the Scripps Research Institute. (*Id.*) Dr. Cowell served as the chief of the Orthopaedic Division at Scripps Clinic and Director of the Lower Extremity Reconstruction Fellowship Program for twenty years. (*Id.*) Dr. Cowell received his medical degree from the University of Michigan in 1962. (Ex. 20, p. 1.) He completed his orthopaedic residency at the Hospital for Special Surgery in New York City, and completed a trauma fellowship at Los Angeles County Hospital. (*Id.*) Dr. Colwell is board certified in orthopaedic surgery. (*Id.* at 3.) Between 1968-1970 Dr. Cowell served in the military as an orthopaedic surgeon at Carswell Air Force Base in Fort Worth, Texas. (*Id.* at 1.) Dr. Colwell has authored over 260 peer-reviewed papers, as well as 19 book chapters, including work related to total shoulder arthroplasty. (*Id.* at pp. 7-21.) He currently serves at the editor for Bone and Joint Disease: Index and Review journal and The Journal of Arthroplasty. (*Id.* at 6.)

shoulder," which Dr. Cowell explains are also consistent with SIRVA. (*Id.* (citing Ex. 4, p. 130.)) Though Dr. DeFalco initially suspected petitioner's shoulder pain came from the cervical spine, Dr. Cowell observes that her MRI taken on June 2, 2017, did not support a cervical spine cause for her symptoms. (*Id.* (citing Ex. 2, pp. 20, 31.)) In fact, Dr. Cowell observes that orthopedist Dr. Salari ordered an MRI which revealed a preliminary finding of "Supraspinatus tendinopathy with mild interstitial tears," which Dr. Cowell stresses is more consistent with SIRVA than a cervical cause for petitioner's pain. (*Id.*) Dr. Cowell suggests that petitioner's surgery performed on August 14, 2017, reduced but did not eliminate her pain, concluding that the surgery "must be considered a successful procedure, and would indicate an injury to the shoulder consistent with SIRVA."[8] (*Id.* at 2-3.)

b. Respondent's Expert, Paul J. Cagle, M.D., initial report (Ex. A)

Respondent relies on the expert opinion of Paul J. Cagle, M.D.[9] Dr. Cagle opines that petitioner's subjective findings do not support the claim of a SIRVA. (Ex. A, p. 3.) Petitioner described shoulder pain for three weeks after a shoulder vaccination, but Dr. Cagle states that her pain was "vaguely described as involving her neck and arm." (*Id.*) Her pain was "nonspecific enough" that Dr. DeFalco suggested that he believed the pain was coming from her neck. (*Id.*) Dr. Cagle concludes that Dr.

[8] Though Dr. Cowell believes that petitioner meets the elements of a SIRVA Table Injury, he also briefly addresses the elements of causation-in-fact. (Ex. 19, p. 3.) Citing an article by Atanasoff et al., Dr. Cowell stresses that the theory behind SIRVA has been "well established medically" and has been described in several well-respected peer reviewed journals. (*Id.* (citing Sarah Atanasoff et al., *Shoulder injury related to vaccine administration (SIRVA),* 28 VACCINE 8049 (2010) (Ex. 24.)) According to Dr. Cowell, this article provides support for the theory that antigenic material from the vaccine is injected into synovial tissues resulting in an immune-mediated inflammatory pain reaction. (*Id.* (citing Atanasoff et al., *supra,* at Ex. 24.) The Arias et al. study in 2017 "adds to the reliability of the theory." (*Id.* (citing Martin Arias et al., *Risk of bursitis and other injuries and dysfunctions of the shoulder following vaccinations,* 35 VACCINE 4870 (2017) (Ex. 25.)) That petitioner's pain began on the day of her vaccination is consistent with Atanasoff and Arias articles. (*Id.*) Dr. Cowell opines that the influenza vaccine, containing antigenic material, "caused [petitioner] to suffer shoulder inflammation and pain caused by an immune-mediated reaction." (*Id.*)

[9] Dr. Cagle serves an as assistant professor and Associate Program Director in the Department of Orthopaedic Surgery at the Icahn School of Medicine at Mount Sinai. (Ex. A, p. 1.) He is a member of the American Shoulder and Elbow Surgeons, and a faculty member of an internationally recognized shoulder surgery fellowship. (*Id.*) His current practice focuses on the shoulder, representing 95% or more of the patients and pathology he treats. (*Id.*) Dr. Cagle conducts clinical, biomechanical, and basic science research. (*Id.*) He has presented scientific work nationally and internationally; and has published over twenty articles related to shoulder injuries and surgery. (Ex. B, pp. 11-12.) Dr. Cagle is a peer reviewer for the Journal of Orthopaedic Research, Techniques in Shoulder and Elbow Surgery, and the Journal of Shoulder and Elbow Surgery. (*Id.* at 13.) He received his medical degree from Loyola University Chicago Stritch School of Medicine in 2008. (*Id.* at 2.) Dr. Cagle completed his orthopaedic residency at the University of Minnesota Academic Health center and Medical School. (*Id.*) He also completed a shoulder and elbow fellowship at Mount Sinai Hospital in New York and is board certified in orthopaedic surgery. (*Id.*)

DeFalco "took this belief quite seriously as this prompted a referral for an evaluation and an MRI of her cervical spine." (*Id.*)

Upon review of objective findings, Dr. Cagle opines that petitioner's physical exam is inconsistent. (Ex. A, p. 3.) Dr. Cagle points to petitioner's first visit with Dr. DeFalco November 11, 2016, where she was noted to have impingement pain. (*Id.*; Ex. 2, pp. 1-3.) However, in petitioner's visit on May 5, 2017, Dr. Cagle stresses that petitioner's physical exam of her left shoulder noted full range of motion and strength with no signs of impingement. (*Id.*; Ex. 2, pp. 19-21.) "[T]here is nothing" in the physical exam from this visit, according to Dr. Cagle, that supports continued bursitis. (*Id.*) Again, on October 30, 2018, Dr. Cagle notes that petitioner had the same physical exam findings, despite an extended time period, multiple cortisone injections, physical therapy and surgery. (*Id.*) Yet, Dr. Cagle observes that in an earlier record from December 13, 2017, petitioner reported to her physical therapist that she had 90% relief. (*Id.* (citing Ex. 7, p. 2.)) Overall, Dr. Cagle opines, that "this demonstrates either an unreliable physical exam or a physical exam pointing away from a diagnosis of bursitis" and towards "another pathology that could cause the same exam findings on the first and last visit with Dr. DeFalco." (*Id.*)

Dr. Cagle opines that the imaging findings are also not consistent with SIRVA. (Ex. A, p. 3.) The MRI findings, he explains, demonstrated no signs of bursitis, the most common finding associated with SIRVA. (*Id.*) According to the medical literature, patients with SIRVA have increased fluid signal and bursal fluid on MRI presentation. (*Id.*)[10] Furthermore, Dr. Cagle notes that the additional finding of rotator cuff tendinopathy is also inconsistent with SIRVA. (*Id.*) Rotator cuff tendinopathy is consistent with chronic rotator cuff degenerative pathology. (*Id.*) Multiple studies, according to Dr. Cagle, have demonstrated through ultrasound and MRI assessments that people over the age of 50 years old can have asymptomatic rotator cuff pathology. (*Id.* at 4.)[11] Over fifty percent of individuals who have asymptomatic rotator cuff

[10] Citing Jean-Hugues Salmon et al., *Bone erosion and subacromial bursitis caused by diphtheria-tetanus-poliomyelitis vaccine,* 33 VACCINE 6152 (2015) (Ex. A, Tab. 1); Patrick Messerschmitt et al., *Progressive osteolysis and surface chondrolysis of the proximal humerus following influenza vaccination,* 35 ORTHOPEDICS e283 (2012) (Ex. A, Tab. 2); Matthew G. Barnes et al., *A "needling" problem: shoulder injury related to vaccine administration,* 25 J. AM. BOARD FAM. MED. 919 (2012) (Ex. A, Tab. 3); Gerald Kuether et al., *Atraumatic osteonecrosis of the humeral head after influenza A-(H1N1) v-2009 vaccination,* 29 VACCINE 6830 (2011) (Ex. A, Tab. 4); Gokean Okur et al., *Magnetic resonance imaging of abnormal shoulder pain following influenza vaccination,* 43 SKELETAL RADIOOGY 1325 (2014) (Ex. A, Tab. 5); Neeti A. Bathia & Todd Stitik, *"Influenza vaccine shoulder" –vaccination related traumatic injury to the infraspinatus: a case report,* 43 AM. J. OF PHYSICAL MED. & REHABILITATION S118 (2009) (Ex. A, Tab. 6.); Soshi Uchida et al., *Subacromial bursitis following human papilloma virus vaccine misinjection,* 31 VACCINE 27 (2012) (Ex. A, Tab 7.)

[11] Citing Jerry S. Sher et al., *Abnormal findings on magnetic resonance images of asymptomatic shoulders,* 77 J. OF BONE & JOINT SURGERY 10 (1995) (Ex. A, Tab. 8); Siegbert Tempelhof et al., *Age-related prevalence of rotator cuff tears in asymptomatic shoulders,* 8(4) J. OF SHOULDER & ELBOW Surgery 296 (1999) (Ex. A, Tab. 9); Hiroshi Minagawa et al., *Prevalence of symptomatic and asymptomatic rotator*

pathology will become symptomatic in an average of 2.8 years. (*Id.* (citing Ken Yamaguchi et al., *Natural history of asymptomatic rotator cuff tears: a longitudinal analysis of asymptomatic tears detected sonographically,* 10 J. OF SHOULDER ELBOW SURG. 199 (2001) (Ex. A, Tab. 11.)) Thus, Dr. Cagle explains, the findings of tendinopathy represent chronic rotator cuff pathology, "and the natural history of the diagnosis is over a fifty percent chance of progression to painful symptoms."[12] (Ex. A, p. 4.)

c. Uma Srikumaran, M.D., M.B.A., M.P.H., Initial Report (Ex. 26)

After respondent filed his initial expert report, petitioner substituted a different orthopedic expert, Uma Srikumaran, M.D., M.B.A., M.P.H.[13] Dr. Srikumaran opines that petitioner's records indicate that her left shoulder condition was caused by the October 21, 2016, flu vaccination. (Ex. 26, p. 6.) He further opines that there are no records suggesting a prior history of left shoulder pain or pathology. (*Id.*)

Dr. Srikumaran emphasizes that petitioner consistently and reliably reported "immediate shoulder pain (same day) with intensification over time after vaccination" to

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cuff tears in the general population: From mass-screening in one village, 10 J. OF ORTHOPAEDICS 8 (2013) (Ex. A, Tab. 10.)

[12] Regarding injection of the vaccine, Dr. Cagle also notes that improper penetration into the bursal layer is a commonly proposed mechanism in SIRVA cases. (Ex. A, p. 4.) However, for this to occur, an inappropriate technique and / or an overly long needle would have to have been used. (*Id.*) Based on current CDC guidelines and studies testing the appropriate needle length, administration of a vaccine in petitioner's case would require a needle over one inch in length in order to penetrate the bursa (based on someone within petitioner's weigh and GMI range). (*Id.* (citing *Dose route site and needle size,* CENTERS FOR DISEASE CONTROL AND PREVENTION, www.immunize.org/catg.d/p3085.pdf. (last accessed Mar. 22, 2019) (Ex. A, Tab. 13); Gregory A. Poland et al., *Determination of deltoid fat pad thickness: implications for needle length in adult immunizations,* 277(21) J. AM. MED. ASSN. 1709 (1997) (Ex. A, Tab. 14); Michael Phillip Koster et al., *Needle length for immunization of early adolescents as determined by ultrasound,* 124 PEDIATRICS 666 (2009) (Ex. A, Tab. 15.)) Based on this data, Dr. Cagle explains that it is highly unlikely that a standard needle would have penetrated past the deltoid. (*Id.*) While this may be potentially relevant regarding a cause-in-fact claim, as long as petitioner demonstrates her injury to be consistent with a Table Injury, she enjoys a presumption that her injury was caused by her vaccination so long as respondent does not prove it was caused by a factor unrelated to vaccination.

[13] Dr. Srikumaran serves as an associate professor in the Shoulder Division at the Johns Hopkins School of Medicine and serves as the Shoulder Fellowship Director and Chair of Orthopaedic Surgery for the Howard County General Hospital. (Ex. 26, p. 1.) He also serves as the Medical Director of the Johns Hopkins Musculoskeletal Service Line in Columbia, Maryland. (*Id.*) Each year Dr. Srikumaran sees approximately 2500-3000 patients for shoulder issues and performs 400-500 shoulder surgeries annually. (*Id.*) He has treated approximately ten to twelve patients with shoulder dysfunction after vaccination in the past five years. (*Id.*) Dr. Srikumaran received his medical degree from Johns Hopkins School of Medicine in 2005. (Ex. 27, p. 1.) He completed his orthopaedic residency at Johns Hopkins Hospital and completed a shoulder surgery fellowship at Massachusetts General Hospital. (*Id.*) Dr. Srikumaran is board certified in orthopaedic surgery. (*Id.* at 10.) He has published numerous articles in the field of shoulder surgery, though none specifically related to SIRVA. (Ex. 26, p. 1.) He also peer reviews journal articles for several orthopaedic journals including The Journal of Bone & Joint Surgery, Orthopedics, Clinical Orthopedics and Related Research, and The Journal of Shoulder and Elbow Surgery. (*Id.*)

several medical providers in various clinical settings. (*Id.* at 7.) Although petitioner's records indicate that her first report of shoulder pain occurred seventeen days post-vaccination, Dr. Srikumaran explains that "[t]he vast majority of patients do not have their pain (outside of acute traumas/emergency room situations) evaluated within 48 hours." (*Id.*) In fact, he explains that it is "quite normal for someone to wait weeks or even longer prior to formal evaluation as in [petitioner's] case." (*Id.*)

Dr Srikumaran opines that petitioner's pain in her shoulder and arm were consistently reported with reduced range of motion in the shoulder, weakness, and positive exam tests extending beyond six months. (Ex. 26, p. 7.) Petitioner's MRI findings showed rotator cuff partial tears and supraspinatus tendinopathy, both common conditions associated with SIRVA. (*Id.* (citing Ex. 2, p. 42.)) Dr. Srikumaran agrees with Dr. Colwell's conclusion that petitioner's clinical course, exam findings, diagnoses, and medical care (including the arthroscopic surgery) are all appropriate and consistent with the management of SIRVA. (*Id.* at 7-8.)

Dr. Srikumaran disagrees with Dr. Cagle regarding the significance of petitioner's reports of pain radiating into her neck and down her arm. (Ex. 26, p. 8 (citing Ex. 8; Ex. 2, pp. 1-6, 22, 29-31, 43-45; Ex. 4, p. 246.)) Dr. Srikumaran stresses that "it is important to recognize 'radiation' of the pain is quite different from pain originating at these other sites (neck/arm)." (*Id.*) Radiation, he explains, "is simply another way medical professionals describe the pain, much like severity, quality (sharp, ache), or associated symptoms (burning, tingling)." (*Id.*) Furthermore, he stresses that shoulder pain is well-known to radiate, or extend to, adjacent areas such as the neck or down the arm. (*Id.*) At petitioner's May 5, 2017, visit with Dr. DeFalco, Dr. Srikumaran highlights the chief complaint of continued left shoulder pain with a final diagnosis of bursitis of the left shoulder. (*Id.* (citing Ex. 2, p. 20.)) It was "very appropriate for DeFalco to have considered potential other sources of shoulder pain" when other treatment methods were not providing relief, according to Dr. Srikumaran. (*Id.*) Like Dr. Colwell, Dr. Srikumaran notes that Dr. DeFalco ruled out a cervical cause for petitioner's pain based on petitioner's MRI and evaluation. (*Id.* (citing Ex. 2, p. 31.)) Even still, Dr. Srikumaran stresses that no other conditions, "such as neuropathies or radiculopathies," can explain petitioner's symptoms. (*Id.*)

In response to Dr. Cagle's report, Dr. Srikumaran explains that the various physical findings in petitioner's visits are quite typical because shoulder pain can present in different ways and can change over time. (Ex. 26, p. 8.) Dr. Srikumaran maintains that petitioner was correctly diagnosed with bursitis and that neither Dr. Cagle nor the medical records suggest any other pathology likely to explain petitioner's symptoms. (*Id.* at 8-9.) While Dr. Cagle suggests that the lack of bursitis in the MRI is inconsistent with SIRVA, Dr. Srikumaran explains that the operative record is in Exhibit 6, where a camera was directly placed into the subacromial space, noting that the subacromial space "had 'thick bursitis' where a 'bursectomy was performed.'" (*Id.* at 9 (citing Ex. 6, p. 86.)) Quoting the MRI, Dr. Srikumaran notes that "[t]here is increased

linear signal along the thickened supraspinatus tendon probably representing tendinopathy with mild interstitial tears." (*Id.*) Dr. Srikumaran explains that the finding of "increased linear signal" could be interpreted as bursitis. (*Id.*) He stresses that in petitioner's case there was direct arthroscopic visualization of bursitis at the time of surgery. (*Id.*) Moreover, Dr. Srikumaran notes that rotator cuff pathology is quite common in individuals over the age of fifty, and the vast majority of cases are asymptomatic. (Ex. 26, p. 9.) In petitioner's case, the immediate and sudden pain occurring soon after vaccination is not consistent with the "slow waxing and waning" development of symptoms of this chronic condition.[14] (*Id.*)

d. First Supplemental Report, Dr. Cagle (Ex. C)

In his first supplemental expert report, Dr. Cagle disputes Dr. Srikumaran's claim that shoulder pain can present in different ways and change over time. (Ex. C, p. 1 (citing Ex. 23, p. 9.)) Suggesting that shoulder pathology can change from time to time, without reason or course, suggests that the pathology is random, Dr. Cagle explains. (Ex. C, p. 1.) Shoulder pathology, however, is not random; and Dr. Cagle further stresses that Dr. Srikumaran has not provided any evidence documenting a change over time with treatments and outcomes. (*Id.*) According to Dr. Cagle, Dr. Srikumaran incorrectly interprets the radiating pain beyond the shoulder as consistent with a SIRVA. (*Id.*) Dr. Cagle observes that petitioner described "symptoms outside of the shoulder area at the first complaint and during a therapy visit 27 post-vaccination." (*Id.*)

[14] Nor, speaking to causation-in-fact, does Dr. Srikumaran expect there to have been a "description of an inappropriate technique in the medical record" of petitioner's vaccine administration. (Ex. 26, p. 9 (citing Dr. Cagle's report (Ex. A, p. 4).) A high position, less than ideal angle, and / or a thin deltoid muscle could result in injection of antigenic material near the bursa. (*Id.*) Citing Bodor & Montalvo, Dr. Srikumaran explains that a "high" position of injection into the deltoid can lead to a subacromial injection rather than an intramuscular injection. (*Id.* at 10 (citing Marko Bodor & Enoch Montalvo, *Vaccination-related shoulder dysfunction,* 25 VACCINE 585 (2007) (Ex. 30).) Moreover, Dr. Srikumaran likewise agrees with Dr. Colwell that the medical literature supports the theory that vaccinations can cause shoulder injuries. (*Id.* at 9-10.) In Atanasoff et al., Dr. Srikumaran stresses that all of the patients had a rapid onset of symptoms isolated to the area of injection. (*Id.* (citing Atanasoff et al., *supra,* at Ex. 24.)) Furthermore Arias et al., in a large systematic review, established the time course of injury with a majority of patients reporting pain within 48 hours, and many reporting a high injection location. (*Id.* (citing Martin Arias et al., *supra,* at Ex. 25.)) Both authors propose an immune mediated response of inflammation related to antigens injected into the bursal tissue, likely from poor administration technique. (*Id.*) Dr. Srikumaran adds that both animal (Dumonde) and human (Trollmo) basic studies support this theory. (*Id.* (citing D.C. Dumonde & L.E. Glynn, *The Production of Arthritis in Rabbits by an immunological reaction to Fibrin,* 43(4) BRIT. J. OF EXPERIMENTAL PATHOLOGY 373 (1961) (Ex. 31); C. Trollmo et al., *Intra-articular immunization induces strong systemic immune response in humans,* 82 IMMUNOLOGY 384 (1990) (Ex. 32.)) Dr. Srikumaran notes that the logical sequence of cause and effect established from the medical theory in petitioner's case suggests that the needle injection of vaccine antigen inadvertently near the bursa or rotator cuff tendon led to a strong immune-mediated inflammatory reaction, causing bursitis and tendinopathy. (*Id.*) In his experience as a shoulder surgeon, Dr. Srikumaran states that patients reliably identify their trigger and can be trusted when they do so. (*Id.*) Ultimately, petitioner's records show consistent and reliable subjective reporting reinforced by objective diagnostic tests and surgical findings – all which support vaccination as the cause of petitioner's shoulder pain.

Therefore, "this radiating pain was specifically noted to have occurred *immediately* upon vaccination." (*Id.*) (emphasis added).

Regarding petitioner's MRI, Dr. Cagle emphasizes that the MRI report does not demonstrate the "classic" findings published in the SIRVA literature, nor does the SIRVA literature correlate MRI findings with arthroscopy findings. (Ex. C, p. 1.) Moreover, suggesting that another radiologist may have interpreted petitioner's MRI differently would be speculative. (*Id.*) According to Dr. Cagle, Dr. Srikumaran selectively focuses on the MRI and the operative findings. (*Id.*) In the MRI, Dr. Cagle notes that Dr. Srikumaran focuses on the rotator cuff pathology while disregarding the AC joint arthropathy and mass effect of the acromion on the supraspinatus tendon. (*Id.*) Both of these findings, according to Dr. Cagle, "can be a source of shoulder pain, and the acromion is a well described source of impingement pain." (*Id.*) Furthermore, "Dr. Srikumaran disregards the SLAP lesion, not appreciated on the MRI, despite SLAP lesions being a common cause of shoulder pain."[15] (*Id.* at 2.)

e. First Supplemental Expert Report, Dr. Srikumaran (Ex. 34)

Dr. Srikumaran maintains that shoulder pain, as a symptom, can present in different ways and change over time with various treatments. (Ex. 34, p. 1.) He suggests that Dr. Cagle conflates the symptom of "pain" with physical findings or shoulder pathology. (*Id.*) A rotator cuff tear, for example, can present with varying degrees of pain or types of pain. (*Id.*) Quoting petitioner's medical records, Dr. Srikumaran stresses that petitioner complained of "superior & posterior *pain shoulder* [*sic*] that radiates up into neck & down arm." (*Id.* (citing Ex. 2, p. 1.))

Dr. Srikumaran clarifies that he did consider both the MRI and arthroscopic findings in petitioner's records. (Ex. 34, p. 1.) He points to "*direct visual evidence* of 'thick bursitis' at the time of surgery." (*Id.*) (emphasis in original). Dr. Srikumaran acknowledges that he is "disregarding the AC joint arthropathy and mass effect of the acromion, or SLAP tear found during surgery" because "these are chronic conditions which did not develop suddenly after injection; they existed for years or decades prior." (*Id.*) Importantly, he stresses that "petitioner never sought treatment for any of them."[16] (*Id.*)

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[15] Dr. Cagle also disputes petitioner's medical theory of causation. (Ex. C, p. 2.) Dr. Cagle acknowledges that the scientific literature supports a theory that vaccination events are "associated with shoulder injuries but the literature does not support the mechanism for how this occurs." (*Id.*) (emphasis in original). Dr. Cagle stresses that the papers cited by Dr. Srikumaran "hypothesize that the injected material (the vaccine and/or adjuvants) cause an inflammatory reaction." (*Id.*) (emphasis in original). However, Dr. Cagle maintains that there is very little supporting data for the mechanism of action theory. (*Id.*) In fact, Trollmo et al., was published thirty years ago, and DuMonde & Glynn was an animal study published fifty-eight years ago – demonstrating "just how little support exists." (*Id.* at 2-3.)

[16] In this report, Dr. Srikumaran also further addresses causation-in-fact. Dr. Srikumaran maintains that the articles from Bodor et al. (*supra,* at Ex. 30), Atanasoff et. al. (*supra,* at Ex. 24), Dumonde & Glynn (*supra,* at Ex. 31), Trollmo et al. (*supra,* at Ex. 32), and Arias et al. (*supra,* at Ex. 25), add reliability to

f. Second Supplemental Expert Report, Dr. Cagle (Ex. D)

Concerning petitioner's MRI data, Dr. Cagle expresses concern over Dr. Srikumaran classification of petitioner's "chronic conditions." (Ex. D, p. 1.) In his final report, Dr. Srikumaran classified petitioner's AC joint arthropathy, mass effect of the acromion and SLAP tear as chronic conditions. (Ex. D, p. 1; Ex. 34, p. 1.) Dr. Cagle criticizes this classification because "Dr. Srikumaran doesn't explain [] how he is determining some findings to be new/acute and some findings to be old/chronic." (Ex. D, p. 1.) In contrast, Dr. Cagle believes that "all the findings on the MRI are chronic." (*Id.*) He concludes that "Dr. Srikumaran has not presented any evidence as to why some findings in the MRI are new while others are chronic, but we are now in agreement that the MRI demonstrates a clear history of chronic pathology." (*Id*.) Finally, Dr. Cagle maintains that SIRVA reports have demonstrated an association between an injection of a vaccine and shoulder injury, but the literature has "not established *how* shoulder injuries can occur." (*Id.* at 2 (citing Paul J. Cagle, *Shoulder Injury after Vaccination: A Systematic Review,* 56 REVISTA BRASILEIRA ORTOPEDIA. 299 (2021) (Ex. D, Tab. 1.))

V. Party Positions

a. Petitioner's contentions

Petitioner contends that she suffered a left-sided shoulder injury meeting all four elements demonstrating a SIRVA Table injury. (ECF No. 73, pp. 5-6.) Petitioner stresses that her pain was limited to her left shoulder. (ECF No. 73, p. 6.) Quoting Dr. Colwell, petitioner stresses that "[i]t is extremely common for patients with injuries to their shoulders to report pain in the neck and arm." (*Id.* at 7 (quoting Ex. 19, p. 2.) Furthermore, "[p]etitioner's SIRVA injury was responsible for the symptoms in her neck, arm, etc." (*Id.* at 7 (quoting Ex. 19, p. 2.)) Although respondent contends petitioner's pain was not limited to her shoulder, petitioner quotes Dr. Srikumaran's report where he explains that "[s]houlder pain is well-known to radiate (extend to) adjacent areas such as the neck or down the arm." (*Id.* at 7 (quoting Ex. 26, p. 8.)) Moreover, petitioner's

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petitioner's causation theory, despite their age. (Ex. 34, p. 2-4.) Moreover, he suggests that this theory has growing acceptance as evidenced by the vaccination guidelines from the CDC and the Journal of the American Pharmacists Association. (Ex. 34, p. 5 (citing *New Shingles Vaccine Fact Sheet for Healthcare Providers,* CDC.GOV, https://www.cdc.gov/shingles/multimedia/shingles-factsheet-hcp.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fhcp%2Finfographics%2Fycts-shingrix.html (last updated July 1, 2019); Foster & Davis, *Vaccine administration: preventing serious shoulder injuries,* 53(1) J. AM. PHARM. ASSOC. 102-03 (2013)). Dr. Srikumaran stresses that new research has provided epidemiologic evidence supporting the association of subdeltoid bursitis after influenza vaccination. (Ex. 34, p. 5.) According to Dr. Srikumaran, Hesse et al. found an increased risk of 7.78 cases per 1 million vaccinations. (*Id.* (citing Hesse et al., *Risk For Subdeltoid Bursitis After Influenza Vaccination: A Population-Based Cohort Study,* 173(4) ANN. INTERN. MED. 253061 (2020) (Ex. 36.)) This epidemiologic evidence can now be "added to the *growing* observational clinical evidence making a strong argument for the validity of shoulder injury related to vaccination." (Ex. 34, p. 5 (citing Elisabeth M. Hesse et al., *Shoulder injury related to vaccine administrations (SIRVA): petitioner claims to the National Vaccine Injury Compensation Program, 2010-2016,* 38 VACCINE 1076 (2020) (Ex. 35.))

medical records indicate "that she did not experience cervical pathology." (*Id.* at 8 (citing Ex. 26, p. 8.))

Petitioner further stresses that her medical record, as a whole, demonstrates that petitioner's pain and reduced range of motion were limited to the shoulder. (ECF No. 75, pp. 2-3.) Petitioner's treating physicians, Dr. DeFalco (orthopedic surgeon), Diane Niestpski (physician assistant), and Ann Riesenman (physical therapist), all provided care and treatment "solely to petitioner's shoulder." (*Id.* at 3.)

Petitioner highlights language from the Secretary prior to adopting the Final Rule adding SIRVA to the Vaccine Injury Table, indicating that "pain in the neck or back without an injury to the shoulder in which an individual received a vaccine would not be considered SIRVA." (*Id.* at 8-9 (quoting 82 Fed. Reg. 6294 (Jan. 19, 2017).) Thus, petitioner stresses that the opposite must also be true. (*Id.* at 9.) "[P]ain in the neck *with* an injury to the shoulder in which an individual received a vaccine must be considered SIRVA." (*Id.*) (emphasis in original).

Petitioner further argues that petitioner's symptoms were not caused by a factor unrelated to vaccination and that respondent ignores the fact that petitioner's shoulder "was asymptomatic prior to her SIRVA injury." (*Id.* at 4.) Petitioner stresses that her treating physicians continued to assess her as suffering from bursitis, and that bursitis was the primary post-surgical diagnosis. (*Id.* at 4-5 (citing Ex. 2, pp. 44; Ex. 6, p. 86.)) Furthermore, there are "no other conditions such as neuropathies or radiculopathies that can explain [petitioner's] symptoms." (*Id.* (quoting Ex. 26, p. 8.).) Petitioner also emphasizes that the QAI does not require petitioner to articulate a mechanism for injury in an On-Table claim; and the lack of bursitis on a single MRI is not dipositive in an On-Table claim.[17] (*Id.* at 10.)

b. Respondent's contentions

Respondent argues that petitioner has not met the elements for an On-Table SIRVA. (ECF No. 74, pp. 10, 14.) Specifically, respondent stresses that petitioner's

[17] Alternatively, petitioner asserts that reliable medical evidence supports a non-Table injury was caused-in fact by her vaccination. (*Id.*) In support of her causation-in-fact claim, petitioner asserts that she has satisfied all three *Althen* prongs. (ECF No. 73, p. 10.) Under *Althen* prong one, petitioner cites Atanasoff et al. as well as epidemiologic evidence (Hesse et al.) supporting the association of subdeltoid bursitis after influenza vaccination. (*Id.* at 10-11.) The "theory is that vaccine antigen injected into synovial tissue has the potential for inducing a prolonged immune-mediated inflammatory reaction." (*Id.*) Under *Althen* prong two, petitioner suggests that the needle injection of the vaccine inadvertently near the bursa or rotator cuff tendon led an immune-mediate inflammatory reaction causing bursitis and tendinitis. (*Id.* at 12.) Although "no treating physician attributed petitioner's shoulder pain as being actually caused by her vaccination," petitioner maintains that several physicians noted the temporal association. (*Id.*) Finally, under *Althen* prong three, petitioner asserts that petitioner's medical records show that the onset of her shoulder pain occurred within 48 hours of receiving her October 21, 2016 influenza vaccination. (*Id.* at 12-13.) Lastly, petitioner stresses that she need not prove a specific mechanism to prove causation, as suggested by Dr. Cagle. (*Id.* at 13-15.)

shoulder pain and reduced range of motion were not limited to her left shoulder. (*Id.* at 10-11.) From petitioner's first complaint she described pain in her left arm "all across the left side," and her left upper back. (*Id.* at 11 (citing Ex. 8.)) Subsequently, respondent emphasizes that petitioner complained of superior and posterior shoulder pain that radiated up into her neck and down her arm and a constant headache, as well as cervical spine pain. (*Id.* (citing Ex. 1, pp. 1-6, 22, 29-31, 43-45; Ex. 4, p. 246).) Respondent suggests that though Dr. Colwell opines that shoulder injuries commonly report pain in the neck and arm, that neither he nor the literature explains "how such pain would occur immediately with shoulder pain, as reported by petitioner." (*Id.* (citing Ex. 19, p. 2.)) In addition, the language of the QAI "specifies that pain outside the shoulder in which the vaccine was administered is sufficient to defeat a Table SIRVA claim." (ECF No. 74, p. 11.)

Respondent also argues that petitioner's symptoms are caused by a factor unrelated to vaccination. (ECF No. 74, p. 12.) Respondent stresses that petitioner's MRI showed no signs of bursitis, but did show rotator cuff tendinopathy, which "is more consistent with chronic rotator cuff degenerative pathology." (*Id.* (citing Ex. A, p. 3.)) In addition, petitioner's MRI showed AC joint arthropathy, a mass effect of the acromion on the supraspinatus tendon, and a SLAP tear—all chronic conditions that predated petitioner's vaccination.[18] (*Id.* (citing Ex. C, p. 2; Ex. D, p. 2.))

VI. Discussion

As explained above, the Vaccine Injury Table lists SIRVA as a compensable injury if it occurs within 48 hours of administration of a vaccine containing the influenza virus. § 300aa-14(a) as amended by 42 C.F.R. § 100.3(a). To be considered a Table "SIRVA," petitioner must show: (i) there is "no history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that

[18] Respondent also contends that petitioner has neither pled nor established a cause-in-fact claim. (ECF No. 74, p. 14.) First, respondent argues that petitioner has not preponderantly established a medically recognized injury. (*Id.* at 15.) Though petitioner contends that her "diagnoses of bursitis, adhesive capsulitis, impingement, and tendinopathy are all associated with SIRVA," respondent's expert Dr. Cagle stresses that petitioner's MRI did not show bursitis, but instead revealed chronic conditions associated with degenerative pathology. (*Id.* at 15-16 (quoting ECF No. 73, p. 12.)) Second, respondent argues that petitioner has not set forth a reliable medical theory explaining how the influenza vaccine can cause bursitis, adhesive capsulitis, impingement, or tendinopathy. (*Id.* at 16.) Atanasoff et al. proposed a potential theory of antigenic material causing an immune response, though respondent suggests that this was not the objective of the article. (*Id.*) Though the medical literature supports the proposition that vaccination can be associated with shoulder injuries, the literature does not preponderantly establish a mechanism for "*how* vaccinations can cause shoulder injuries." (*Id.* at 17) (emphasis in original). A "plausible" or "possible" causal link does not meet the preponderant standard. (*Id.*) Lastly, respondent argues that petitioner fails to show a logical sequence of cause and effect because petitioner's expert fails to explain how he distinguishes between petitioner's chronic conditions not caused by the vaccination and the new, acute, conditions that he considers vaccine-related. (*Id.* at 18.) Nor does a proximate temporal association between vaccination and injury satisfy petitioner's burden to prove causation in fact. (*Id.*)

would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection"; (ii) that "onset of pain occurred within the specified timeframe," i.e. within 48 hours; (iii) that "pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered"; and (iv) that "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(a); 42 C.F.R. § 100.3(c)(10).

In this case there is no dispute as to the first and second QAI SIRVA criteria. Respondent agrees that "[p]etitioner did not have a history of left shoulder pain or injury." (ECF No. 74.) Additionally, respondent raises no argument in either his Rule 4 report or his response to petitioner's motion for a ruling on the record that petitioner's injury arose outside of the 48-hour timeframe identified by the Vaccine Injury Table. (ECF Nos. 49, 74.) My own review of the record confirms these points. Based on the record as a whole, petitioner has preponderantly established that she suffered onset of *new* shoulder pain within 48 hours of the vaccination at issue in this case. Rather, respondent's defense against petitioner's Table Injury claim hinges on the third and fourth SIRVA QAI prongs. Respondent contends that petitioner's pain was not limited to the shoulder in which she received her vaccination and also that her condition is better explained by chronic shoulder pathology that predated her vaccination. (ECF No. 74, pp. 10-13.) However, neither argument is persuasive given the record of this case.

With regard to the third SIRVA criterion, which requires that the petitioner's pain and reduced range of motion be limited to the shoulder at issue, petitioner stresses language included in the preamble to the final regulation placing SIRVA on the Vaccine Injury Table. (ECF No. 73, pp. 8-9 (citing 82 Fed. Reg. 6294 (Jan. 19, 2017).) Specifically, the government addressed this QAI criterion in response to public comment. For clarity and context, the comment summary and response are worth quoting in full:

> Comment: A commenter suggested that shoulder injury related to vaccine administration (SIRVA) as defined in the QAI is too restrictive because the recipient's pain and reduced range of motion must be limited to the shoulder in which the intramuscular vaccine was administered. The commenter stated that such language was an artificial and unnecessary qualification, and expressed concern that recipients who have other symptoms, such as shoulder pain radiating to the neck or upper back, will not have the benefits of a Table injury. The commenter suggested that the QAI be expanded to include the shoulder and parts of the body attributed to that injury.
>
> Response: SIRVA is a musculoskeletal condition caused by injection of a vaccine intended for intramuscular administration into the shoulder, and, as its name suggests, the condition is localized to the shoulder in which the

> vaccine was administered. In other words, pain in the neck or back without an injury to the shoulder in which an individual received a vaccine would not be considered SIRVA. Shoulder injuries that are not caused by injection occur frequently in the population. Thus, it is important to have a definition of SIRVA that is clearly associated with vaccine injection. The portion of the QAI limiting the pain and reduced range of motion to the shoulder in which the vaccine was administered is necessary to accurately reflect the vaccine-associated condition.

82 Fed. Reg. 6294, 6296.

I am not persuaded by petitioner's argument that, by including the example of neck or back pain without shoulder injury, the above response language accepts broadly that shoulder pain with accompanying neck pain necessarily falls under the SIRVA rubric in all events. (ECF No. 73, p. 9.) However, the government's comment response reveals that the third SIRVA criterion is intended to ensure that SIRVA claims are limited to instances in which "*the condition* is localized to the shoulder in which the vaccine was administered" (emphasis added). Thus, it is clear that 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. *See Werning v. Sec'y of Health & Human Servs.,* No. 18-0267V, 2020 WL 5051154, at *10 (Fed. Cl. Spec. Mstr. July 27, 2020) (finding that a petitioner satisfied the third SIRVA QIA criterion where there was a complaint of radiating pain, but the petitioner was "diagnosed and treated solely for pain and limited range of motion to her right shoulder.")

In this case, it is true that there are subjective complaints by petitioner suggesting that she experienced pain beyond the confines of her shoulder. Moreover, for a period of time her treating physician suspected that her condition might be attributable to cervical spine based on those complaints. However, despite these complaints, petitioner's first post-vaccination orthopedic assessment included multiple findings suggestive of shoulder pathology while noting full range of motion without pain in her neck. (Ex. 2, p. 2.) Moreover, despite some ongoing suspicion, a cervical origin for petitioner's complaints was later ruled out explicitly by her treating physician based on MRI study. Specifically, MRI of petitioner's cervical spine revealed only mild degenerative changes that do "not suggest cervical spine pathology or cervical radiculopathy," (Ex. 2, p. 31) while MRI of the left shoulder revealed findings that led to an arthroscopic surgery recommendation with a preoperative diagnosis of shoulder impingement. (*Id*. at 41-44; Ex. 6, p. 85).

Although petitioner's subjective complaints are probative as to the severity and timing of her symptoms, she is not herself competent to speak to the medical significance of her complaints. *See James-Cornelius on Behalf of E. J. v. Sec'y of Health & Human Servs*., 984 F.3d 1374, 1380 (Fed. Cir. 2021) ("While lay opinions as to causation or medical diagnosis may be properly characterized as mere 'subjective

belief' when the witness is not competent to testify on those subjects, the same is not true for sworn testimony as to facts within the witness's personal knowledge. . . .") In that regard, petitioner's experts are instead persuasive in opining for the reasons discussed more fully above that petitioner's own pain complaints are consistent with the expected manifestations of the type of musculoskeletal injuries associated with SIRVA. (Ex. 19, p. 2 (Dr. Cowell); *see also* Asher, *supra*, at Ex. 23; Ex. 26, p. 8 (Dr. Srikumaran).) And, in any event, the government's own expert in effect disclaims petitioner's subjective pain complaints as vague and non-specific, suggesting they may not have been diagnostically useful. (Ex. A, p. 3.)

Thus, the evidence does not preponderate in favor of any finding that petitioner had diagnostically meaningful complaints of pain or reduced range of motion beyond her left shoulder. Nor does the evidence preponderate in favor of any finding that petitioner's reported pattern of pain is otherwise suggestive of an etiology for that pain beyond her diagnosed musculoskeletal shoulder injury. Accordingly, petitioner has satisfied the third SIRVA QAI criterion.

The remaining question is whether any other condition could explain petitioner's symptoms. Respondent, and Dr. Cagle, contend based on imaging and operative findings that petitioner's condition is more consistent with chronic degeneration. (ECF No. 73, p. 12.) Respondent stresses Dr. Cagle's observation that petitioner did not show the "classic" signs of bursitis typical of SIRVA (a point disputed by Dr. Srikumaran) while also demonstrating pathology such as rotator cuff tendinopathy that Dr. Cagle suggests is more consistent with degeneration. (*Id*.) However, there is an inherent tension in respondent's position. On the one hand, respondent agrees that "[p]etitioner did not have a history of left shoulder pain or injury" (ECF No. 74) and further does not dispute that petitioner's symptoms began abruptly within 48 hours of her vaccination. On the other hand, respondent contends that petitioner's post-vaccination presentation is nonetheless explained by chronic, degenerative, pre-existing shoulder dysfunction despite all outward appearances of petitioner's clinical history suggesting, consistent with SIRVA, a temporal association with petitioner's vaccination. Respondent's argument is ultimately unpersuasive.

Because SIRVA is by definition an unspecified "injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.)" (*see* 42 C.F.R. §100.3(c)(10)), respondent does not defeat petitioner's claim simply by noting the presence of shoulder dysfunction beyond deltoid bursitis. Nor, alternatively, does respondent defeat petitioner's claim by asserting a lack of evidence of bursitis. Although deltoid bursitis is the specific condition that has been most clearly associated with vaccine-related shoulder injuries, the QAI definition of SIRVA was specifically drafted to encompass shoulder dysfunction beyond that condition.[19] Proposed

[19] Specifically, respondent's proposed rulemaking stated in relevant part:

> The IOM reviewed the scientific and medical literature finding evidence that convincingly supports a causal relationship between vaccine injection (with a needle) into an arm and

Rulemaking, 2015 WL 4538923, at *45136; *See also Gurney v. Sec'y of Health & Human Servs.*, No.17-481V, 2019 WL 2865490, at *7 (Fed. Cl. Spec. Mstr. Apr. 24, 2019) (finding that "the timing and course of petitioner's adhesive capsulitis remains consistent with a post-vaccination sequela to her SIRVA as described in the [Atanasoff study] and as envisioned by the rulemaking which created SIRVA as a Table Injury."). The Atanasoff article relied upon in creating QAI for SIRVA (and filed in this case as Exhibit 24) in turn states that:

> In general, chronic shoulder pain with or without reduced shoulder joint function can be caused by a number of common conditions including impingement syndrome, rotator cuff tear, biceps tendonitis, osteoarthritis and adhesive capsulitis. In many cases these conditions may cause no symptoms until provoked by trauma or other events. Reilly et al reviewed a series of shoulder ultrasound and MRI studies obtained in asymptomatic persons past middle age and found partial or complete rotator cuff tears in 39% of those individuals. Therefore, some of the MRI finding in our case series, such as rotator cuff tears, may have been present prior to vaccination and became symptomatic as a result of vaccination-associated synovial inflammation.

(Atanasoff et al., *supra* at Ex. 24, p. 3.)

Here, the specific diagnoses explored by petitioner's treating physicians – bursitis, impingement, and adhesive capsulitis – fall under the umbrella of SIRVA.[20] Moreover, Atanasoff shows that pre-vaccination subclinical degenerative changes, even including rotator cuff tears, are not in themselves incompatible with SIRVA or with the

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> deltoid bursitis. The report noted that the published VICP case series (Atanasoff et al.), as described, were clinically consistent with deltoid bursitis. The VICP case series found that 93 percent of patients had the onset of shoulder pain within 24 hours of vaccine administration and 54 percent had immediate pain following vaccine injection. *The VICP case series found several diagnoses, beyond deltoid bursitis, that resulted in shoulder pain following vaccination, including tendonitis, impingement syndrome, frozen shoulder syndrome, and adhesive capsulitis.* Another case series reported two cases of shoulder pain, weakness and reduced range of motion following vaccination with onset of symptoms within 48 hours of vaccination. [Bodor M, Montalvo E, Vaccination related shoulder dysfunction, Vaccine 25(2007) 585-587.] *In order to capture the broader array of potential injuries, the Secretary proposes to add SIRVA for [certain influenza] vaccines that are administered intramuscularly through percutaneous injection into the upper arm.*

Proposed Rulemaking, 2015 WL 4538923, at *45136 (emphasis added).

[20] *Compare* and Ex. 2, p. 2 (initial orthopedic assessment of bursitis on November 15, 2016); Ex. 4, p. 127, 130 (presenting to physical therapy on November 18, 2016, with diagnoses of impingement syndrome and adhesive capsulitis); Ex. 2, p. 41 (radiologists interpreting MRI as showing, *inter alia*, tendinopathy, mild interstitial tears, and mild impingement); Ex. 6, p. 85-86 (pre- and post-operative diagnoses of impingement syndrome and labral tear along with operative finding of thick bursitis) and Proposed Rulemaking, 2015 WL 4538923, at *45136 (explaining that SIRVA encompasses tendonitis, impingement syndrome, frozen shoulder syndrome, and adhesive capsulitis).

suspected mechanism by which SIRVA manifests.[21] Additionally, under the first three SIRVA criteria, petitioner's clinical history is consistent with a temporally appropriate post-vaccination onset of new shoulder pain.

It would not be in keeping with intention of the Vaccine Injury Table to require petitioner to further prove mechanistically how her vaccination could have caused the specific musculoskeletal condition constituting her own SIRVA. Thus, without more, respondent is unpersuasive in asserting that previously asymptomatic degenerative changes otherwise explain petitioner's post-vaccination clinical history to the exclusion of a SIRVA. *See Lang v. Sec'y of Health & Human Servs.*, No. 17-995V, 2020 WL 7873272, at *13 (Fed. Cl. Spec. Mstr. Dec. 11, 2020) (explaining that "findings consistent with impingement, rotator cuff tears, or AC arthritis do not *per se* preclude a finding that a Table SIRVA exists. Rather, the question raised by respondent's argument is whether petitioner's own clinical history indicates that her shoulder pathology wholly explains her symptoms independent of vaccination."); *Yost v. Sec'y of Health & Human Servs.,* No. 18-288V, 2021 WL 2326403, at *15 (Fed. Cl. Spec. Mstr. May 6, 2021) (rejecting Dr. Cagle's opinion that post-vaccination bursitis was more likely explained by overuse and a history of vigorous exercise, noting that that the Atanasoff study considered and rejected mechanical overuse as an explanation); *see also O'Leary v. Sec'y of Health & Human Servs.*, No. 18-584V, 2021 WL 3046617, at *12 (Fed. Cl. Spec. Mstr. June 24, 2021) (finding that respondent's argument that petitioner's adhesive capsulitis was "coincidental" to vaccination was contrary to the causal presumption made available under the Vaccine Injury Table).

Once petitioner has made a *prima facie* showing of a Table Injury, respondent may still present evidence that the injury was nonetheless caused by a factor unrelated to vaccination. § 300aa-13(a)(1)(B); *Deribeaux v. Sec'y of Health & Human Servs.*, 717 F.3d 1363, 1367 (Fed. Cir. 2013). In that context the burden of proof shifts to respondent to make such a claim by preponderant evidence. In order to meet his burden, respondent must demonstrate "that a particular agent or condition (or multiple agents/conditions) unrelated to the vaccine was in fact the sole cause (thus excluding the vaccine as a substantial factor)." *de Bazan v. Sec'y of Health & Human Servs*., 539 F.3d 1347, 1354 (Fed. Cir. 2008). In that regard respondent remains unpersuasive for the same reasons discussed above. Petitioner's overall clinical course is more consistent with onset of SIRVA than with any inevitable clinical manifestation of chronic degeneration.

VII. Conclusion

For all the reasons discussed above, after weighing the evidence of record as a whole, I find by preponderant evidence that petitioner suffered a Table Injury of SIRVA

[21] Notably, the SIRVA QAI includes a list of examples of the "other condition[s] or abnormalit[ies]" that may be incompatible with a SIRVA claim – "e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy." 42 C.F.R. § 100.3(c)(10). All of the listed examples relate to neurological conditions that may affect the shoulder and none of these examples are applicable to petitioner's own case or Dr. Cagle's proffered opinion regarding degenerative changes such as tendinopathy.

following her October 21, 2016 influenza vaccination as alleged. She is therefore entitled to compensation. Because I have found the presence of a Table Injury in this case, it is not necessary to address whether petitioner has presented a cause-in-fact claim. A separate damages order will be issued.

IT IS SO ORDERED.

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