

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

No. 17-995V

Filed: December 11, 2020

PUBLISHED

CHERI LANG,

Petitioner,

v.

SECRETARY OF HEALTH AND  
HUMAN SERVICES,

Respondent.

Special Master Horner

Table Injury; Shoulder Injury  
Related to Vaccine  
Administration (SIRVA);  
Influenza Vaccine

*Leah Durant, Law Offices of Leah V. Durant, PLLC, Washington, DC, for petitioner.  
Colleen Clemons Hartley, U.S. Department of Justice, Washington, DC, for respondent.*

### **RULING ON ENTITLEMENT**<sup>1</sup>

On July 24, 2017, petitioner, Cheri Lang, filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-10-34 (2018)<sup>2</sup> (“the Act” or “the program”). (ECF No. 1.) Petitioner alleges that she suffered a Table Injury of shoulder injury related to vaccine administration (“SIRVA”), resulting from an influenza (“flu”) vaccine she received on October 11, 2016. (*Id.*) For the reasons set forth below, I find that petitioner is entitled to compensation for a Table Injury of SIRVA.

#### **I. Procedural History**

Petitioner filed her petition on July 24, 2017. (ECF No. 1.) The case was initially assigned to the Special Processing Unit. (ECF No. 4.) Petitioner filed medical records between August 7, 2017 and March 13, 2019. (ECF Nos. 7, 12, 14, 19, 24, 25, 27, 36,

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<sup>1</sup> 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.

<sup>2</sup> Within this decision, all citations to § 300aa will be the relevant sections of the Vaccine Act at 42 U.S.C. § 300aa-10-34.

47, 48.) Respondent filed his Rule 4 Report on May 30, 2019, identifying additional outstanding records, but also recommending against compensation. (ECF No. 53.) Petitioner's outstanding medical records were filed on September 11, 2019. (ECF No. 58.) Petitioner later filed an expert report by Dr. Lesley J. Anderson on November 8, 2019. (ECF Nos. 59, 60.) This case was subsequently assigned to my docket on January 14, 2020. (ECF No. 63.)

Respondent filed an expert report by Dr. Jennifer Winell on March 23, 2020. (ECF Nos. 66.) Petitioner filed a supplemental expert report by Dr. Uma Srikumaran on April 27, 2020. (ECF No. 68.) On May 14, 2020, respondent filed a supplemental expert report by Dr. Winell. (ECF No. 71.) Petitioner's final supplemental expert report from Dr. Srikumaran was filed on June 8, 2020. (ECF No. 72.)

On July 8, 2020, the parties advised that, despite prior efforts, they are unable to resolve the case informally. (ECF No. 73.) I advised that I intend to resolve the issue of entitlement in this case on the written record and directed the parties to file briefs in support of their respective positions. (ECF No. 74.) Respondent filed his brief on September 14, 2020. (ECF No. 76.) Petitioner filed her initial brief on September 17, 2020, and a reply to respondent's brief on October 19, 2020. (ECF Nos. 81, 84.)

Upon my review, the parties have had a full and fair opportunity to present their cases and it is appropriate to resolve this case 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 case is now ripe for a ruling on the record.

## **II. Factual History**

### **a. As reflected in petitioner's medical records**

Prior to her October 11, 2016 vaccination, petitioner was a relatively healthy 45-year old woman with no significant medical history. She was capable of lifting over fifty pounds, and had received the flu vaccine for years without issue. (Ex. 2, p. 6.) On October 11, 2016, petitioner received a flu vaccine at her place of employment, Dawn Food Products. (Ex. 1, p. 1.)

Petitioner presented to Dr. Rebecca Kelley at SSM Family Healthcare ("SSM") on December 28, 2016. (Ex. 2, p. 5.) Petitioner's chief complaint was "pain in her right deltoid." (*Id.*) She reported that she had experienced this pain "since receiving flu shot on 10-11-16" and that her "pain is worse if [she] raises the arm." (*Id.*) Petitioner described her pain as gradually worsening, dull, and constant. (*Id.* at 6.) Petitioner reported that her pain was 2/10 while resting, and 6/10 when raising her arm. (*Id.*) Dr. Kelley noted that petitioner's symptoms were "in her upper arm near the shoulder joint," while gesturing to her acromioclavicular ("AC") joint. (*Id.* at 7.) Dr. Kelley's exam revealed decreased abduction, flexion, extension, internal rotation, and external rotation

in petitioner's right shoulder. (Ex. 2, p. 8.) Although petitioner reported pain in her right shoulder, her muscle strength was only somewhat diminished, showing 4/5 strength in her flexion, extension, adduction, abduction, external rotation, and internal rotation, and 5/5 strength in her scapula elevation, retraction, and protraction. (*Id.*) Petitioner's supraspinatus and impingement tests were both positive. (*Id.*) Dr. Kelley diagnosed petitioner with SIRVA and ordered shoulder x-rays with a potential MRI pending the x-ray results.<sup>3</sup> (*Id.* at 9.) Petitioner's shoulder x-ray was negative. (*Id.*)

Following her initial visit to SSM, petitioner filed a VAERS report on January 12, 2017. (Ex. 23, pp. 7-11.) Petitioner was next seen by radiologist Dr. George Cyriac for an MRI at St. Mary's Hospital on January 16, 2017. (Ex. 4, p. 19.) Petitioner's MRI revealed a mild interstitial tear and small subchondral cyst in the humeral head, but nothing remarkable in her AC joint. (*Id.*)

On January 19, 2017, petitioner was evaluated for physical therapy at Peak Sport and Spine. (Ex. 3, p. 7.) During this evaluation, petitioner again reported that her shoulder pain began immediately after her flu vaccination. (*Id.*) She described her pain as 2/10 at best and 7/10 at worst. (*Id.* at 7, 8.) Petitioner was scheduled for four weeks of physical therapy with two sessions per week. (*Id.* at 9.) By January 24, 2017, petitioner indicated that she was improving, and by February 14, she was tolerating her physical therapy without pain or difficulty. (*Id.* at 12, 28.)

Petitioner received an orthopedic evaluation at SSM from Nurse Practitioner ("NP") Carrie Lucas and Dr. Richard White on February 21, 2017. (Ex. 6, p. 1.) During this evaluation, petitioner reported that her physical therapy had "helped a little," but that she still experienced daily pain, specifically when lifting. (*Id.*) Petitioner exam revealed tenderness to palpation over her lateral shoulder with a "deep pain," mild tenderness of the AC joint and biceps tendon, full active range of motion, pain with abduction, normal strength, and a positive impingement test. (*Id.* at 2.) Reviewing petitioner's MRI, NP Lucas noted a subtle abnormality in the supraspinatus consistent with tendinopathy and in the humeral head consistent with impingement. (*Id.*) Petitioner was diagnosed with rotator cuff impingement syndrome and received a steroid injection in her subacromial space. (*Id.* at 3.)

Petitioner was again seen by NP Lucas on April 4, 2017. (*Id.* at 10.) During this visit petitioner reported that the steroid injection she received during her previous visit reduced her pain for approximately two weeks, but that it had since returned. (*Id.*) Petitioner reported that she had pain even at rest, but no pain past her elbow, no numbness, and occasional neck stiffness related to the way she postured her shoulder to account for her pain. (*Id.*) Petitioner showed full range of motion and did not appear

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<sup>3</sup> Interestingly, respondent argues that because SIRVA is a concept developed "by administrative rulemaking" it cannot serve as the basis for a cause-in-fact claim in lieu of the diagnosis of a specific shoulder injury. (ECF No. 76, n.18.) As noted here, petitioner's medical records show that at least one of her physicians specifically used the term SIRVA in her assessment. (Ex. 2, p. 9.) This may suggest that, regardless of its origin, the SIRVA concept is beginning to make inroads into the medical lexicon as a diagnostic entity. However, since this claim does resolve on the basis of the Vaccine Injury Table it is not necessary to reach that question.

to have tenderness to palpation at the AC joint, but did show tenderness in the bicipital groove. (*Id.*) NP Lucas noted that physical therapy, home exercises, and subacromial steroid injections all failed to resolve petitioner's pain and scheduled an MRI arthrogram to evaluate for a labral pathology. (*Id.* at 11.)

Petitioner received an MRI arthrogram on April 14, 2017, which showed no rotator cuff tears, mild increased signal in the supraspinatus consistent with tendinosis, minimal fluid in the subacromial and subdeltoid bursa, mild deformity of the superior labrum, and a small subchondral cyst near the supraspinatus insertion. (Ex. 4, p. 42.) It was noted that it was uncertain whether petitioner's mild labrum deformity was due to a "normal variation" or labral injury. (*Id.*)

Petitioner returned to Peak Sport and Spine for her final appointment on April 14, 2017. (Ex. 3, p. 33.) During this visit, petitioner reported that her pain had decreased to a 2/10 at worst, and that she was able to perform daily activities and work activities with little or no pain. Petitioner's discharge assessment noted that she exhibited "an excellent prognosis at time of discharge from skilled rehabilitative therapy in conjunction with a home exercise program." (*Id.*)

On April 18, 2017, petitioner returned to NP Lucas and Dr. White reporting the same symptoms that she had on April 14, now with occasional pain in her right shoulder radiating to her neck and right elbow. (Ex. 6, p. 12.) NP Lucas noted that petitioner's prior MRI arthrogram demonstrated "some supraspinatus tendinopathy and some cystic changes of the humeral head consistent with impingement." (*Id.*) There were "no obvious findings" in petitioner's right shoulder, but NP Lucas did note that "[t]here are symptoms that point to her cervical spine as the source of her pathology." (*Id.*) NP Lucas ordered cervical spine x-rays to evaluate a possible spinal pathology for petitioner's injury; however, no such x-ray report is included in petitioner's records. (*Id.*)

Petitioner was seen on April 27, 2017 by orthopedic surgeon Dr. Tameem Yehyawawi of Columbia Orthopedic Group. (Ex. 5, p. 7.) Petitioner again reported that onset of her pain began immediately after receiving the flu shot in October 2016. (*Id.*) She explained to Dr. Yehyawawi the medical treatment she had received up to that point and indicated that she did not believe the steroids or physical therapy had worked due to the fact that her pain persisted. (*Id.*) Petitioner described her pain as a "constant dull ache that feels deep within the joint." (*Id.*) Dr. Yehyawawi noted some localization of petitioner's pain over the lateral aspect of her shoulder that worsened with overhead activity and external rotation. (*Id.*) Petitioner denied any weakness, stiffness, numbness, or paresthesias. (*Id.*) During this exam, petitioner described her pain as 4/10 and characterized the sensation as aching and shooting. (Ex. 5, p. 7-8.) Dr. Yehyawawi noted that petitioner had "an excellent range of motion" but showed painful Hawkins and Neer impingement tests. (*Id.* at 8.) Dr. Yehyawawi believed that the majority of petitioner's pain was coming from her rotator cuff and bursitis that was "triggered by a flu shot with inflammation there." (*Id.* at 9.) Dr. Yehyawawi believed that, due to the failure of other conservative treatments, surgery was the best option for petitioner. (*Id.*)

Petitioner received arthroscopic shoulder surgery including rotator cuff debridement, subacromial decompression with acromioplasty, labrum debridement, and a bursectomy on June 19, 2017. (Ex. 7, pp. 1, 4.) Dr. Yehyawī's operative report notes a degenerative right shoulder partial-thickness supraspinatus rotator cuff tear, subacromial impingement, and a degenerative superior labrum tear, anterior to posterior. (*Id.* at 1.) Following the surgery, Dr. Yehyawī recorded in addition to his initial diagnosis findings of "anterolateral acromial spurring and CA ligament fraying and bursitis of the subacromial space suggestive of impingement . . . ." (*Id.* at 2.)

On a June 29 follow-up, Dr. Yehyawī again noted that petitioner's October 2016 flu vaccine "very likely could've caused an inflammatory response in the tendon and the bursa that persisted . . . ." (*Id.*) Following her surgery, petitioner began a new round of physical therapy on July 5, 2017 with therapist Calvin Canine at Peak Sport and Spine. (Ex. 28, p. 5.)

On July 25, 2017, petitioner was again seen by Dr. Yehyawī, and reported that physical therapy had mildly improved her range of motion, but that her lateral shoulder discomfort persisted. (Ex. 11, p. 1.) Dr. Yehyawī believed that this would resolve with time. (*Id.*) Petitioner completed her post-operation physical therapy on August 30, 2017. (Ex. 28, p. 53.) Petitioner's final physical therapy record notes that she was able to tolerate all exercises with mild pain and recommended continued home exercise. (*Id.* at 51.)

Petitioner saw Dr. Yehyawī for several post-surgery follow-up exams between September and December of 2017. (Ex. 13, p. 1, 2-3, 4-5, 6-8.) On September 5, Dr. Yehyawī observed that petitioner only felt pain at the extremes of flexion and abduction, but was otherwise pain free. (*Id.* at 1.) On October 17, petitioner reported that her pain was improving and that she was making progress, but still experienced some pain with certain movements. (*Id.* at 2.) Dr. Yehyawī administered a cortisone injection into petitioner's subacromial space without complication. (*Id.* at 3.) On November 21, petitioner indicated that the October 17 cortisone injection provided temporary relief but that her pain returned within a week. (*Id.* at 4.) Dr. Yehyawī noted that petitioner experienced some pain as a result of her rotator cuff tendinopathy, but believed that the primary pain she complained of was coming from the AC joint. (*Id.* at 5-6.) He recommended an ultrasound-guided AC joint injection for diagnostic and therapeutic purposes. (Ex. 13, p.6.) Dr. Yehyawī believed that if the injection did not cause any significant relief, it would mean that petitioner's discomfort was due to her rotator cuff tendinopathy. (*Id.*) Petitioner received this injection from Dr. Farmer on November 29, 2017. (Ex. 26, pp. 4-6.) Petitioner's final post-surgery follow-up with Dr. Yehyawī was on December 28, 2017. (Ex. 13, p. 6-8.) During this visit, Dr. Yehyawī reported that petitioner had "developed symptoms over the [AC] joint that were not necessarily present prior to her first surgery. Her pain is localized there." (*Id.* at 7.) Further, Dr. Yehyawī noted that petitioner's AC joint injection alleviated her pain for around nine days, but that it had returned. (*Id.*) Dr. Yehyawī again felt that the best course of action was surgery, and petitioner agreed. (*Id.* at 8.)

Petitioner underwent a right shoulder arthroscopy with distal right clavicle resection on January 29, 2018 to treat “right shoulder [AC] joint arthritis.” (Ex. 14, p. 1.) On March 13, 2018, Dr. Yehyawawi indicated that petitioner had no pain at rest, but that she may continue to experience occasional soreness due to her mild rotator cuff tendinopathy. (Ex. 15, p. 3.) On April 24, 2018, petitioner indicated that she was “much better than before surgery.” (Ex. 20, p. 1.)

Petitioner returned to Dr. Yehyawawi on August 2, 2018, complaining of continued discomfort in her anterolateral shoulder and AC joint. (Ex. 22, p. 1.) Dr. Yehyawawi believed that petitioner was suffering from an AC arthritis flare up and planned for an ultrasound guided steroid injection. (*Id.*) Petitioner’s physical examination revealed decreased range of motion, 130 degrees flexion, and minimal discomfort with Hawkins and Neer testing. (*Id.* at 2.) Dr. Yehyawawi concluded that petitioner now presented “with some inflammation potentially from some scar tissue in the [AC] joint with some crepitus and discomfort there as well as rotator cuff tendinopathy.” (*Id.* at 2.)

By August 30, 2018, Dr. Yehyawawi could no longer explain petitioner’s discomfort. (Ex. 26, pp. 1-2.) Instead, he ordered anti-inflammatories and an MRI. (*Id.*) Several days later, on September 5, 2018, Dr. Yehyawawi noted that petitioner still had an insertional cyst in her infraspinatus. (*Id.* at 3.) He also believed that petitioner’s “primary pain generator” was a persistent rotator cuff tendinopathy and some bursitis that had reformed. (*Id.*) Dr. Yehyawawi’s conclusion notes that petitioner had suffered “months and months of significant pain and inflammation as she had a flu shot which set off an inflammatory storm throughout her rotator cuff and significant pain that persisted for several months.” (*Id.*) Dr. Yehyawawi recommended physical therapy, an MRI, and a course of anti-inflammatories to manage petitioner’s pain. (*Id.* at 2.)

Petitioner began another round of physical therapy on September 12, 2018 at Peak Sport and Spine. (Ex. 27, p. 75.) Although the physical therapist indicated January 29, 2018 as the date of onset for petitioner’s pain, they also noted “a long history of initial onset [from] 10-11-16 after a flu shot in the right shoulder. . . .” (*Id.*) Petitioner’s physical therapist noted “popping, crunching with elevation” and some right shoulder weakness. (*Id.* at 76-77.)

On December 3, 2018, petitioner was examined by orthopedist Dr. Christopher Farmer. (Ex. 26, p. 9.) Petitioner’s exam revealed a mildly flared AC joint and mild rotator cuff tendinopathy. (*Id.*) He discussed potential treatment options including oral and injectable medications, therapy, additional imaging, and surgery. (*Id.* at 10.) Petitioner chose to receive an injection Autologous Conditioned Plasma into her right shoulder. (*Id.*) Petitioner was seen again by Dr. Farmer on December 31, 2018. (*Id.* at 12.) At that time, Dr. Farmer believed petitioner was suffering from adhesive capsulitis based on her complaints of stiffness. (*Id.*) He prescribed an oral steroid and encouraged continued home exercise. (*Id.*)

Dr. Farmer followed up with petitioner one month later, on January 31, 2019. (Ex. 26, p. 14.) Petitioner reported that the oral steroid provided relief for her shoulder

pain and that her symptoms had not worsened. (*Id.*) On April 16, 2019, Dr. Farmer noted that petitioner had almost full abduction and flexion with a “much better” range of motion in her right shoulder. (Ex. 29, p. 1.) Petitioner’s internal rotation was mildly painful, but without weakness. (*Id.*) Dr. Farmer believed that petitioner was suffering from a mildly flared AC joint and mild rotator cuff tendinopathy. (*Id.* at 2.) He recommended a glenohumeral injection and home exercise. (*Id.*)

Dr. Farmer saw petitioner for the last time on June 13, 2019. (Ex. 29, p. 4.) During this visit, he indicated that the only option left to diagnose petitioner’s shoulder pain was to check for underlying neurogenic causes. (*Id.*) Consequently, Dr. Farmer ordered a nerve conduction test which showed no abnormalities. (*Id.*) He concluded that petitioner was simply suffering from a chronic impingement syndrome in the AC joint and that “we may just have to consider her to be at maximal medical improvement.” (*Id.*)

Following treatment from Dr. Farmer, petitioner sought another evaluation of her shoulder, this time from Dr. Matthew Smith. (Ex. 38, p. 1.) Petitioner rated her pain as a 3/10 at this visit and described it as a “deep aching.” (*Id.*) She related a medical history of two shoulder surgeries, and pain following her flu shot. (*Id.*) Dr. Smith observed good rotator cuff strength, but deltoid atrophy and mid-arm pain. (*Id.* at 2.) Dr. Smith ordered an MRI, which revealed mild infraspinatus and subscapularis tendinosis and mild glenohumeral osteoarthritis. (*Id.* at 2, 4.)

Petitioner had an ultrasound-guided right suprascapular nerve block procedure on November 27, 2019. (Ex. 38, p. 9.) She was seen by Dr. Smith for a follow-up on December 23, 2019. (*Id.* at 5.) Petitioner reported that the nerve block did not help her pain at all. (*Id.*) Dr. Smith noted that petitioner’s pain was “potentially the result of a post vaccine inflammatory neuropathy” and referred her to pain management for further evaluation. (*Id.*)

Petitioner’s medical record concludes with a report from Dr. Ebby George Varghese on January 13, 2020. (Ex. 48, p. 1.) Dr. Varghese explained that it is unlikely petitioner will ever be pain free, prescribed Neurontin, a nerve-pain management drug, and noted that “her shoulder is not the same shoulder she had prior to her flu shot.” (*Id.* at 2-3.) Petitioner has not filed any other medical records.

#### **b. As reflected in the Affidavits**

In addition to the above medical records, petitioner filed affidavits of her husband, sister, and coworker to support her claim. (Exs. 31-33.) She also filed a letter to the court explaining why she chose to postpone medical treatment for her shoulder. (Ex. 47.) These materials all purport to provide specific recollections that demonstrate petitioner’s shoulder pain began immediately after her vaccination and in some instances also seek to explain petitioner’s delay in seeking treatment. Comparing these written submissions to each other and to the medical records, I do not find any obvious

inconsistencies. Nonetheless, for the reasons discussed in section IV(b), below, it is not necessary to address the specific recollections described.

### **III. Expert opinions**

#### **a. Petitioner's Initial Expert Report - Dr. Lesley J. Anderson**

Petitioner initially filed an expert report by orthopedist Dr. Lesley J. Anderson to support her claim.<sup>4</sup> (Ex. 34.) Dr. Anderson does not believe petitioner's condition is due to arthritis because "arthritis is extremely unlikely to have an acute onset causing significant pain the day after vaccination with the pain and the new onset of decreased range of motion requiring treatment for a long period thereafter." (Ex. 34, p. 3.) Dr. Anderson notes that petitioner had no history of shoulder issues, onset of pain within 48 hours of vaccination, that petitioner's primary pain and injury were confined to her right shoulder, and that there is no evidence of any alternative cause of her pain. (*Id.*) Consequently, Dr. Anderson believes that petitioner has satisfied the four elements for a Table SIRVA. (*Id.*)

Although petitioner reported pain in her neck and upper arm, she described it as radiating to those areas from her shoulder. (*Id.*) Per Dr. Anderson: "[i]t is extremely common in patients with shoulder impairment . . . to use other muscles . . . to lift their arm and therefore develop pain in the posterior and lateral neck muscles." (*Id.*) In Dr. Anderson's experience, roughly 50% of patients with shoulder injuries report pain radiating to the elbow due to "the anatomy of the subdeltoid bursa which is contiguous with the subacromial bursa." (Ex. 34, p. 2.) Dr. Anderson reviewed petitioner's medical imaging records and found no alternative explanation for her pain other than an anatomic shoulder injury. (*Id.*) Studies have shown a link between shoulder impingement and neck pain, meaning that petitioner's neck pain does not rule out the fact that her injury was confined to her shoulder. (Jerrold M. Gorski & Lawrence H. Schwartz, *Shoulder Impingement Presenting as Neck Pain*, 85-A J. OF BONE & JOINT SURGERY 635 (2003) (Ex. 36).) Dr. Anderson concludes that these facts suggest petitioner's condition is consistent with a Table SIRVA. (Ex. 34, p. 3.)

#### **b. Respondent's Initial Expert Report - Dr. Jennifer Winell**

Respondent relied upon the opinion of orthopedist Jennifer Winell, M.D.<sup>5</sup> (Ex. A.) Dr. Winell concedes that nothing in the record suggests that petitioner had any history

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<sup>4</sup> Dr. Anderson received her medical degree from Hershey Medical School in 1976 and completed her residency at UCLA's Department of Orthopaedic Surgery. (Ex. 35, p. 1.) She is board certified by the American Board of Orthopedic Surgery. (*Id.* at 2.) Dr. Anderson currently runs her own practice as an orthopedic surgeon, specializing in arthroscopy and knee and shoulder surgery. (*Id.* at 1.) She has authored fourteen publications and presented over one hundred times on subjects involving arthroscopy, orthopedics, and diagnosis of various shoulder and knee injuries. (*Id.* at 3-8.)

<sup>5</sup> Dr. Winell received her medical degree from New York University School of Medicine in 1996 and completed her residency in orthopedic surgery at New York Orthopaedic Hospital in 2007. (Ex. B, p. 1.) She is board certified by the American Board of Orthopaedic Surgery. (*Id.*) Dr. Winell is currently



of pain or dysfunction affecting her shoulder prior to her vaccination and therefore, she has met the first element of a SIRVA claim. (Ex. A, p. 5.) However, because petitioner offered no objective evidence of onset and waited two and a half months to seek treatment for her injury, Dr. Winell believes that petitioner has failed to establish onset of pain within 48 hours. (*Id.*) Dr. Winell also suggests that, although the record fails to rule out that petitioner's pain was confined to her shoulder, it likewise fails to confirm that fact. (*Id.* at 5.) According to Dr. Winell, it is possible petitioner was suffering from an alternative pathology because her initial orthopedist suspected her symptoms caused by a cervical spine issue. (*Id.*) Additionally, Dr. Winell notes several underlying degenerative conditions that could cause petitioner's injury including a "degenerative tear of the superior labrum, [a] partial thickness articular sided tear of [the] supraspinatus tendon, anterolateral acromial spurring, and CA ligament fraying." (*Id.*) According to Dr. Winell, "these are well known common causes of shoulder pathology cited in hundreds of scientific papers regarding shoulder impingement and were documented by Dr. Yehyaw in his operative report." (Ex. A, p. 6.)

Dr. Winell believes that the subacromial bursitis noted in Dr. Yehyaw's operative report "likely resulted from an anatomic degenerative pathology rather than an unintentional injection of the subacromial space." (*Id.* at 6.) This is because, according to Dr. Winell, "if there was only bursitis of the subacromial space from an inflammatory reaction to the injection, then one could expect improvement from a bursectomy alone." (*Id.*) However, because petitioner's surgeon "chose to also address the abnormal anatomic pathology that was found intra-operatively," it follows that the surgeon believed petitioner's pain was caused by the anatomic degeneration. (*Id.*) Because neither of these operations alleviated petitioner's pain, and even required additional surgeries, Dr. Winell believes that petitioner suffered from an anatomic degenerative process and not SIRVA. (*Id.*)

### **c. Petitioner's Supplemental Expert Report - Dr. Uma Srikumaran**

Petitioner later filed a supplemental report by shoulder specialist Uma Srikumaran, M.D., M.B.A., M.P.H.<sup>6</sup> (Ex. 39.) Dr. Srikumaran agrees with Dr. Anderson that patients with shoulder injuries will often develop neck pain when they use other muscles to account for their lack of shoulder function. (Ex. 39, p. 8.) He suggests this is the case with petitioner, considering the fact that her April 4, 2017 medical records specifically state that she suffers occasional neck pain because of "the way she postures her shoulder due to the pain." (*Id.*) Dr. Srikumaran notes, petitioner's pain

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employed by the University of Pennsylvania – School of Medicine. (*Id.*) She has published several peer reviewed reports on pediatric orthopedics, and several chapters in pediatric textbooks. (*Id.* at 4.)

<sup>6</sup> Dr. Srikumaran received his medical degree from Johns Hopkins University School of Medicine in 2005 and completed his residency in orthopedic surgery at Johns Hopkins Hospital in 2010. (Ex. 40, p. 1.) He is board certified by the American Board of Orthopaedic Surgery. (Ex. 39, p. 1.) Dr. Srikumaran is currently Chair of the Department of Orthopaedic Surgery at Howard County General Hospital and an attending physician at Johns Hopkins Hospital in Bayview Medical Center at Howard County General Hospital. (Ex. 40, p. 1.) He has published over one hundred articles, reports, chapters, and editorials on orthopedics and shoulder injuries. (*Id.* at 2-6.)

stopped at her elbow and that her nerve conduction test ruled out any cervical spine issues. (*Id.*) Further, petitioner experienced substantial pain relief following subacromial cortisone and steroid injections which suggests that her pain was anatomical and not neurologic. (*Id.*) Based on these facts, Dr. Srikumaran concludes that petitioner's injury was confined to her shoulder and that her neck and arm pain were secondary to that injury. (*Id.*)

Dr. Srikumaran disagrees with the suggestion that AC joint arthritis is a more likely explanation of petitioner's symptoms. (Ex. 39, p.8.) He explains that neither the medical records nor the timeline of events supports this conclusion. (*Id.*) According to Dr. Srikumaran, AC joint arthritis would not be so acute following a vaccination, nor would it be expected to cause the substantial loss of shoulder function that petitioner experienced. (*Id.*) Dr. Srikumaran notes that petitioner's primary care physician and two orthopedic surgeons each diagnosed petitioner with either general SIRVA, rotator cuff impingement, rotator tendinopathy, subacromial impingement, or bursitis, which are "all diagnoses consistent with SRIVA." (*Id.*) He believes that the AC joint pain petitioner experienced was likely a result of diffuse inflammation of the AC joint which can be triggered by vaccinations. (*Id.*) Dr. Srikumaran opines that Dr. Winell's conclusion that petitioner's condition was most likely due to a degenerative condition is "not logical and directly refuted by the operative surgeon as he believed . . . the bursitis was triggered by a flu shot [causing inflammation]." (*Id.*) Dr. Srikumaran explains that petitioner had no history of shoulder issues, and that her anatomy could not suddenly change within 48 hours to cause her shoulder pain. (Ex. 39, p. 8.) Consequently, Dr. Srikumaran believes that petitioner's vaccination was a clear trigger causing an inflammatory response involving the AC joint. (*Id.*)

Dr. Srikumaran also questions the significance of the fact that petitioner's pain did not resolve after her first surgery. (*Id.*) He notes that petitioner's general shoulder pain substantially improved after her first surgery, and that it only persisted in her AC joint. (Ex. 39, p. 9.) According to Dr. Srikumaran, petitioner's initial surgery substantially improved her lateral shoulder pain while the subsequent surgery improved her AC joint pain. Dr. Srikumaran explains that this is not unusual and, in fact, appropriate care. (*Id.*) He ultimately concludes that based on the above analysis, petitioner's pain cannot be explained by a degenerative process, and is much more likely a result of an inflammatory response caused by petitioner's flu vaccination. (*Id.*)

#### **d. Respondent's Supplemental Expert Report – Dr. Jennifer Winell**

In response to Dr. Srikumaran's opinion, Dr. Winell notes that petitioner's MRI findings show a shoulder pathology caused by a degenerative condition; not a vaccine-mediated immune regulated inflammatory response. (Ex. C, p. 1.) She also reiterates that because there is no imaging to rule out cervical spine involvement, there remains a possibility that petitioner's pain localized in her neck and referred to her shoulder. (*Id.*) Dr. Winell concludes that at best, it is unclear whether petitioner's primary pain was localized in her shoulder, and therefore, she cannot prove that she has met this element of a Table SIRVA. (*Id.*)

In her supplemental report, Dr. Winell clarifies that she only opines that petitioner did not have resolution of her shoulder pain following her initial surgery, and that the additional surgery was required, which suggests that her pain was the result of an ongoing degenerative process. (Ex. C, p. 2.) She explains that her only conclusion regarding AC arthritis was that “petitioner’s AC arthritis would not have been caused by the vaccine.” (*Id.*) Instead Dr. Winell indicates that “it was clear that petitioner had generalized shoulder pain consistent with impingement as well as AC joint pain, both of which are commonly seen together in this age group and many times addressed with one surgery.” (*Id.*)

However, Dr. Winell takes issue with Dr. Srikumaran’s opinion that petitioner’s vaccination initiated a biological mechanism resulting in petitioner’s AC joint inflammation. (*Id.*) She indicates that “it is unclear how an unintentional injection of this area would cause a synovitis of the AC joint,” because “the subacromial space is enclosed by the bursa which does not have a direct connection to the synovium of the AC joint other than being adjacent to it.” (*Id.*) Dr. Winell also points out that Dr. Yehyaw’s second report explicitly states that petitioner’s AC joint was “very arthritic with minimal to no joint space remaining.” (Ex. C, p. 3.) According to Dr. Winell, this finding does not indicate a “simple synovitis” but instead “almost complete joint obliteration, consistent with an advanced degenerative process.” (*Id.*) Dr. Winell stresses that there are “hundreds of scientific peer reviewed articles in orthopedic literature discussing this exact pathology as the cause of her type of symptoms, some of which were cited in my original report.” (*Id.*) Dr. Winell reiterates that the degenerative condition she cites as the cause of petitioner’s symptoms is “extremely common in petitioner’s age group.” (*Id.*)

Dr. Winell disagrees with Dr. Srikumaran’s assertion that petitioner’s pain substantially improved after her first surgery. (*Id.* at 3-4.) She cites several medical records created after petitioner’s first surgery, each noting that petitioner continued to suffer some mild pain or discomfort. (*Id.* at 4 (citing Ex. 7, pp. 1-4; Ex. 7, p. 5; Ex. 11, p. 1; Ex. 13, pp. 2-3).) Dr. Winell suggests that based on this documentation, petitioner’s pain did not resolve after her surgery. (Ex. C, p. 4.)

#### **e. Petitioner’s Final Expert Report – Dr. Uma Srikumaran**

Dr. Srikumaran notes that petitioner’s anatomy did not abruptly change and degenerate to the extent that it suddenly became painful. (Ex. 46, p. 2.) Based on petitioner’s medical history and imaging, Dr. Srikumaran believes that petitioner had this degenerative condition for a significant period of time without pain. Instead, Dr. Srikumaran suggests that, “[c]onsidering the time course of events, no prior issues with that shoulder, and objective evidence on MRI of inflammation as well as during surgery (“extensive bursitis”) noted by the operative surgeon, the most logical and likely cause was the vaccination eliciting an inflammatory response in the shoulder.” (*Id.*) Dr. Srikumaran says that Dr. Winell’s conclusion that the inflammation in petitioner’s

shoulder is caused by a degenerative process “completely ignores the time course of events.” (*Id.*)

Dr. Srikumaran clarified that he does not believe petitioner’s injection was directed into the AC joint, but he opines that inflammation from the injection site spread to the AC joint from the subacromial bursa. (Ex. 46, p. 2.) According to Dr. Srikumaran, degeneration of AC joint ligaments is common, and when this happens, it makes the subacromial bursa continuous with the AC joint synovium. (*Id.*) Thus, Dr. Srikumaran points out, direct connections of the AC joint to the subacromial space are common in patients like petitioner who suffer from AC joint arthrosis. (*Id.*) Dr. Srikumaran explains that this is consistent with Dr. Winell’s conclusion that petitioner’s AC joint was “completely obliterated” due to her arthrosis. (*Id.*) Consequently, Dr. Srikumaran indicates that Dr. Winell is incorrect to conclude that petitioner could not have developed a synovitis in her AC joint from inflammation in the subacromial space.

Dr. Srikumaran questions the reliability of the “hundreds of articles” that Dr. Winell cites to support the theory that abnormal acromial pathology can cause petitioner’s shoulder pain symptoms. (Ex. 46, p. 2.) According to Dr. Srikumaran, the articles that Dr. Winell cites “1) do not state abnormal pathology as the only cause of pain and 2) are refuted by many other articles suggesting acromial morphology does not play a role in typical shoulder pathology.” (*Id.*) Dr. Srikumaran points out that the time course of events suggest that petitioner’s shoulder degeneration was not the cause of her pain. (Ex. 46, p. 3.) Petitioner’s pain began immediately following the vaccination, inflammation was observed following her vaccination, and her degeneration was of a degree that indicates it had been occurred prior to her vaccination. (*Id.*) There are many things that can trigger inflammation and cause a pre-existing degenerative condition to become symptomatic, vaccination is shown to have a “strong, reliably and consistently, temporal association” with this condition and petitioner was vaccinated immediately before her pain began. (*Id.*)

#### **IV. Analysis**

In this case, petitioner has alleged a so called “Table Injury.” That is, petitioner alleges that she 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 the presence of a Table Injury is proven, it is presumed to have been caused by 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, 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). The Act’s “Qualifications and aids in interpretation” (“QAI”) provide specific guidelines used to evaluate Table Injury SIRVA claims. See 42 C.F.R. § 100.3(c)(10). 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 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).

If petitioner can prove that her alleged injury meets these four elements, she will be entitled to compensation unless the government can show the injury was caused by a factor unrelated to vaccination. § 300aa-13(a)(1)(B). Petitioner bears a “preponderance of the evidence” burden of proof. § 300aa-13(a)(1).

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

Nothing in the medical record suggests that petitioner ever had any manifestation of pain or dysfunction in her right shoulder prior to the vaccination at issue. Respondent has made no argument on this point, and his expert, Dr. Winell, concedes this element is met. (Ex. A, p.5.)

**b. Pain occurs within the specified timeframe (48 hours)**

Based on the record as a whole, I find that there is preponderant evidence that the onset of petitioner’s shoulder pain was within 48 hours of her October 11, 2016 flu vaccination. On this point, respondent argues only that:

Petitioner did not seek initial treatment for her right shoulder pain until more than 11 weeks following the subject vaccination, on December 28, 2016. Simply, preponderant evidence does not support the onset of petitioner’s right shoulder complaints within 48 hours of the flu vaccination. Petitioner’s statement, the affidavits submitted on her behalf, and the sweeping conclusions of petitioner’s experts do not cure the evidentiary deficiencies with respect to onset this case.

(ECF No. 76, p. 21 (internal citations omitted).)

However, absent additional factors, respondent’s suggestion that an 11-week delay in seeking treatment in itself constitutes an evidentiary deficiency is not persuasive. Respondent’s argument is inconsistent with the Vaccine Act insofar as the statute instructs that the special master may find the time period for the first symptom or manifestation of onset required for a Table Injury is satisfied “even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such a period.” §300aa-13(b)(2). Moreover, prior decisions by myself and other Special Masters have found that postponing treatment for a limited number of months is not *per se* dispositive of whether onset of shoulder pain

occurred within the specified time period for a SIRVA. See e.g., *Forman-Franco v. Sec’y of Health & Human Servs.*, No. 15-1479V, 2018 WL 1835203 (Fed. Cl. Spec. Mstr. Feb. 21, 2018); *Tenneson v. Sec’y of Health & Human Servs.*, No. 16-1664V, 2018 WL 3083140 (Fed. Cl. Spec. Mstr. Mar. 30, 2018), *mot. rev. denied* 142 Fed. Cl. 329 (2019); and *Gurney v. Sec’y of Health & Human Servs.*, No. 17-481V, 2019 WL 2298790 (Fed. Cl. Spec. Mstr. Mar. 19, 2019).

For example, in *Williams v. Secretary of Health & Human Services*, I found that the petitioner had established onset within 48 hours even though he had delayed treatment for his shoulder injury by roughly five months, a period significantly longer than the delay seen in this case. No. 17-1046V, 2020 WL 3579763, at \*2 (Fed. Cl. Spec. Mstr. Apr. 1, 2020). Typically, when delays in seeking treatment have contributed to dismissal of prior SIRVA claims, it has been because the contemporaneous medical records that do exist have otherwise been inconsistent with petitioner’s allegation of immediate post-vaccination onset. See e.g., *Small v. Sec’y of Health & Human Servs.*, No. 15-478V, 2019 WL 6463985, at \*11 (Fed. Cl. Spec. Mstr. Nov. 1, 2019); *Demitor v. Sec’y of Health & Human Servs.*, No. 17-564V, 2019 WL 5688822, at \*10 (Fed. Cl. Spec. Mstr. Oct. 9, 2019).

Here, although the record for petitioner’s December 28, 2016 encounter was made 11 weeks after her vaccination, it is nonetheless trustworthy as a medical record contemporaneous to her treatment, having been created to facilitate diagnosis and care for her shoulder pain. See e.g., *Cooper v. Sec’y of Health & Human Servs.*, No. 16-1378V, 2018 WL 1835179, at \*6 (Fed. Cl. Spec. Mstr. Jan. 18, 2018); see also *Cucuras v. Sec’y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993); *Doe v. Sec’y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010). The history petitioner provided at that time is consistent with an immediate post-vaccination onset (Ex. 2, p. 5) and respondent has not identified any basis for questioning the accuracy and completeness of the record itself. Moreover, despite her apparent skepticism regarding petitioner’s own clinical history, respondent’s expert has conceded that there is no such thing as an “appropriate” time to seek treatment. (Ex. C, p. 1.) Further, all of petitioner’s later treatment records consistently associate onset to her vaccination. (Ex. 3, p. 7; Ex. 5, p. 7; Ex. 6, p. 1; Ex. 26, p. 7; Ex. 27, p. 75; Ex. 38, p. 1; Ex. 48, p.1) Apart from petitioner’s initial delay in seeking treatment, respondent has not identified any piece of evidence on this record that is inconsistent with onset occurring within 48 hours of vaccination. Accordingly, there is no basis for questioning the time of onset accepted by the treating physicians in the facially valid medical records.

### **c. Pain and reduced range of motion confined to the shoulder**

With regard to the third SIRVA QAI prong, respondent argues that petitioner’s injury was not confined to her shoulder based on a suspicion of a cervical etiology for petitioner’s condition, evidenced by a record by Dr. White as well as petitioner’s reported pain radiating from her shoulder to her neck and bicep. This is not persuasive.

Dr. White only preliminarily considered a possible cervical spine etiology as an explanation for petitioner's condition. (Ex. 6, p. 12.) Respondent himself acknowledges that there was no further follow up or evaluation to suggest a cervical pathology of petitioner's condition. (ECF No. 76, p. 21.) Moreover, respondent's expert acknowledged that "[w]hile this was one area to explore and rule out, there is little to go off of here . . ." (Ex. A, p. 5.) Ultimately, she characterized this issue as only "questionable." (*Id.*) In the context of the complete record, including petitioner's extensive orthopedic treatment, there is not preponderant evidence on this record that petitioner suffered any cervical spinal condition.<sup>7</sup> Moreover, there is no evidence of any reduced range of motion beyond petitioner's shoulder. Nor are there any objective findings that suggest any neck, elbow, or other etiology for petitioner's injury, which was consistently treated as a shoulder injury.

Additionally, based on the pattern of treatment petitioner received over an extended period from multiple physicians and the additional opinions of her experts, it does not appear that petitioner's subjective report of some radiating pain, without more, provides any meaningful basis for questioning the etiology of petitioner's shoulder pain as stemming from her shoulder injury. Petitioner's experts persuasively explain that secondary neck and arm pain often occur in shoulder injuries because patients compensate for their lack of shoulder function by using their arm and neck muscles to conduct daily activities or support their injured shoulder. (Ex. 34, p. 2; Ex. 39, p. 8.) In that regard, petitioner's medical records do reflect that she related to Dr. White that she felt her neck pain was related to postural changes due to her shoulder injury. (Ex. 6, p. 10.) Moreover, Dr. White specifically confirmed that petitioner's pain did not radiate below the elbow, a point stressed by the experts as distinguishing shoulder pain from cervical pain. (Ex. 6, p. 15.) Although Dr. Winell interprets petitioner's medical records differently, she did not dispute Drs. Anderson's and Srikumaran's explanation of the association between shoulder dysfunction and radiating pain. (Ex. C, pp. 1-2.)

#### **d. No other condition or abnormality explains petitioner's symptoms**

Finally, relying on Dr. Winell's assessment of petitioner's presentation, respondent argues that petitioner's Table Injury allegation fails because she suffered a degenerative shoulder condition unrelated to her vaccination that represents a more likely cause of her pain. Specifically, Dr. Winell opined in her first report that "[t]he pathology noted on Dr. Yehwahi's operative reports are indicative of an underlying degenerative condition. These included: degenerative tear of the superior labrum, partial thickness articular sided tear of supraspinatus tendon, anterolateral acromial spurring and CA ligament fraying." (Ex. A, p. 5.) First, Dr. Winell opined that these findings are well known causes of shoulder impingement and that they constitute a more likely explanation of petitioner's undisputed bursitis than does petitioner's vaccination. (*Id.* at 5-6.) Second, Dr. Winell discussed the acromioclavicular arthritis

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<sup>7</sup> For the same reasons discussed in this section, a cervical spinal condition also does not constitute a condition or abnormality explaining petitioner's symptoms as discussed relative to the fourth SIRVA QAI prong discussed below.

evidenced in Dr. Yehwahi's operative report and noted that it would not be vaccine-caused. (*Id.* at 6.)

However, 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. 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.<sup>8</sup> Proposed 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 41) 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.

(S. Atanasoff et al., *Shoulder Injury Related to Vaccine Administration (SIRVA)*, 28 VACCINE 8049, 8051 (2010) (Ex. 41, p. 3).)

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<sup>8</sup> 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 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).



A further study by Hesse et al., conducted by the Department of Health and Human Services and Centers for Disease Control, examined the characteristics of 476 SIRVA cases conceded by the government as meeting the regulatory definition of SIRVA. (Elizabeth M. Hesse et al., *Shoulder Injury Related to Vaccine Administration (SIRVA): Petitioner Claims to the National Injury Compensation Program, 2010-2016*, 38 Vaccine 1076 (2020) (Ct. Ex. I).) Consistent with both Atanasoff and the respondent's own rulemaking, the Hesse study observed SIRVA alongside or in connection with degenerative changes, including rotator cuff degeneration and/or tendinopathy and acromioclavicular arthritis, in a significant number of cases. For example, among the compensated claims examined, 16.2% had evidence on MRI of acromioclavicular arthritis, a further 16.2% had labral tears, and over 40% had either complete or partial rotator cuff tears.<sup>9</sup> (*Id.* at 5 (Table 5).)

Accordingly, 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. In that context, Dr. Winell's opinion that petitioner did not suffer a SIRVA is far less persuasive. In fact, Dr. Winell's opinion is actually somewhat unclear in even asserting the presence of any separate explanation for petitioner's shoulder pain.

In her supplemental report, Dr. Winell clarified that, although petitioner's AC arthritis would not be vaccine caused, she does *not* opine that AC arthritis is a more likely explanation for petitioner's shoulder pain. (Ex. C, p. 2.) Rather, she explained that "[i]t was clear that petitioner had generalized shoulder pain consistent with impingement as well as AC joint pain, both of which are commonly seen together in this age group . . ." (*Id.*) As explained above, however, to the extent Dr. Winell opines that petitioner's specific findings add up to a presentation of impingement syndrome as the likely cause of her shoulder pain, that condition was explicitly included in respondent's regulatory rulemaking as among the conditions intended to fall within the scope of SIRVA. 2015 WL 4538923, at \*45136.

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<sup>9</sup> Dr. Winell questioned the value of the Hesse study as a piece of medical literature. (Ex. C, p. 4.) Specifically, she indicated that, while descriptive, studies such as Hesse, et al, are inadequate to assess causation. (*Id.*) And, indeed, the Hesse article itself includes a similar disclaimer, indicating that "MRI findings in our cases should be interpreted with caution and not be equated with *prima facie* evidence of a causally associated injury. Such findings are not uncommon among people in the age group of our cases, independent of vaccination (i.e., shoulder pathology is common in middle age and old age)." (Hesse et al., *supra*, at Ct. Ex. I, p. 6.) In presenting her *prima facie* case under the Vaccine Injury Table, however, petitioner does not bear any burden of proving causation generally or to show that her shoulder pathology can be directly related to her vaccination as causal. It would be incompatible with the very idea of the Vaccine Injury Table to hold petitioner to a burden of proving causation to establish a Table Injury. Accordingly, descriptive evidence from this medical literature relating to the nature of prior SIRVA claims brought in this program need not represent evidence of causation in order to be relevant and valuable. In any event, Dr. Srikumaran opined that the Hesse study constitutes valuable observational data. (Ex. 46, p. 3.)

Moreover, while it may be true that certain of petitioner's MRI and surgical findings can be associated with impingement even in the absence of vaccination, Dr. Winell appears to somewhat overstate or oversimplify the cause and effect relationship among these findings in the presentation of impingement syndrome. Impingement syndrome itself "consists of a spectrum of clinical findings, NOT injury to a specific structure." (Stephen M. Simons et al., *Shoulder Impingement Syndrome*, WOLTERS KLUWER UPTODATE, <https://www.uptodate.com/contents/shoulder-impingement-syndrome> (Dec. 8, 2020) (Ex. A, Tab 1, p. 14 (emphasis original)).) In her first report Dr. Winell highlighted a report by Harrison and Flatow which found that intrinsic degeneration, including tearing and fraying of rotator cuff tendons, and extrinsic compression factors, such as acromial spurs, have been linked to shoulder impingement syndrome. (Alicia Harrison & Evan Flatow, *Subacromial Impingement Syndrome*, 19 J. OF THE AM. ACAD. OF ORTHOPAEDIC SURGEONS 701 (2011) (Ex. A, Tab 5).) However, those authors cautioned that "[t]he relationship between subacromial impingement and rotator cuff disease in the etiology of rotator cuff injury is a matter of debate." (Harrison & Flatow, *supra*, at Ex. A, Tab 5, p. 1.) They further explained that "the etiology of rotator cuff disease has long been debated and the cause is likely multifactorial . . ." (*Id.* at 2.) Upon my review, Harrison and Flatow neither supports nor refutes the understanding of SIRVA discussed above.

Additionally, Dr. Winell's reliance material suggests that "[p]ain from shoulder impingement syndrome (SIS) may result from injury to a number of involved structures, including: the rotator cuff (RC), subacromial bursa, biceps tendon, and labrum. The history and physical examination are used to identify the structures involved and direct treatment." (Simons et al., *supra*, at Ex A, Tab 1, p. 5). This is consistent both with the concept of SIRVA generally and with Dr. Yehyaw'i's initial opinion that petitioner's shoulder pain was specifically related to post-vaccination inflammation of the bursa and rotator cuff. (Ex. 5, p. 9.) Dr. Srikumaran also contends that the acute inflammation that was observed around petitioner's AC joint would be unexpected for a degenerative process, and that it is more likely the result of a vaccine-mediated inflammatory response. (Ex. 39, p. 9.)

Significantly, Dr. Winell's competing opinion that petitioner's condition is better explained as a degenerative condition is premised in part on her disbelief that onset of petitioner's condition was sudden and related to vaccination. (See, e.g., Ex. A, p. 6 (discounting petitioner's recollection of any temporal association to vaccination and explaining "[t]he natural histories of shoulder subacromial impingement/AC arthritis are that they frequently occur in this age group (>40) and pain can be brought on by actions of movements that may seem inconsequential or routine in activities of daily living.")) However, as described in section IV(b) above, there is preponderant evidence of a temporal relationship between petitioner's vaccination and the onset of her shoulder pain. "When an expert assumes facts that are not supported by a preponderance of the evidence, a finder of fact may properly reject the expert's opinion." *Dobrydnev v. Sec'y of Health & Human Servs.*, 566 Fed. Appx. 976, 982-83 (Fed. Cir. 2014) (citing *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993)). In contrast to Dr. Winell, and consistent with my own fact finding, Drs. Anderson and Srikumaran both concluded that the abrupt onset of post-vaccination shoulder pain

documented in the medical record is inconsistent with clinical onset of a degenerative condition. (Ex. 34, p. 3; Ex. 39, p. 8.)

Finally, to the extent respondent may argue that Dr. Winell's opinion supports the position that the *degree* of dysfunction related to either a rotator cuff pathology or arthritis must necessarily preclude vaccination as the cause, that represents a question of clinical judgment. However, Dr. Winell's assessment that it was more likely petitioner's degenerative findings explained her bursitis rather than her bursitis explaining the clinical activation of her shoulder pain (Ex. A, pp. 5-6) is directly contradicted by the clinical judgment of petitioner's own treating orthopedic surgeon. In his first post-operative report, Dr. Yehyawawi specifically maintained his opinion "that the injection that started all of her pain very likely could've caused an inflammatory response in the tendon and the bursa that persisted . . ." (Ex. 7, p. 5.) Dr. Yehyawawi continued to maintain his opinion that petitioner's pain was primarily due to rotator cuff and bursal inflammation even after accounting for the presence of AC arthritis. (Ex. 26, pp. 1-3.) Nothing in the record of this case calls into question Dr. Yehyawawi's clinical care and, given his in-person treatment of petitioner and first-hand observation of her shoulder during surgery, he is better positioned than Dr. Winell to make judgments as to the clinical significance of his own post-operative findings. *E.g.*, *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1327, 1326 (Fed. Cir. 2006) ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show [s] that the vaccination was the reason for the injury'").

#### **e. Factor unrelated**

Pursuant to the Vaccine Act, once petitioner has met her *prima facie* burden of demonstrating a Table Injury, respondent may still prove the condition is "due to factors unrelated to the administration of the vaccine describe in the petition." § 300aa-13(a)(1)(B). In this case, apart from the cervical spinal condition and degenerative shoulder pathology discussed above, respondent has not raised any issue as to any factor unrelated to vaccination.

#### **V. Conclusion**

For all the reasons discussed above, after weighing the evidence of record within the context of this program, I find by preponderant evidence that petitioner suffered a Table Injury of SIRVA following her October 11, 2016 flu vaccination as alleged. A separate damages order will be issued.

**IT IS SO ORDERED.**

**s/Daniel T. Horner**

Daniel T. Horner  
Special Master