In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 18-166V
Filed: May 27, 2022
UNPUBLISHED

LISA COLBERT, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Special Master Horner Shoulder Injury Related to Vaccine Administration ("SIRVA"); Tetanus diphtheria acellular pertussis ("Tdap") Vaccine; Ruling on the Record

John Robert Howie Jr., Howie Law P.C., Dallas, TX, for petitioner.
Ryan Pyles, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT[1]

On February 1, 2018, petitioner, Lisa Colbert, filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012),[2] alleging that her receipt of a Tetanus-Diphtheria-Acellular Pertussis ("Tdap") vaccine on February 2, 2015, caused a left shoulder injury related to vaccine administration ("SIRVA").[3] (ECF No. 1.) On February 12, 20218, petitioner filed her First Amended Petition with additional citations to the medical records. (ECF No. 7.) On March 2, 2021, petitioner filed her Second Amended Petition, alternatively alleging that her "SIRVA injury to her left

[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.

[3] In her original petition, petitioner indicated that she "anticipates filing a complete First Amended Petition in proper form and with citations in the next fourteen days or on or before any deadline set by the Court." (ECF No. 1, p. 1.)

shoulder was caused in fact by her Tdap vaccination."[4] (ECF No. 57, p. 8.) 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, 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 a vaccine containing either tetanus toxoid or pertussis. § 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 definition:

> SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies

[4] Although petitioner's Second Amended Petition uses the phrase "SIRVA injury to her left shoulder" (ECF No. 57, p. 8), which mimics the language of a Table injury, petitioner alleges that she suffered pain and dysfunction in her left shoulder *caused-in-fact* by her Tdap vaccination.

> 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 show that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (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 F.3d 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).

Once a petitioner has established their *prima facie* case, the burden then shifts to respondent to prove, also by preponderant evidence, that the alleged injury was caused by a factor unrelated to vaccination. *Althen,* 418 F.3d at 1278 (citations omitted);

§ (a)(1)(B). The Vaccine Act requires respondent to establish that the factor unrelated to the vaccination is the more likely or principal cause of the injury alleged. *Deribeaux v. Sec'y of Health & Human Servs.*, 717 F.3d 1363, 1369 (Fed. Cir. 2013). Such a showing establishes that the factor unrelated, not the vaccination, was "principally responsible" for the injury. *See* 42 U.S.C. § 300aa–13(a)(2)(B). The factor unrelated must be the "sole substantial factor," therefore respondent must establish that the factor unrelated, not the vaccination, actually caused the injury alleged. *See de Bazan,* 539 F.3d at 1354.

In this case, petitioner stresses that she suffered a left-sided shoulder injury preponderantly demonstrating a SIRVA Table injury. (*See* ECF No. 54, pp. 11-18.) Alternatively, petitioner asserts that reliable medical evidence supports a non-Table shoulder injury was caused-in-fact by her vaccination. (ECF Nos. 57, 58.)

II. Procedural History

Petitioner filed her petition on February 1, 2018. (ECF No. 1.) This case was initially assigned to the Court's Special Processing Unit ("SPU") on February 2, 2018. (ECF Nos. 4, 5.) On February 12, 2018, petitioner filed her First Amended Petition, her sworn statement, medical records, and a statement of completion. (ECF Nos. 7-8.) Petitioner filed additional medical records on March 21, 2018. (ECF No. 14.) An initial status conference was held on March 23, 2018. (ECF No. 15.) Petitioner filed additional medical records on May 4 and May 22, 2018. (ECF Nos. 17, 19.)

On March 5, 2019, respondent filed his Rule 4(c) report recommending against compensation. (ECF No. 32.) Respondent contended that petitioner failed to demonstrate either a Table Injury SIRVA or that her shoulder injury was caused-in-fact by her vaccination. (ECF No. 32, pp. 9-11.) Thereafter petitioner was ordered to file an expert report. (ECF No. 33.) In that order, former chief special master Dorsey ordered: "[i]f petitioner is alleging actual causation, the expert report must establish the three requirements of *Althen*[.]" (*Id.*) On September 10, 2019, petitioner filed an expert report authored by her treating physician, Daniel Schwartz, M.D., with accompanying medical literature. (ECF Nos. 39, 40.) In his report Dr. Schwartz opines that petitioner suffered a SIRVA, and alternatively, that petitioner's Tdap vaccination caused her shoulder injuries. (*See* Ex. 17.)

On October 28, 2019, this case was reassigned to Special Master Roth. (ECF No. 44.) On January 22, 2020, respondent filed an expert report authored by David Ring, M.D. (ECF No. 45.) On June 23, 2020, petitioner filed a responsive expert report from Dr. Schwartz. (ECF No. 49.) On August 31, 2020, respondent filed a status report indicating that he did not wish to submit an additional responsive expert report. (ECF No. 50.) Subsequently, petitioner filed a status report on September 30, 2020, electing to proceed with a motion for a ruling on the record. (ECF No. 51.) On December 1, 2020, petitioner filed additional medical literature and a motion for a ruling on the record. (ECF Nos. 53, 54.) On January 14, 2021, respondent filed his responsive brief. (ECF

No. 55.) Respondent argued that petitioner neither pleaded nor preponderantly proved a cause-in-fact claim. (*Id.*) Petitioner filed a second amended petition, pleading an alternative causation-in-fact theory, and her reply to respondent's response on March 2, 2021. (ECF Nos. 57, 58.) Petitioner asserted that the second amended petition cures the defect raised by respondent but also contended that respondent had notice of the claim. (*Id.*)

Subsequently, this case was reassigned to my docket on February 4, 2022. (ECF No. 60.) On February 8, 2022, I issued a NON-PDF Order indicating that "[a]t the time of reassignment, a ripe motion for a ruling on the written record [] was pending" and "[a]bsent action by the parties, I intend to act on the pending motion in due course without further proceedings." (Docket Text 2/8/2022.) On February 8, 2022, petitioner filed a status report indicating that she did not intend to take any further action and requested that the court rule on the motion as filed. (ECF No. 61.) Respondent did not file any response to the February 8, 2022, order or petitioner's status report.

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) (citing *Simanski v. Sec'y of Health & Human Servs.*, 671 F.3d 1368, 1385 (Fed. Cir. 2012) (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

On February 2, 2015, petitioner received an intramuscular Tdap vaccination in her left arm at Southwest Care Center. (Ex. 2, pp. 9, 11, 12.) Petitioner's prior medical history was significant for fibromyalgia, chronic fatigue syndrome, depression, left femoral artery stenosis, chronic pain syndrome, and migraines. (Ex. 2, pp. 10, 13.) Prior to vaccination, petitioner had no history of trauma or injury to her left shoulder, arm, or hand. (*See generally,* Ex. 3; Ex. 4, pp. 1-68; Ex. 5.)

On February 20, 2015, eighteen days post-vaccination, petitioner presented to Aspen Medical Center complaining of left arm pain, dizziness, and a three-day cold. (Ex. 6, p. 1.) She was seen by Sean Wilson, PA-C, who recorded that petitioner had pain in her left arm since receiving a Tdap vaccination "high in [her] deltoid." (*Id*.) He noted that petitioner "fe[lt] like it may have hit a nerve" and noted some "mild swelling" in her left upper extremity. (*Id.*) Petitioner reported experiencing no relief from her symptoms since this happened "almost two weeks ago." (*Id.*) On examination, P.A. Wilson observed that petitioner had full range of motion in both upper extremities, with medial, ulnar, and radial nerves intact bilaterally, and deep tendon reflexes within a normal range. (*Id.* at 2.) He assessed her with "traumatic injection [to] axillary nerve" in

her left upper extremity and prescribed a narcotic pain medication. (*Id.*) He further instructed petitioner to rest and told her that she should recover in 8-12 weeks. (*Id.*)

On March 2, 2015, petitioner returned to Southwest Medicine for multiple concerns, including left arm pain. (Ex. 2, pp. 13-15.) Suzanne Gagnon, N.P., recorded petitioner's description of her symptoms:

> left arm pain since getting the Td shot, she went to Urgent Care and was told she may have had some irritation to a nerve, she is in daily chronic pain at her deltoid area, she is unable to sleep at night due to the pain.

(*Id.* at 13.) Petitioner also complained of leg pain, hot flashes, sweats, fatigue, and a scalp skin lesion. (*Id.*) On examination, N.P. Gagnon noted tenderness in petitioner's left deltoid. (*Id.* at 14.) Petitioner was diagnosed with "chronic pain syndrome left deltoid pain s/p [status post] injection tetanus." (*Id.*) Petitioner received a prescription for Tramadol and was advised to follow up in 2-3 weeks. (*Id.*)

On July 4, 2015, petitioner presented to the Emergency Room at Jefferson Healthcare Hospital ("Jefferson Hospital") for left-sided pelvic pain. (Ex. 4, p. 71.) There is no mention of shoulder pain. (*Id.* at 69-95.)

On July 28, 2015, Petitioner had an initial evaluation at Northwest Acutonics[5] for her left shoulder pain. (Ex. 11, pp. 10-16.) At the time of the visit, petitioner completed a Client Health Information Sheet. (*Id.* at 10.) On that form, petitioner specifically located her pain as follows, "intense pain at several points in left shoulder and left arm. Also pain/discomfort in surrounding areas." (*Id.*) Petitioner characterized her pain as, "a deep, sharp ache from inside [her] shoulder." (*Id.*) She denied experiencing burning, numbness, or pins and needles. (*Id.*) Petitioner also documented that she first noticed her symptoms, "Feb 2nd 2015 – at time of shot – Tdap. There was a deep & intense ache that seemed unusually painful." (*Id.* at 11.) During the evaluation, the therapist documented that petitioner presented with complaints of "significant, intense pain throughout her entire shoulder region that is constant." (*Id.* at 8.) The therapist further noted that petitioner, "said at times it is a throbbing sensation with a knife stabbing-sharp pain that comes from deep inside her shoulder that does not let up." (*Id.*) On physical examination, the therapist observed that petitioner "holds her left arm close to her torso in a guarded fashion." (*Id.*) Petitioner's range of motion in her left shoulder was normal, range of motion in petitioner's left shoulder was "limited moderately in abduction (raising to the side) and severely limited in forward flexion (straight arm raise) and also in external rotation with significant pain in the deltoid muscle." (*Id.*) The

[5] According to their website, "The Acutonics System incorporates the use of precision calibrated tuning forks, planetary chimes and symphonic gongs, each tuned to a specific frequency that carries with it unique properties for healing and cellular communication." *Sound Healing Tools,* http://www.northwestacutonics.com/content/sound-healing-tools/desc/sound-healing-tools (last accessed May 16, 2022).

therapist also documented the presence of "weakness in the bicep with supine flexion of the left arm." (*Id.*)

Petitioner returned for acutonics treatment on August 11, September 8, and September 30, 2015. (Ex. 11, pp. 3-6, 14-19.) During these sessions, improvement was noted in Petitioner's postural distortions with minimal torsion displaying in Petitioner's left shoulder. (*Id.* at 9.) Petitioner showed 20% to 25% improvement following treatment but reported that her symptoms would gradually return within the following days. (*Id.*) Petitioner had continued pain and restricted range of motion in her left shoulder. (*Id.*) Petitioner did not complain of numbness, tingling, burning, or pins-and-needles sensations until her final acutonics treatment session. (*See id.* at 14-20.) On November 5, 2015, petitioner reported "pins and needles and numbness in various points and down L arm into hand." (*Id.* at 20.) She reported that the pain in her left upper extremity was worse. (*Id.*) The therapist referred petitioner to a neurologist or shoulder specialist "because of numbness and pins + needles." (*Id.*)

On December 3, 2015, petitioner returned to Jefferson Hospital for a thyroid problem and was evaluated by Charles Schott, ARNP. (Ex. 4, pp. 95-107.) Petitioner also reported that she "had tetanus shot, [and] now has numbness / tingling in [her] arm." (Ex. 4, p. 105.) Petitioner was diagnosed with paresthesia of the arm and referred for a Nerve Conduction Studies ("NCS"). (Ex. 4, pp. 95, 101.)

On December 14, 2015, petitioner presented to the Emergency Department at Jefferson Hospital for pain related to her fibromyalgia. (Ex. 4, p. 122.) She also complained of upper back pain on her right side. (*Id.*) Petitioner believed that her pain resembled her past fibromyalgia flares. (*Id.* at 122.) She commented that oxycodone helped with her pain in prior flare ups. (*Id.*) Ronald W. Irick, D.O., performed a physical examination and noted "right periscapular musculature tension, [and] tenderness over right rhomboid musculature." (*Id.* at 124.) Petitioner was diagnosed with a fibromyalgia flare and prescribed Oxycodone and Naprosyn. (*Id.* at 121.) She returned to Jefferson Hospital the next day complaining of arm paresthesia. (*Id.* at 143.) She was given a neurology referral for further treatment. (*Id.* at 146.)

On January 26, 2016, petitioner presented to neurologist Jennifer Carl, M.D. (Ex. 7, pp. 1-11.) In petitioner's symptom history, Dr. Carl noted:

> She tells me that following the injection she developed discomfort like a tight band around her arm with some radiation distally and relatively mild associated paresthesias. This persisted for about 2 months with significant pain and then significantly improved. Unfortunately, the patient tells me that left upper extremity symptoms recurred about 2 months ago for unclear reasons. She denies unusual activity, associated illness, or new injury. She says that she has generally relatively mild pain affecting her left arm and shoulder region, but the paresthesias are more prominent and affect the same area and radiate down her anterior arm, dorsal forearm, to the hand.

> She reports that pain is generally 2-3 out of 10 and tolerable but that at night it is very troublesome.

(*Id.* at 2.) On examination, Dr. Carl observed that petitioner's cervical range of motion was within normal limits for her age. (*Id.* at 3.) Dr. Carl did not observe "tenderness, effusion, erythema, or increased warmth in the left shoulder subdeltoid region." (*Id.*) Impingement testing was positive on the left but not right shoulder. (*Id.*) Petitioner's NCV and EMG neuro-diagnostic studies revealed "a diagnosis of past versus chronic, low-grade C5 radicular injury versus, possibly, past upper brachia/plexus injury as a cause of her left upper extremity paresthesias and related discomfort, including her squeezing left arm discomfort." (*Id.* at 4.) She explained that the NCV findings revealed no evidence of a brachial plexus injury, though the abnormal EMG findings could alternatively be explained by a prior injury to the left upper brachial plexus. (*Id.*) Dr. Carl indicated that it was not possible to distinguish between the two potential interpretations based on the EMG findings alone. (*Id.*) With respect to the timing of petitioner's peripheral nerve injury, she opined "I can state only that it began or occurred at least 3 months ago." (*Id.*) The study was also interpreted to show no electrodiagnostic evidence of left median neuropathy, left ulnar neuropathy, left radial sensory neuropathy, or peripheral polyneuropathy affecting the left upper extremity. (*Id.*)

On February 10, 2016, petitioner presented to Michael Dam at Peninsula Chiropractic, complaining of shoulder pain, tingling, and numbness in the left side of petitioner's neck, arm, and shoulder. (Ex. 8, pp. 2-4.) Dr. Dam observed "pain and tenderness in the cervical, thoracic, and lumbar spine" as well as reduced range of motion in the cervical and lumbar spine. (*Id.* at 3.) Petitioner returned to see Dr. Dam the next day, noting that she felt improved after the initial treatment, except for her right arm which remained the same. (*Id.* at 5.) She described a "band of tightness around her left shoulder" with tingling pain/pins/needles in her left hand "with a heavy feeling."[6] (*Id.*)

On February 14, 2016, petitioner presented to Jefferson Hospital after hurting her left arm when she slammed her van door the night before.[7] (Ex. 15, p. 38.) She was examined by Lawrence Duane Sherman, M.D., who observed that she had a "good range of motion in all major joints." (*Id.* at 41.) Dr. Sherman further observed that petitioner had "pain at the left shoulder diffusely. No swelling, full sensation distal and pulses are strong." (*Id.*) Dr. Sherman offered petitioner an x-ray, but petitioner

[6] Petitioner presented to Dr. Dam for follow-up chiropractic visits on February 18 and 23, 2016. (Ex. 8, pp. 7-11.) She continued to complain of neck, arm, and shoulder pain/tingling/numbness. (*Id.* at 7, 10.) She reported mild improvement in the cervical, thoracic, and lumbar spine. (*Id.*) On examination petitioner continued to demonstrate reduced range of motion in the cervical and lumbar spine. (*Id.* at 8, 11.)

[7] However, petitioner already had left shoulder impingement documented in her medical history prior to this. (Ex. 7, p. 3.)

declined, explaining that her arm was "not broken" and that "it was coming from [her] spine." (*Id*.)

On February 17, 2016, petitioner underwent a cervical spine MRI which revealed:

> [m]ultilevel disc, uncovertebral, and facet degenerative changes, reactive endplate marrow edema in the left posterior aspect of C5-6[,] C5-6 left more than right, moderate, broad-based disk bulge/osteophyte complex mildly indenting the left-side of the cord but with the cord retaining normal signal[,] C5-6 moderate left lateral recess stenosis with disc bulge/osteophyte complex abutting the left C6 nerve root[,] and multilevel foraminal narrowing by uncovertebral osteophytes, severely at left C3-4 and bilateral C5-6, moderately at left C3-4, left C4-5, and right C6-7 levels.

(Ex. 8, p. 17.)

On July 6, 2016, petitioner presented to David Cox, D.C., of Sound Health Chiropractic. (Ex. 9, pp. 1-4.) She sought treatment for pain, tingling, and numbness in her left shoulder and arm. (*Id.*) Dr. Cox observed that petitioner had a significant decrease in cervical range of motion. (*Id.* at 2.) He assessed her with segmental and somatic dysfunction of the cervical and thoracic regions, "spondylosis without myelopathy or radiculopathy, cervical region," and "strain of muscle and tendon of back wall of thorax." (*Id.*) At her second appointment on July 11, 2016, Dr. Cox recommended that petitioner see an orthopedic surgeon and that she begin a home exercise program. (*Id.* at 4.)

On August 26, 2016, petitioner presented to orthopedist John Osland, M.D. (Ex. 15, pp. 148-158.) Petitioner reported pain and tingling, with occasional numbness in her left arm and occasional pain in her shoulder. (*Id.* at 149.) She denied any neck pain. (*Id.*) Dr. Osland noted that petitioner had had EMG and nerve studies that "indicated more of a cervical disc problem." (*Id.*) Dr. Osland remarked that her MRI showed "some changes at the C5-C6 disc going towards the left side." (*Id.*) On examination petitioner had full range of motion of her shoulder, elbow, wrist, and fingers. (*Id.* at 150.) Dr. Osland concluded that:

> I'm not sure or why [petitioner] has on and off numbness and tingling in different nerve distributions in her upper extremity. It fits more with her cervical problem. I'm not sure the injection caused all this in fact they [*sic*] does not fit with anatomic distributions w[h]ere she got injection and lateral aspect of her arm.

(*Id.* at 148.) He added "[n]ot sure there is much else I have offered at this time." (*Id.*)

On September 7, 2016, petitioner presented to Shauna Keeley, P.T., for a physical therapy evaluation at Jefferson Hospital, complaining of left upper extremity pain and paresthesia. (Ex. 15, p. 161.) On examination petitioner had reduced cervical active range of motion with "tightness sensation [in] [left] upper trap area;" spinal active

range of motion within normal limits, "slight pain over left SI [sacroiliac] joint;" and shoulder active range of motion within normal limits. (*Id.* at 163.) Petitioner attended approximately thirteen physical therapy sessions between September and December 2016. (*Id.* at 172-385.)

On November 14, 2016, petitioner presented to Daniel Schwartz, M.D., Ph.D. (Ex. 12, pp. 1-9.) Petitioner reported that "her symptoms ha[d] been ongoing for [*sic*] 02/02/2015" and that "[s]he received tetanus shot and arm has not been the same since." (*Id.* at 1.) On examination, petitioner had painless cervical range of motion and a negative Spurling sign. (*Id.* at 3.) Her left shoulder range of motion was normal, and petitioner had no scapular winging, no atrophy of the supraspinatus or infraspinatus fossa, and no crepitus. (*Id.*) Petitioner's strength was a 5/5 in abduction and external rotation, with tenderness to palpation over the bicipital groove and the AC joint in the left shoulder. (*Id.*) Dr. Schwartz concluded that he:

> [could not] fully explain some of [petitioner's] symptoms – numbness tingling for example which could represent more cervical related etiology. This in and of itself does not rule out, in my opinion, her shoulder being a contributor to her discomfort. Her examination is positive testing impingement – positive in chemical bursitis – and demonstrates good ROM/good strength. This condition can be seen from time to time on MRI, therefore I'd recommend getting an MRI to evaluate for a[n] immune response.

(*Id.*)

That same day petitioner underwent an x-ray of her shoulder which showed no glenohumeral arthritis, no fracture, no acromioclavicular arthritis, and a well centered glenohumeral joint. (*Id.* at 6-7.) On November 21, 2016, petitioner underwent an MRI on her left shoulder. (*Id.* at 10-13.) The radiologist's impression was mild subacromial / subdeltoid bursitis, partial tearing of the superior labrum, and mild subscapularis tendinosis. (*Id.* at 13.)

On December 5, 2016, petitioner returned to Dr. Schwartz to review her MRI results. (Ex. 12, pp. 16-17.) At the time of the visit, petitioner reported that she continued to experience paresthesia and pain in her left, upper extremity. (*Id.* at 16.) On examination, petitioner demonstrated painless cervical range of motion and a negative Spurling sign. (*Id.* at 17.) Petitioner had full strength and range of motion in her left shoulder. (*Id.*) She continued to demonstrate tenderness to palpation over her bicipital groove and her AC joint. (*Id.*) Dr. Schwartz noted that the MRI showed signs of bursitis, "probable pre-existing labral tear – [discussed with] her how common labral tears are in the general population especially with age above 40, likely observe for now." (*Id.*) He administered a steroid injection into petitioner's shoulder, noting that it was "unlikely to help with nerve symptoms although [we] will see." (*Id.*)

On January 16, 2017, petitioner returned to see Dr. Schwartz. (Ex. 12, pp. 20-21.) She reported that the injection had alleviated her pain, but not her paresthesia. (*Id.* at 20.) Dr. Schwartz was not surprised by this result. (*Id.*) He noted that petitioner seemed "more concerned with nerve symptoms." (*Id.* at 21.) Dr. Schwartz advised petitioner that he did not think that her nerve symptoms would get better with shoulder surgery, and he referred her to neurology. (*Id.*)

On January 28, 2017, petitioner presented to Dr. Sherman at Jefferson Hospital complaining of increased shoulder pain. (Ex. 15, p. 441.) Petitioner denied numbness, tingling, or weakness distally. (*Id.*) She indicated that she was considering surgery to manage her pain. (*Id.*) On examination, petitioner exhibited weakness on abduction, "intact rotation with pain," and that she could not raise her arm past 45 degrees. (*Id.* at 444.) Dr. Sherman concluded that "[t]his is primarily a pain control problem until [petitioner] arranges for surgery from her point of view." (*Id.*) He prescribed Percocet for the weekend. (*Id.*)

On February 22, 2017, petitioner presented to Victor Manuel Erlich, M.D., for a neurology consult. (Ex. 13, pp. 1-8.) Based on Dr. Erlich's examination of petitioner and his review of her medical history, he opined that she "likely suffers from a left C5 and/or C6 radiculopathy." (*Id.* at 6.) Dr. Erlich ordered a repeat EMG. (*Id.* at 17-20.) Dr. Erlich interpreted the results the next day, finding that:

> [Petitioner's] neurologic exam is notable for 5-/5 weakness in the left C6 myotome. Electrodiagnostic studies today show a moderately severe, acute and chronic, left C6 radiculopathy… [*sic*] Her MRI of the C-spine from Port Townsend on 2/17/2016 showed moderate left later-recess stenosis at C5-6 abutting [*sic*] the left C6 nerve root.

(*Id.* at 14.) Dr. Erlich referred petitioner for a surgical consultation. (*Id.*)

On May 8, 2018, petitioner returned to see Dr. Schwartz. (Ex. 16, pp. 1-3.) Petitioner reported that her neck pain improved from physical therapy, but her shoulder pain continued. (*Id.* at 1.) On examination, petitioner had painless cervical range of motion and her Spurling sign was negative. (*Id.*) Her Neer, Hawkins, Yocum tests were positive. (*Id.* at 2.) In his evaluation, Dr. Schwartz noted that her pain is still persisting, which was "not surprising given that the previous CSI [corticosteroid injection] helped her shoulder pain but not her neck; and now her neck is resolve[d] but her shoulder pain has persisted." (*Id.* at 3.) He concluded, "[t]his implies that these issues are separate and distinct. This is related to a chemical bursitis." (*Id.*)

b. As reflected in petitioner's sworn statement

On February 12, 2018, petitioner filed a sworn statement. (Ex. 1.) Petitioner averred that prior to her Tdap vaccination on February 2, 2015, she never experienced any significant problems with her left shoulder arm or hand. (*Id.* at 1.) On February 2,

2015, she presented to Southwest Care Center for a colonoscopy referral. (*Id.*) After receiving the Tdap vaccination petitioner felt more discomfort in her shoulder than she had previously experienced with past vaccinations. (*Id.*) Petitioner states that the "vaccine was administered too high on [her] shoulder[.]" (*Id.*) She avers that her shoulder pain significantly worsened over the course of forty-eight hours post-vaccination. (*Id.*) After a couple weeks of "enduring persistent and ongoing pain" in her left shoulder, petitioner sought medical intervention. (*Id.* at 2.)

On February 20, 2015, petitioner presented to Aspen Medical Center complaining of cold symptoms and continuing shoulder pain. (Ex. 1, p. 2.) Petitioner avers that the reference in the records regarding the "onset of two days prior" refers to her cold symptoms, and not her shoulder pain. (*Id.*) Petitioner stresses that her shoulder pain "began immediately after [her] Tdap vaccination." (*Id.*) She felt that the injection may have hit a nerve in her shoulder. (*Id.*)

Petitioner states that the pain medication failed to relieve her symptoms and she experienced "intense pain constantly shooting through [her] arm and shoulder." (Ex. 1, p. 2.) On March 2, 2015, petitioner returned to Southwest Care Center for a follow-up after her colonoscopy and still suffering constant shoulder pain. (*Id.*) Over the next couple of months, petitioner states that she continued to struggle with left shoulder pain. (*Id.*) Although her "left shoulder pain seemingly subsided for a short time," petitioner indicates that her "pain never completely resolved." (*Id.*) In July of 2015, petitioner states that her shoulder pain worsened again. (*Id.*) At this time petitioner began acutonics therapy. (Ex. 1, pp. 2-3.) She attended five sessions of acutonics therapy. (*Id.* at 3.) Prior to her final acutonics session on November 5, 2015, petitioner "began to experience a sudden and acute onset of numbness and tingling in [her] left arm which [she] had never before experienced." (*Id.*) On December 3, 2015, petitioner presented to her primary care physician Dr. Schott, who ordered an EMG/NCS. (*Id.*)

On February 10, 2016, petitioner sought treatment from Dr. Michael Dam at Peninsula Chiropractic. (Ex. 1, p. 4.) She described numbness and "muscle jerks" in her left arm with a pins-and-needles-like sensation from her left shoulder down to her fingers. (*Id.*) After four chiropractic treatments, petitioner states that she experienced no relief from her shoulder pain. (*Id.*) Furthermore, she stresses that she never experienced any cervical or thoracic spine symptoms, and therefore Dr. Dam's final report which indicates that she experienced improvement in her cervical and thoracic spine was clearly erroneous. (*Id.*)

On July 6, 2016, petitioner presented to Dr. David Cox at Sound Health Chiropractic for further medical evaluation and treatment. (Ex. 1, p. 4.) After one additional session of manipulation, petitioner states that there was still no improvement in her shoulder pain. (*Id.*) Petitioner stresses that she was not experiencing problems with her neck, and Dr. Cox's notes which state that her neck and shoulder were better is also an erroneous entry. (*Id.*)

On November 14, 2016, petitioner presented to Dr. Daniel Schwartz. (Ex. 1, p. 4-5.) Petitioner described pain "in the axilla area" which was "sharp and aching[.]" (*Id.*) She further located pain "in [her] anterior, posterior, and lateral shoulder, and rated it a 9 out of 10." (*Id.* at 5.) Petitioner returned to Dr. Schwartz on December 5, 2016, to discuss her MRI results. (*Id.*) Petitioner observed that her pain had not improved, rating it as a "5 to 6 out of 10," and her neuropathic pain as a "10 out of 10." (Ex. 1, p. 5.)

On January 16, 2017, petitioner returned for a follow-up visit with Dr. Schwartz. (Ex. 1, p. 5.) Petitioner states that her "symptoms returned to their pre-cortisone injection levels." (*Id.*) Petitioner recalls that her "left arm was weakening, and [her] nerve discomfort was causing most of [her] irritation." (*Id.*) During this visit Dr. Schwartz referred her to a neurologist, Dr. Erlich. (*Id.*)

Dr. Erlich referred petitioner to a neurosurgeon, however, petitioner indicates that she has "no interest in having cervical spinal surgery," and therefore she has "forego[ne] neurosurgical evaluation." (Ex. 1, pp. 5-6.) Presently, petitioner continues to suffer "intense and continuous pain" in her left shoulder. (*Id.* at 6.) Petitioner describes pain "at the top of [her] shoulder join, directly at and just below the location of the Tdap injection, high and close to the bone and just below that point on [her] upper left shoulder." (*Id.*) She also reports daily pain in "the back of [her] left shoulder, as well as inside [her] shoulder joint[.]" (*Id.*) Petitioner states that the pins-and-needles sensation, including the numbness in her left arm and hand, "completely resolved" in the "middle of the summer of 2017." (*Id.*) She adds that these symptoms have not returned, although the pain in her left shoulder has not dissipated. (*Id.*)

IV. Summary of Expert Opinions

a. Petitioner's expert Daniel Schwartz, M.D.

Dr. Schwartz currently serves as an orthopedic surgeon at The Polyclinic Madison Center in Seattle, Washington. (Ex. 18.) Prior to that Dr. Schwartz served as an orthopedic surgeon at the Sports and Medicine Clinic at Northwest Hospital – UW Medicine in Seattle. (*Id.*) The focus of his practice has been evaluating, diagnosing, and treating conditions involving the elbow and shoulder. (Ex. 17, p. 1.) Dr. Schwartz received his medical degree from Rush Medical College. (*Id.*) He completed an internship at the Feinberg School of Medicine Department of General Surgery in 2007. (*Id.*) After completing his residency, Dr. Schwartz participated in three fellowship programs, including a program in shoulder reconstruction at a hospital in Nice, France, a program in shoulder reconstruction in Annecy, France, and a program in shoulder and elbow surgery at the Florida Orthpaedic Institute in Tampa, Florida. (*Id.*) He is board certified by the American Board of Orthopedic Surgeons. (*Id.*) Dr. Schwartz is also one of petitioner's treating physicians. (*See* Exs. 12, 16.)

Dr. Schwartz explains that SIRVA is generally described as shoulder pain and limited range of motion after the administration of an intramuscular injection into the shoulder joint rather than the deltoid muscle. (Ex. 17, p. 3.) The introduction of the vaccination into the shoulder joint can result in an inflammatory process which damages the musculoskeletal structures within the shoulder joint including bursae, tendons, and ligaments. (*Id.* (citing A. Bancsi et al., *Shoulder injury related to vaccine administration and other injection site events,* 65 CAN. FAM. PHYS. 40 (2019) (Ex. 19).) He explains that symptoms primarily include shoulder pain and limited range of motion in the affected joint where the vaccination was administered. (Ex. 17, p. 3; Bancsi et al., *surpa,* at Ex. 19.) While injection site and shoulder pain are typical after intramuscular injection into the deltoid, Dr. Schwartz stresses that SIRVA involves a longer-term injury that is typically not responsive to over-the-counter treatments. (*Id.*) Dr. Schwartz notes that SIRVA are typically diagnosed through a combination of patient history, physical exam, and objective findings. (*Id.*)

Dr. Schwartz explains that cervical radiculopathy is the impingement of a nerve in the cervical portion of the spine. (Ex. 17, p. 3 (citing C. Onks & G. Billy, *Evaluation and Treatment of Cervical Radiculopathy,* 40 PRIM. CARE CLIN. OFFICE PRACT. 837 (2013) (Ex. 20).) He stresses that while impingement of a nerve in the cervical spine can be asymptomatic, in many cases, it can cause pain, sensory dysfunction, and motor dysfunction in the area of the body innervated by the impinged nerve. (*Id.*) Frequent symptoms of impingement of the nerve in the cervical spine include a combination of strength and sensory disturbances starting the area of the neck and radiating down one or both upper extremities. (Ex. 17, p. 3 (citing S. Bokshan et al., *An Evidence-Based Approach to Differentiating the Cause of Shoulder and Cervical Spine Pain,* 129 AM. J. MED. 913 (2016) (Ex. 21).) Dr. Schwartz explains that the specific neurological symptoms depend on which nerve or nerves in the cervical spine are being affected. (*Id.*)

Dr. Schwartz stresses that a high percentage of individuals, namely older individuals, have degenerative spine conditions but are entirely asymptomatic. (Ex. 17, p. 3 (citing M. Matsumoto et al., *Tandem age-related lumbar and cervical intervertebral disc changes in asymptomatic subjects,* 22 EUR. SPINE J. 708 (2012) (Ex. 22); M. Matsumoto et al., *Age-Related Changes of Thoracic and Cervical Intervertebral Discs in Asymptomatic Subjects,* 35 SPINE 1359 (2010) (Ex. 23).) Dr. Schwartz opines that simply identifying degenerative conditions on a radiological study is an insufficient and ineffective method of diagnosing a patient with upper extremity neurological dysfunction and emphasizes that clinical correlation is imperative to developing a proper diagnosis. (Ex. 17, p. 4 (citing R. Dunn, B*rachialgia: Cervical Radiculopathy and Differential Diagnosis,* 9 CONT. MED. ED. 359 (2011) (Ex. 24).)

In support of petitioner's cause-in-fact claim, Dr. Schwartz explains that a vaccine injected into the subdeltoid bursa can cause a robust immune mediated inflammatory response resulting in pain and reduced range of motion. (Ex. 17, p. 6.) Citing Atanasoff

et al., Dr. Schwartz relies on the theory that "the rapid onset of pain with limited range of motion following vaccination … is consistent with a robust and prolonged immune response within already sensitized shoulder structures following injection of antigenic substance into the subacromial bursa or the area around the rotator cuff tendon." (*Id.* (quoting S. Atanasoff, *Shoulder injury related to vaccine administration (SIRVA),* 28 VACCINE 8049 (2010) (Ex. 26).)[8] Dr. Schwartz stresses that shoulder injuries related to vaccine administration are not limited to cases of bursitis. (Ex. 17, p. 6.) He highlights cases involving tendonitis, impingement syndrome, rotator cuff tears, and adhesive capsulitis. (*Id.* (citing M. Bodor & E. Montalvo, *Vaccine-related shoulder dysfunction,* 25 VACCINE 585 (2007) (Ex. 25); Atanasoff et al., *supra,* at Ex. 26).) Lastly, Dr. Schwartz observes that some studies have suggested that females have a higher incidence of SIRVA; and in many cases, vaccination was administered high on the shoulder. (Ex. 17, pp. 6-7 (citing Arias et al., *supra,* at Ex. 29).)

Dr. Schwartz opines that petitioner's Tdap vaccination was more likely than not administered into her subdeltoid bursa and rotator cuff, which caused her to suffer prolonged shoulder pain and range of motion limitations. (Ex. 17, p. 7.) Prior to her Tdap vaccination on February 2, 2015, Dr. Schwartz observes that there is no indication in the medical records that petitioner ever experienced "any sort of problems with her left shoulder." (*Id.* (citing Ex. 7, p. 2.)) On November 5, 2015, approximately nine months post-vaccination, petitioner attended acutonics therapy. (Ex. 11, p. 10.) Dr. Schwartz stresses that petitioner did not report numbness or tingling as a symptom of her shoulder injury at this visit. (Ex. 17, p. 7.) According to Dr. Schwartz, "[a]bout this time, petitioner began to experience radiating pain in her left upper extremity accompanied by paresthesia. (*Id.* (citing Ex. 11, p. 20.)) In support, Dr. Schwartz highlights multiple objective tests confirming that this radiating pain with paresthesia "was probably related to petitioner's cervical disc disease[,]" including two EMG/NCS studies and a cervical spine MRI. (Ex. 17, p. 7 (citing Ex. 7, pp 1-4; Ex. 13, pp. 17-20; Ex. 8, pp. 16-17.) He opines that "the presence of symptomatic cervical disc disease in no way impacts whether [p]etitioner was also suffering a SIRVA at the time." (Ex. 17, p. 7.) Furthermore, Dr. Schwartz opines that petitioner's left shoulder MRI findings of subacromial / subdeltoid bursitis are consistent with a SIRVA injury, and his own physical exam findings from petitioner's evaluations on November 21, 2016, and December 6, 2016, are consistent with a SIRVA injury. (*Id.*) Lastly, Dr. Schwartz explains that petitioner's shoulder symptoms responded to a left shoulder corticosteroid

[8] Dr. Schwartz also cites the Institute of Medicine's report from 2012, which reviewed scientific and medical literature and found evidence that convincingly supports a causal relationship between vaccine injection (with a needle) and deltoid bursitis. (Ex. 17, p. 6 (citing Institute of Medicine, *Injection-Related Adverse Events,* in *Adverse Effects of vaccines: Evidence and Causality* (2012) (Ex. 28).) Moreover, Dr. Schwartz cites Arias et al. and Barnes et al., though he acknowledges that case studies and case reports do not establish causation. (Ex. 17, p. 6 (citing L.H. Martin Arias et al., *Risk of bursitis and other injuries and dysfunctions of the shoulder following vaccinations,* 35 VACCINE 4870 (2017) (Ex. 29); M. Barnes, *A "Needling" Problem: Shoulder Injury Related to Vaccine Administration,* 25(6) J. AM. BOARD FAMILY MED. (2012) (Ex. 30).)

injection, albeit temporarily, which provides further evidence of the presence of a SIRVA injury. (*Id.*)

Dr. Schwartz opines that the timing of petitioner's shoulder injury is consistent with what has been reported in the literature. (Ex. 17, p. 7.) He notes that SIRVA is expected to present as pain and or limited range of motion within the first 48 hours post-vaccination. (*Id.* (citing Bancsi et al., *supra,* at Ex. 19).) Accordingly, petitioner reported worsening pain over 48-hours following vaccination. (Ex. 17, pp. 7-8 (citing Ex. 1, ¶ 4.)) Petitioner also reported experiencing more discomfort post-vaccination than in prior vaccinations and noted that her vaccination was administered high on the shoulder. (Ex. 17, p. 7 (citing Ex. 1, ¶ 4.)) During her first visit 18 days post-vaccination with PA-C Wilson, petitioner reported that her "pain has been since shot." (Ex. 17, pp. 7-8 (citing Ex. 6, p. 1.)) Similarly, petitioner presented to NP Gagnon on March 2, 2015, reporting "left arm pain since getting TD shot." (Ex. 17, pp. 7-8.) These statements, Dr. Schwartz notes, are consistent with petitioner's sworn statement. (Ex. 17, pp. 7-8.) Likewise, he found no evidence suggesting that petitioner's pain did not begin within 48-hours post-vaccination. (*Id.*)

Finally, Dr. Schwartz opines that petitioner's cervical degenerative disease is distinct from her SIRVA injury. (Ex. 17, p. 8.) Based on his review of the medical records, Dr. Schwartz opines that petitioner suffered a symptomatic degenerative condition in her neck at or around November 2015. (*Id.* (citing Ex. 11, p. 20.)) More specifically, Dr. Schwartz posits that petitioner's degenerative condition presented as worsening pain and radicular symptoms of pain and paresthesia at or around her visits with her acutonics therapist on November 5, 2015. (*Id.* at 8 (citing Ex. 11, p. 20.)) Thereafter, petitioner was referred to a neurologist, and diagnosed with a cervical radiculopathy based on EMG/NCS and cervical spine MRI findings. (Ex. 17, p. 8.) Thus, Dr. Schwartz opines that "[w]hile [p]etitioner probably does have cervical radiculopathy, this is no way diminishes the SIRVA injury she suffered." (*Id.*)

b. Respondent's Expert, David Ring, M.D., Ph.D.

Dr. Ring currently serves as an Associate Dean for comprehensive care, professor of surgery, and professor by courtesy in psychiatry at the University of Texas Austin Dell Medical School. (Exs. A, B.) Dr. Ring received his medical degree from the University of California at San Diego in 1993. (Ex. B, p. 1.) He completed his orthopedic residency at the Harvard Combined Orthopedic Residency, and a fellowship in upper limb surgery at Massachusetts General Hospital. (Ex. A, p. 1.) He was awarded a Ph.D. in psychosocial aspects of arm pain from the University of Amsterdam in 2005. (Ex. B, p. 1.) Thereafter Dr. Ring worked at Massachusetts General Hospital for thirty-three years, where he was awarded with full professorship. (Ex. A, p. 1.) Dr. Ring explains that he is "particularly expert in the psychological and social determinants of illness[.]" (*Id.*) He has treated patients with shoulder problems in his independent clinical practice since 2000. (*Id.*) In the last five years, Dr. Ring has treated approximately 50 patients with adhesive capsulitis and approximately 500 patients with

rotator cuff tendinopathy. (*Id.*) He is board certified in orthopedic surgery and hand surgery.[9] (*Id.*)

Dr. Ring observes that petitioner's Tdap vaccination was administered into her left shoulder on February 2, 2015, which "seemed too high." (Ex. A, p. 2 (citing Ex. 1, p. 4.) Petitioner described worsening pain over the next 48 hours, which Dr. Ring describes as "typical of post-vaccination pain." (Ex. A, p. 2.) Petitioner described in her sworn statement that she rested her arm and shoulder as much as possible, and although her shoulder pain seemingly subsided for a short time, the pain never completely resolved. (*Id.* at 3 (citing Ex. 1, ¶ 7.)) Dr. Ring explains that the mention of rest is common and "tends to reflect the cognitive bias that the pain reflects new damage or prevention of healing." (Ex. A, p. 3.) Furthermore, he opines that petitioner's improvement is inconsistent with a harmful inflammatory process or infection. (*Id.*) Petitioner also described worsening pain in July 2015, particularly at night. (Ex. A, p. 3 (citing Ex. 1, ¶ 7.)) Night symptoms, according to Dr. Ring, are "characteristic of age appropriate changes in the rotator cuff tendons." (Ex. A, p. 3.)

Dr. Ring stresses that petitioner's neurodiagnostic testing on January 26, 2016, identified a C6 radiculopathy. (Ex. A, p. 3 (citing Ex. 7, p. 4.)) Moreover, a cervical MRI taken on February 17, 2016, showed age-appropriate arthritis in the cervical spine with narrowing consistent with C6 radiculopathy on the left. (Ex. A, p. 3 (citing Ex. 8, p. 16.) Dr. Ring opines that "[t]his is a clear, long-standing pathophysiology that accounts for many of [petitioner's] symptoms." (Ex. A, pp. 3-4.) The arthritis in the neck, Dr. Ring explains, develops gradually, and the symptoms may be unnoticed or well adapted at first. (*Id.* at 4.) Dr. Ring disagrees with Dr. Schwartz, he opines that "[t]here is a high probability of new symptoms coincident, but not causally related to vaccination." (*Id.*) Dr. Ring stresses that petitioner's numbness developed eight months post-vaccination. (*Id.*) Notably, he opines that "[t]he symptoms from the radiculopathy are like a completely separate process from the shoulder soreness, which is likely caused by her

[9] Petitioner argues that "Dr. Ring has not established in this case that he is properly qualified to offer opinions about shoulder injuries or, more importantly, SIRVA." (ECF No. 54, p. 17.) The focus of Dr. Ring's practice "is, and always has been, on the hand and not the shoulder." (*Id.)* Moreover, petitioner contends that Dr. Ring's "entire source of knowledge of SIRVA is limited to his retrospective review of a handful of SIRVA cases." (*Id.*) Lastly, petitioner accuses Dr. Ring of "obvious financial bias" that "undermines his opinions offered in this case." (*Id.* at 18.) However, as petitioner indicates, Dr. Ring has served as an expert in prior SIRVA cases in the Program. *Desai v. Sec'y of Health & Human Servs.*, No. 14-811V, 2020 WL 4919777, at *3 (Fed. Cl. Spec. Mstr. July 30, 2020); *Lesher v. Sec'y of Health & Human Servs.*, No. 17-1076V, 2020 WL 4522381, at *8 (Fed. Cl. Spec. Mstr. July 2, 2020); *Forman-Franco v. Sec'y of Health & Human Servs.*, No. 15-1479V, 2019 WL 7602582, at *5 (Fed. Cl. Spec. Mstr. Dec. 19, 2019); *Wellen v. Sec'y of Health & Human Servs.*, No. 17-767V, 2019 WL 5802344 (Fed. Cl. Oct. 17, 2019). As each of the special masters in those cases have indicated, Dr. Ring is a board-certified orthopedic surgeon who completed his orthopedic residency at Harvard, in addition to a fellowship in upper limb surgery at Massachusetts General Hospital, where subsequently worked for thirty-three years. (*See id.*; Ex. A, p. 1.) Moreover, Dr. Ring has treated patients with shoulder problems in his independent practice since 2000, and in the past five years, has treated 50 patients with adhesive capsulitis and 500 patients with rotator cuff tendinopathy—both common SIRVA diagnoses. (*Id.*)

age-appropriate rotator cuff tendinopathy, not the vaccination [petitioner received on 2/2/15." (*Id.*)

Dr. Ring also disputes the accuracy of the objective findings showing petitioner's SIRVA diagnoses. (Ex. A, p. 4.) Petitioner presented to Dr. Schwartz on November 14, 2016, who ordered an MRI. (*Id.*) Petitioner underwent an MRI arthrogram on November 21, 2016. (*Id.* (citing Ex. 12, p. 10.)) Dr. Ring opines that this type of MRI "is a good option for evaluating the labrum, but not as good for evaluating rotator cuff tendinopathy." (Ex. A, p. 4.) This is because "the arthrogram makes it impossible to address fluid in the joint or bursa: because of common connections it makes it difficult to distinguish reactive fluid from intentionally injected contrast." (*Id.*) Therefore, Dr. Ring opines that the findings were "age appropriate and unlikely to be related to vaccination: mild labral changes and mild subscapularis tendinosis." (*Id.* (citing Ex. 12, pp. 12-13.)) Although petitioner recalls in her statement that "Dr. Schwartz advised [her] that [she] was experiencing inflammation in [her] shoulder probably caused by [her] Tdap vaccination (Ex. 1, ¶ 15), Dr. Ring observes that the coded diagnosis from petitioner's December 5, 2016, visit was rotator cuff syndrome (Ex. A, p. 4 (citing Ex. 12, p. 16)). Dr. Ring stresses that rotator cuff tendinopathy is the most frequent cause of shoulder pain after the age of 40. (Ex. A, p. 4.) He explains that petitioner's symptoms and physical exam were consistent with rotator cuff tendinopathy, specifically, anterior shoulder pain reproduced with impingement maneuvers. (Ex. A, pp. 4-5 (citing Ex. 15, pp. 2-3.)) However, Dr. Ring maintains that petitioner's rotator cuff tendinopathy, seen on MRI, is "age appropriate and cannot be related to vaccination." (Ex. A, p. 5.) Dr. Ring suggests that Dr. Schwartz both dismisses petitioner's age-related changes in her neck and also over-interprets the age-appropriate changes in the shoulder. (*Id.* at 5-6.) According to Dr. Ring, the probability that petitioner's symptoms are from the identified, expected pathology is much higher than the speculation that the vaccine can injure the shoulder. (*Id.*)

Dr. Ring explains that rotator cuff tendinopathy (also known as impingement syndrome, bursitis, and other terms) "is the age-related change that occurs in the tendons that surround or 'cuff' the head of the humerus (the ball of the ball and socket shoulder joint)." (Ex. A, p. 6.) The rotator cuff of the tendons degenerates and thins with age, Dr. Ring explains, like the greying and thinning of the hair on a man's head. (*Id.*) The thinning can progress to a defect in the tendon, "like the bald spots many of us develop." (*Id.*) When there is a large, long-standing defect, Dr. Ring notes that the muscles are replaced by fat. (*Id.*) MRI and CT can detect this change of muscle to fat. (*Id.*) Dr. Ring observes that most people have some detectable changes in the tendon with age, starting around age 40. (Ex. A, p. 6 (citing T. Liu et al., *Patients Older Than 40 Years With Unilateral Occupational Claims for New Shoulder and Knee Symptoms Have Bilateral MRI Changes,* 475 CLIN. ORTHOP. RELAT. RES. 2360 (2017) (Ex. C).) Most of these changes, however, are asymptomatic. (Ex. A, p. 6 (citing K. Yamaguchi et al., *The Demographic and Morphological Features of Rotator Cuff Disease,* 88-A J. BONE & JOINT SURG. 1699 (2006) (Ex. D).) In contrast, "a less common way to get a

defect is by injury (usually a high-energy fall), where the tendon pulls off the bone." (Ex. A, p. 6.) Those tendon defects, Dr. Ring explains, are typically large (involving both the supraspinatus and the infraspinatus tendon) and there are no fatty changes in the muscle. (*Id.*) Dr. Ring stresses that most small defects are part of the aging process. (*Id.*) Diagnosis can be difficult, according to Dr. Ring, because surgeons and radiologists are in the habit of referring to all signal changes on MRI as "tears." (*Id.* at 6-7.) He explains that this is inaccurate because signal changes represent "increased water where it isn't usually found—changes that are rarely related to trauma." (*Id.* at 7.)

Ultimately, Dr. Ring opines that petitioner suffered symptoms of cervical radiculopathy and there is objective evidence supporting this diagnosis. (Ex. A, p. 7.) Likewise, he emphasizes that petitioner also has age-appropriate changes in the labrum and rotator cuff tendons. (*Id.*) According to Dr. Ring, petitioner has the expected and extremely common change in the neck and shoulder that come with age and nothing that can be uniquely ascribed to vaccine or vaccination. (*Id.*)

c. Dr. Schwartz's Supplemental Expert Report

In his supplemental expert report, Dr. Schwartz disagrees with Dr. Ring on the accuracy of MRI arthrograms. (Ex. 32, p. 1.) Rather, Dr. Schwartz stresses that an MRI arthrogram can be useful for diagnosing conditions ranging from capsulitis to bursitis. (*Id.* (citing J. Jung et al., *Adhesive capsulitis of the shoulder: evaluation with MR arthrography,* 16 EUR. RADIOL. 791 (2006) (Ex. 33).) Dr. Schwartz suggests that chemical bursitis is best diagnosed via a process of diagnosis of exclusion. (*Id.*) In petitioner's case, Dr. Schwartz first ruled out petitioner's cervical issue as well as any significant shoulder pathology "prior to being convinced that the reason for her pain (other than a temporal relation) was from her vaccine." (*Id.*) In the absence of an inciting event from any other study, and in the presence of petitioner's pain/dysfunction, he opines that petitioner's Tdap vaccination on February 2, 2015, caused petitioner's pain and shoulder dysfunction. (*Id.*)

V. Party Positions

a. Petitioner's contentions

Petitioner alleges that she suffered a vaccine-related shoulder injury (SIRVA) after receiving a Tdap vaccination administered in her left shoulder (a Table injury). (ECF No. 54, p. 1; ECF No. 7, p. 1.) Alternatively, petitioner asserts that reliable medical evidence supports a non-Table injury was caused-in-fact by her vaccination. (ECF No. 58, p. 16; ECF No. 57, ¶ 20.)

In support of her Table claim, petitioner stresses that her symptoms were limited to the left shoulder and that no other condition or abnormality would explain her symptoms. (*See* ECF No. 54, pp. 11-16.) Specifically, petitioner stresses that she suffered "two separate and distinct conditions – a shoulder injury and a C6 radiculopathy." (*Id.* at 11.) Petitioner does not dispute that "she had signs and

symptoms consistent with a cervical radiculopathy (paresthesias and weakness of the left upper extremity)." (*Id.*) However, petitioner asserts that cervical radiculopathy, caused by compression of a nerve root in the neck, does not cause impingement (pinching) of tissue in the shoulder and does not result in positive impingement testing of the shoulder. (*Id.* at 12.) Furthermore, petitioner stresses that her MRI was interpreted to show mild subacromial / subdeltoid bursitis, consistent with Dr. Schwartz's assessment. (*Id.*) To evaluate whether petitioner's pain was related to her shoulder or her cervical spine, Dr. Schwartz elected to treat petitioner with a steroid injection. (*Id.*) Though the steroid would not relieve all of petitioner's symptoms (namely, her cervical spine symptoms), petitioner emphasizes that if some of her symptoms were related to her shoulder, "then the steroid injection could be diagnostic." (*Id.*) After the steroid injection, petitioner showed improvement. (*Id.*) Petitioner's expert and treating orthopedic physician, Dr. Schwartz, concluded that "it is not surprising given that the previous CSI [corticosteroid injection] helped her shoulder pain but not her neck…[t]his implies that these issues are separate and distinct." (*Id.* at 13 (quoting Ex. 16, p. 3.))

In support of her causation-in-fact claim, petitioner asserts that she has satisfied all three *Althen* prongs. (*See* ECF No. 54, pp. 11-16; ECF No. 58, p. 16.) Related to prong one, petitioner stresses that respondent regularly concedes that intramuscular deltoid region vaccinations, including Tdap, can and do cause SIRVA. (ECF No. 54, p. 16.) Alternatively, petitioner relies on the medical literature cited by Dr. Schwartz—where in Atanasoff et al., hypothesized that "the rapid onset on pain with limited range of motion following vaccination…is consistent with a robust and prolonged immune response within already-sensitized shoulder structures following injection of antigenic substance into the subacromial bursa or the area around the rotator cuff tendon." (*See* Atanasoff et al., *supra,* Ex. 26, p. 3.)) Related to prong two, petitioner stresses that she had no prior history of injury to her left shoulder, arm, or hand, and presented to her primary care physician eighteen days post-vaccination with "pain [] since shot" and mild swelling. (ECF No. 54, p. 3 (citing Ex. 6, pp. 1-2).) Moreover, petitioner reported to PA-C Wilson that the "tetanus shot [was given] in left UE [upper extremity], high in deltoid." (ECF No. 54, p. 3 (citing Ex. 6, p 1).) Subsequently, petitioner's orthopedist Dr. Schwartz diagnosed petitioner with bursitis, which was later confirmed on MRI, in addition to mild subscapularis tendinosis. (ECF No. 54, pp. 11-12 (citing Ex. 12, pp. 3, 13).) Petitioner also suggests that other treating physicians recognized the temporal relationship between her symptoms and her Tdap vaccination. (ECF No. 54, p. 14.) At a follow-up visit for her colonoscopy, petitioner complained of pain post-vaccination. (*Id.* (citing Ex. 2, pp. 13-15.)) In that visit petitioner was diagnosed with "chronic pain syndrome left deltoid pain s/p injection tetanus." (*Id.*) Finally, related to the third prong, petitioner stresses that she developed symptoms consistent with a SIRVA injury beginning within forty-eight hours of her vaccination. (ECF No. 54, p. 19.) Moreover, Dr. Schwartz opines that the timing of petitioner's shoulder injury is consistent with what has been reported in the literature. (Ex. 17, p. 7.) SIRVA is expected to present as pain and/or limited range of motion with 48 hours of vaccination. (*Id.*) Dr. Schwartz notes that this medically accepted timeframe is also contained within the Vaccine Injury

Table's definition for a SIRVA injury. (*Id.*) Lastly, petitioner emphasizes that a cervical radiculopathy manifesting 8-months post-vaccination wholly fails to explain petitioner's shoulder-related symptoms, including her acute onset of pain at the time of her Tdap administration, her limited range of motion, and the objective findings on MRI. (ECF No. 58, pp. 10-13.)

b. Respondent's contentions

Respondent argues that petitioner is not entitled to compensation because she has not met the elements for an On-Table SIRVA, nor has she presented preponderant evidence showing that her injury was caused-in-fact by her Tdap vaccination. (ECF No. 55, pp. 9-17.)

Specifically, respondent stresses that petitioner's symptoms were caused by a factor unrelated to her vaccination and her pain was not limited to her left shoulder. (ECF No. 55, pp. 10-16.) Respondent contends that petitioner carries several diagnoses related to cervical region radiculopathy and degenerative disc disease which preclude the Table presumption of vaccine causation. (*Id.* at 10.) First, respondent "does not dispute the possibility of co-existing conditions," but rather, argues that petitioner's multiple co-existing conditions "*are* the more likely cause of her symptoms than the vaccination." (*Id.*) Petitioner's NCV and EMG testing revealed a C5-C6 radiculopathy and arthritis in her cervical spine. (*Id.* (citing Ex. 8, p. 16.)) As Dr. Ring opines, respondent stresses that the conditions revealed in that testing represent a long-standing pathophysiology that accounts for petitioner's symptoms. (ECF No. 55, p. 11, (citing Ex. A, p. 4.)) In addition to petitioner's cervical conditions, petitioner's MRI results showed mild labral changes and mild subscapularis tendinosis, which Dr. Ring opines are age-appropriate and unlikely to be related to vaccination. (ECF No. 55, p. 12.) According to Dr. Ring, "bursitis" and "impingement" are other words for "rotator cuff tendinopathy," which is also an age-appropriate condition, that is unrelated to vaccination, and would certainly explain petitioner's shoulder symptoms. (ECF No. 55, pp. 12-13.) Next, respondent stresses that petitioner has failed to show that her pain and reduced range of motion were limited to her left shoulder. (*Id.* at 14.) Petitioner's medical records show that she experienced numbness and pain radiating down her arm to her hand. (*Id.* (citing Ex. 7, p. 111.)) At a visit on February 23, 2016, petitioner also reported pain in her neck. (ECF No. 55, p. 14 (citing Ex. 8, pp. 1-2.) Respondent argues that petitioner's symptoms were never limited to the shoulder in which the vaccine was received, but rather always included symptoms outside of the shoulder. (ECF No. 55, p. 14.) Accordingly, petitioner is not entitled to a presumption of vaccine causation. (*Id.*)

Respondent further contends that petitioner has neither pled nor preponderantly proven causation-in-fact. (ECF No. 55, p. 14.) Under *Althen* prong one, respondent notes that Dr. Schwartz relies upon Atanasoff's over-penetration theory. (*Id.* at 16.) However, respondent stresses that petitioner did not have reduced range of motion post-vaccination—and in fact, petitioner had full range of motion at all medical visits until

July 2016, seventeen months post-vaccination. (*Id.*) At that time petitioner developed numbness and tingling. (*Id.*) This presentation of symptoms, respondent contends, is inconsistent with SIRVA and the literature cited by Dr. Schwartz. (*Id.*) Accordingly, if petitioner had pled a cause-in-fact claim, it would fail. (*Id.* at 16-17.) Respondent did not address prongs two or three, proof of a logical sequence of cause and effect and a proximate temporal relationship between vaccination and injury. (*See* ECF No. 55, pp. 14-19.)

c. Petitioner's reply

In response to respondent's contentions, petitioner stresses that her medical records do not suggest a nine-month gap in treatment. (ECF No. 58, pp. 2-3.) Between July 4, 2015, and December 3, 2015, petitioner presented to Northwest Acutonics and Jefferson Hospital, complaining of shoulder pain and numbness and tingling. (*Id.*) Furthermore, petitioner asserts that respondent's response omits several subjective and objective documentations of petitioner's reduced range of motion. (*Id.* at 4-6.) Over the course of her acutonics visits, petitioner demonstrated persistent painful and restricted range of motion. (*Id.* at 5 (citing Ex. 11, pp. 8-9, 15).) Petitioner later underwent a left shoulder MRI which showed mild subacromial/subdeltoid bursitis, mild subscapularis tendinosis, and a mild labral tear. (ECF No. 58, p. 9.) Petitioner maintains that cervical radiculopathy, however, "does not cause bursitis and tendinosis." (*Id.* at 12.) Therefore, cervical radiculopathy wholly fails to explain why petitioner, who has no prior history of shoulder dysfunction, suddenly developed decreased range of motion. (*Id.*) Crucially, petitioner stresses that petitioner's only degenerative injury was the partial labral tear, while Dr. Schwartz opined that the other findings on MRI were caused by chemical bursitis. (*Id.* at 14 (citing Ex. 12, p. 17).) In addition to her reply brief, petitioner filed a second amended petition, pleading an alternative causation-in-fact theory. (ECF No. 57.)

VI. Analysis

a. Petitioner's Table Injury claim

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 either tetanus toxoid or pertussis. § 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 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 raises no argument in either his Rule 4 report or his response to petitioner's motion for a ruling on the record that petitioner had a prior history of shoulder dysfunction, or that petitioner's injury arose outside of the 48-hour timeframe identified by the Vaccine Injury Table. (ECF Nos. 32, 55.) My own review of the record confirms these points. (Ex. 3; Ex. 4, pp 1-68; Ex. 5.) 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 shoulder pain was not limited to her left shoulder, and that she carries several diagnoses related to cervical region radiculopathy and degenerative disc disease which explain her symptoms. (ECF No. 55, pp. 10-14.)

With regard to the third SIRVA criterion, respondent stresses that petitioner experienced numbness and pain radiating down her left arm to her hand. (ECF No. 55, p. 14 (citing Ex. 7, p. 111).) By February 2016, petitioner also reported pain in her neck. (ECF No. 55, p. 14 (citing Ex. 8, pp. 1-2).) In response, petitioner "does not dispute that she had a concurrent, degenerative cervical condition at the time she experienced her vaccine-related injury." (ECF No. 54, p. 14.) Instead, she contends that her degenerative cervical condition does not preclude a vaccine-related shoulder injury. (*Id.* at 15.) However, "the gravamen of [the third criterion] is to guard against compensating claims involving patterns of pain or reduced range of motion indicative of a contributing etiology beyond the confines of a musculoskeletal injury to the affected shoulder." *Grossmann v. Secretary of Health & Human Services*, 18-13V, 2022 WL 779666, at *15 (Fed. Cl. Spec. Mstr. Feb. 15, 2022) (citing *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, petitioner voiced subjective complaints demonstrating that she experienced pain beyond the left shoulder. Petitioner frequently complained of numbness and tingling down her left arm and into her hand. (Ex. 11, p. 20; Ex. 4, p. 105, 143; Ex. 5, p. 125; Ex. 7, p. 2; Ex. 8, pp. 2, 5, 7, 10; Ex. 9, p. 1; Ex. 15, pp. 150, 162; Ex. 12, pp. 3, 16, 20.) In her July 28, 2015, evaluation at Northwest Acutonics she identified "intense pain at several points in left shoulder and left arm. Also pain/discomfort in surrounding areas." (Ex. 11, p. 10.) In fact, a neurologic etiology was initially suspected for petitioner's shoulder pain (axillary nerve damage) and a brachial plexopathy was also briefly questioned. (Ex. 6, p. 2; Ex. 7, p. 4.) Petitioner's medical records include multiple co-existing diagnoses that could cause these symptoms, including impingement, subacromial / subdeltoid bursitis, subscapularis tendinosis, *and cervical radiculopathy*. (Ex. 7, pp. 3-4; Ex. 12, p. 13.) In cases of cervical radiculopathy, the most common physical findings include numbness or sensory

changes, weakness, and abnormal deep tendon reflexes. (Onks & Billy, *supra,* at Ex. 20, p. 840.) C4-C5 radiculopathy in particular presents with neck, shoulder, and lateral arm pain; and C5-C6 radiculopathy presents with pain distribution in the neck, radial arm, and thumb. (*Id.*) Dr. Schwartz acknowledges that "multiple objective tests confirmed that this radiating pain with paresthesias was probably related to [p]etitioner's cervical disc disease including two EMG/NCS studies and a cervical spine MRI." (Ex. 17, p. 7.) However, Dr. Schwartz stresses that "the presence of symptomatic cervical disc disease in no way impacts whether [p]etitioner was also suffering a SIRVA at the time." (*Id.*) Be that as it may, given the language of the third SIRVA criterion, and the likelihood that petitioner's cervical radiculopathy presented as a co-existing etiology that likely caused numbness and tingling, and potentially pain beyond the confines of petitioner's musculoskeletal injury to her left shoulder, petitioner has not satisfied the third SIRVA QAI. Based on her medical records and the expert opinions, it does not appear that petitioner's clinical presentation can be definitively parsed between her various overlapping diagnoses such that petitioner can clearly demonstrate the third QAI criterion.

Relatedly, the fourth QAI SIRVA criterion requires that petitioner demonstrate that no other condition or abnormality is present that would explain her symptoms. Petitioner argues that neither her pre-existing degenerative shoulder conditions nor her degenerative spinal condition were the cause of petitioner's left shoulder pain. (ECF No. 54, pp. 1, 11-16.) In support, petitioner's expert stresses that prior to vaccination petitioner denied any prior injury or trauma to her left shoulder or upper arm. (Ex. 17, p. 7 (citing Ex. 7, p. 2).) Dr. Schwartz opines that petitioner's physical examination findings on 11/21/16 and 12/5/16 and the left shoulder MRI findings of subacromial / subdeltoid bursitis are consistent with a SIRVA injury; and the fact that petitioner's shoulder symptoms responded to a left shoulder corticosteroid injection, provides further evidence of a SIRVA injury. (*Id.*) The presence of symptomatic cervical disc disease "in no way impacts whether [p]etitioner was also suffering a SIRVA at the time." (*Id.*) Despite petitioner's contentions, the SIRVA QAI specifically identifies *evidence* of radiculopathy as a condition which precludes a Table SIRVA. 42 C.F.R. § 110.3(b)(10(iv) (petitioner must have "No other condition or abnormality that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy)"). Petitioner's January 26, 2016, EMG/NCS findings were interpreted to include a chronic or past cervical radicular injury, most likely at the C5 level. (Ex. 7, p. 4.) A repeat EMG/NCS on April 24, 2017, was interpreted to show acute and chronic left C6 radiculopathy. (Ex. 13, pp. 17-18.) As a result, Dr. Erlich assessed petitioner with left C6 radiculopathy, with a referral for neurosurgical evaluation. (*Id.* at 14.) The parties and their experts disagree as to whether onset of cervical radiculopathy was coincident to vaccination to later. (Ex. A, p. 4; Ex. 17, p. 8.) Yet, in light of these clinical findings and diagnoses, petitioner has not satisfied the fourth SIRVA QAI criterion. Therefore, petitioner cannot demonstrate that she has suffered a Table injury.

b. Petitioner's Cause-in-Fact Claim

i. Medical theory causally connecting the vaccination and the injury (*Althen* prong one)

The first *Althen* prong requires petitioner to present a persuasive medical theory of causation demonstrating that the Tdap vaccine could have caused her alleged shoulder injury. *Althen,* 418 F.3d at 1278. It is well-established in the Vaccine Program that compensation may be awarded for shoulder injuries on a cause-in-fact basis. *See, e.g.*, *A.P. v. Sec'y of Health & Human Servs.,* No. 17-784V, 2022 WL 275785 (Fed. Cl. Spec. Mstr. Jan. 31, 2022); *L.J. v. Sec'y of Health & Human Servs.,* No. 17-0059V, 2021 WL 6845593 (Fed. Cl. Spec. Mstr. Dec. 2, 2021); *Tenneson v. Sec'y of Health & Human Servs.*, No. 16-1664V, 2018 WL 3083140 (Fed. Cl. Spec. Mstr. Mar. 30, 2018) *rev. den.*, 142 Fed. Cl. 329 (2019). However, petitioner's medical theory must be supported by "reputable" scientific evidence and must "pertain[] specifically to the petitioner's case." *Moberly,* 592 F.3d at 1322.

In her motion, petitioner asserts that respondent "regularly concedes that intramuscular deltoid region vaccinations, including Tdap, can and do cause SIRVA." (ECF No. 54, p. 16.) Alternatively, petitioner relies on Dr. Schwartz's theory linking petitioner's Tdap vaccination to her chemical bursitis. (ECF No. 54, p. 16.) Namely, Dr. Schwartz relies upon literature wherein Atanasoff et al., hypothesized that "the rapid onset of pain with limited range of motion following vaccination…is consistent with a robust and prolonged immune response within already-sensitized shoulder structure…" (Ex. 17, p. 6.) Respondent does not contest that a petitioner can present a medical theory causally connecting a specific shoulder condition to vaccination under *Althen* prong one but contends that petitioner's own presentation is inconsistent with Atanasoff. (*See* ECF No. 55, pp. 14-17.)

The mechanism set forth in Atanasoff is "the unintentional injection of antigenic material into synovial tissues resulting in an immune-mediated inflammatory reaction." (Atanasoff et al., *supra,* at Ex. 26, p. 1.) This results in an inflammatory response which may be prolonged due to pre-existing antibody in the synovial tissue from an earlier, naturally occurring infection or vaccination. (*Id.* at 3.) Atanasoff et al. further observed that bursitis and greater fluid in the bursa were two of the findings often seen in MRI studies of vaccine injured shoulders. (*Id.* at 2.) The authors speculated that the patients they studied may have had prior conditions such as rotator cuff tears which only became symptomatic following the improper vaccine injection. (*Id.* at 3.) Notably, Atanasoff et al. distinguished vaccine-related shoulder injuries from conditions caused by a mechanical injury or overuse by "the rapid onset of pain with limited range of motion following vaccination." (*Id.*) The Institute of Medicine ("IOM")[10] subsequently reviewed scientific and medical literature finding evidence that convincingly supports a

[10] The Institute of Medicine (known as the National Academy of Medicine since 2015) is the medical arm of the National Academy of Sciences. The National Academy of Sciences ("NAS") was created by Congress in 1863 to be an advisor to the federal government on scientific and technical matters (*see* An Act to Incorporate the National Academy of Sciences, ch. 111, 12 Stat. 806 (1863)), and the Institute of Medicine is an offshoot of the NAS established in 1970 to provide advice concerning medical issues. When it enacted the Vaccine Act in 1986, Congress directed that the IOM conduct studies concerning potential causal relationships between vaccines and illnesses. *See* § 300aa–1.

causal relationship between vaccine injection into an arm and deltoid bursitis. (*See Injection-Related Adverse Events, supra,* at Ex. 28.) Arias et al., lent additional support for this proposed mechanism in a large systematic review, with a majority of cases reporting pain within 48 hours, and many reporting a high injection location. (Arias et al., *supra,* at Ex. 29.)

This medical literature comprises preponderant evidence supporting the conclusion that the Tdap vaccine, when administered intramuscularly but improperly injected in the synovial space, can cause an inflammatory response resulting in shoulder injury, especially bursitis.

ii. Logical sequence of cause and effect showing that the vaccination was the reason for the injury (*Althen* prong 2)

The second *Althen* prong requires proof of a logical sequence of cause and effect showing that the vaccine was the reason for the injury, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu ex rel. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1375–77 (Fed. Cir. 2009); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006); *Grant,* 956 F.2d at 1148. However, medical records and/or statements of a treating physician do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. *See* 42 U.S.C. §300aa-13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing ... that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted").

Prior to her February 2, 2015, vaccination petitioner had no prior history of pain or dysfunction in her upper left extremity or left shoulder. (*See generally,* Ex. 3; Ex. 4, pp. 1-68; Ex. 5.) Respondent raises no argument to the contrary in either his Rule 4 report or his response to petitioner's motion for a ruling on the record. (ECF Nos. 32; 55). My own review of the record confirms these points.

Petitioner's presentation to Aspen Medical Center on February 20, 2015, eighteen days post-vaccination, is strong evidence in support of a logical sequence of cause and effect showing that petitioner's shoulder injury was caused by her Tdap vaccination. Petitioner complained of left arm pain, dizziness, and a three-day cold.[11] (Ex. 6, p. 1.) Petitioner reported that she "had tetanus shot in left UE [upper extremity],

[11] The chief complaint portion includes a notation indicating "onset: 2 days ago." (Ex. 6, p. 1.) Petitioner in her sworn statement indicates that the reference regarding the onset of two days "refers to [her] cold symptoms and not to [her] shoulder pain, as [her] shoulder pain began immediately after my Tdap vaccination." (Ex. 1, p. 2.) When read in conjunction with the subjective portion of the report, it is clear that petitioner reported onset of her left arm pain "since [her] shot" which was "almost two weeks ago." (Ex. 6, p. 1.) Petitioner's later reports confirm that her left arm / shoulder pain began immediately after her Tdap vaccination. (Ex. 2, p. 13; Ex. 11, p. 11; Ex. 7, p. 2; Ex. 15, p. 38.)

high in deltoid" and "[f]elt like it may have hit a nerve." (*Id.*) She also reported some mild swelling in her left upper extremity, with no relief of the symptoms. (*Id.*) On examination, P.A. Wilson observed that petitioner had full range of motion in both upper extremities, with medial, ulnar, and radial nerves intact bilaterally, and deep tendon reflexes within a normal range. (*Id.* at 2.) He assessed petitioner with "traumatic injection [to] axillary nerve in left [upper extremity]." (*Id.*) Likewise, in her sworn statement petitioner states that the "vaccine was administered too high on [her] shoulder[.]" (Ex. 1, p. 1.) Over the course of forty-eight hours post-vaccination she describes significantly worsening pain in her shoulder. (*Id.*) After a couple weeks of "enduring persistent and ongoing pain" in her left shoulder, petitioner indicates that she sought medical intervention. (*Id.* at 2.)

Atanasoff et al., explain that the simple act of inserting a needle into the deltoid muscle would not be expected to cause an immune-mediated inflammatory response. (Atanasoff et al., *supra,* at Ex. 18.5, p. 3.) Even when an individual is vaccinated in the deltoid muscle with a previously administered vaccine, "any local injection site reaction caused by vaccine-antigen antibody interaction is expected to be relatively brief and resolve as the antigen is cleared from the soft tissues over a period of several days." (*Id.*) If, however, "a vaccine is injected into the synovial space of the shoulder (bursa or joint), pre-existing antibody in the synovial tissues…may lead to a more prolonged inflammatory response." (*Id.*) In "a great number of cases," Arias et al. found that "the vaccine had been administered into a 'very high site' in the arm, at a distance between 1 and 3 cm from the acromion." (Arias et al., *supra,* at Ex. 29, p. 5.) PA Wilson's note that the injection site was "in left UE high in deltoid" thus supports petitioner's theory that her Tdap vaccination was injected into the synovial space of the shoulder, superior to the deltoid muscle. (Ex. 6, p. 1.)

Respondent argues that petitioner did not have reduced range of motion in her left shoulder following vaccination, suggesting that petitioner has not preponderantly proven Atanasoff et al.'s theory that shoulder injuries related to vaccine administration present with "rapid onset of pain *with* limited range of motion following vaccination." (ECF No. 55, p. 16 (emphasis in respondent's brief).) Respondent stresses that petitioner demonstrated full range of motion in her first visit post-vaccination, on February 20, 2015, and at all medical visits until July 2016. (*Id.*) Specifically, respondent highlights full range of motion in petitioner's visits on January 26, 2016, and February 14, 2016—approximately one year post-vaccination. (ECF No. 55, p. 16 (citing Ex. 7, p. 3.; Ex. 15, p. 38.) Regarding the visit on January 26, 2016, on physical examination Dr. Carl observed that petitioner's "*cervical* ROM [range of motion] is WNL [within normal limits] for age" but "impingement testing[12] is positive at the left but not right shoulders." (Ex. 7, p. 3.) There is no indication that petitioner had full range of

[12] Impingement tests are "for rotator cuff tendinitis." *Impingement test,* DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=134132&searchterm=impingement%20test (last accessed May 11, 2022).

motion in her *shoulder* at this visit.[13] (*See id.*) Moreover, petitioner's Spurling's sign[14] was negative bilaterally at that time, further suggesting that her pain was not caused by cervical radiculopathy. (*See id.*) It is true that on February 14, 2016, petitioner was documented as having "good range of motion in all major joints."[15] (Ex. 15, p. 41.) However, petitioner demonstrated persistent painful and restricted range of motion over the course of her acutonics visits. (Ex. 11, pp. 8-9, 15.) In petitioner's initial evaluation on July 28, 2015, the therapist noted in the "initial objective findings:"

> Range of motion in the left shoulder is moderately [limited] in abduction (raising to the side) and severely limited in forward flexion (straight arm raise) and also in external rotation with significant pain the deltoid muscle.

(Ex. 11, p. 8.) Petitioner's range of motion measured forward flexion to 45 degrees / 180 degrees, abduction to 120 degrees / 150 degrees, and external rotation to 30 degrees / 90 degrees. (*Id.* at 15.) In the "progress summary," petitioner's therapist indicated that her "pain and restricted range of motion remains in the left shoulder and arm." (*Id.* at 9.) The fact that petitioner did not present, initially, with reduced range of motion does not preclude a finding of a logical sequence of cause and effect showing that petitioner's Tdap vaccination caused her shoulder injuries. Atanasoff et al.'s findings indicate that limited range of motion was present in eleven out of thirteen patients, or in 85% of cases. (Atanasoff et al., *supra,* at Ex. 26, p. 2.) The authors stress the following characteristics among the patients: none of the patients had a history of symptomatic shoulder problems prior to vaccination, all of the patients received a vaccine to which they had been previously exposed, all experienced rapid onset of shoulder pain following vaccination, all developed symptoms limited to the vaccinated shoulder, and all had symptoms and physical findings consistent with a local immune-mediated inflammatory musculoskeletal shoulder injury. (*Id.* at 3.) Petitioner meets all of these criteria, and her records indicate that she suffered rapid onset of pain, worsening over 48-hours following vaccination with subsequent limited range of motion. (Ex. 17, pp. 7-8.)

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[13] There is no presumption that medical records are complete. *Kirby v. Sec'y of Health & Human Servs*., 997 F.3d 1378, 1383 (Fed. Cir. 2021). Thus, for example, in *Kirby* respondent argued that a medical record documenting a neurologic exam that stated only "Neurological: Not Present – Dizziness" could not be taken in isolation as proof that petitioner had undergone a complete neurologic exam with no reproducible neurologic findings. *Id*. In this case, petitioner's January 26, 2016 physical exam was not recorded by separate body system (e.g. neurologic, musculoskeletal, etc). However, the appointment was in connect with a referral for electrodiagnostic testing and the physical exam description is clearly focused on potential neurologic symptoms. With regard to the shoulder the exam focuses on reflexes, strength, touch sensation, atrophy, fasciculations, and tone. The only exam finding that speaks directly to any orthopedic condition is the impingement testing, which was abnormal on the left. (Ex. 7, pp. 2-3.)

[14] Spurling tests are "(for cervical radiculopathy) [where] the examiner presses down on the top of the head while the patient rotates the head laterally and into hyperextension; pain radiating into the upper limb ipsilateral to a rotation position of the head indicates radiculopathy." *Spurling test,* DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=112983 (last accessed May 11, 2022).

[15] It should also be noted, however, that at this encounter petitioner requested and was given a sling for her arm. (Ex. 15, p. 41.)

Respondent's expert Dr. Ring also disputes the accuracy of Dr. Schwartz's diagnoses for her shoulder pathology. (Ex. A, pp. 3-5.) Dr. Ring's opinion is ultimately less persuasive for the following reasons. Dr. Ring preferentially cites Dr. Schwartz's record that used the diagnostic code for rotator cuff syndrome while ignoring that Dr. Schwartz's descriptive assessment specifically included chemical bursitis. (*Compare* Ex. A, p. 4 *with* Ex. 12, pp. 16-17.) Furthermore, Dr. Ring's opinion is premised on his assertion that rotator cuff tendinopathy is not readily distinguished from impingement syndrome, bursitis, or other terms; however, this is not consistent with the evidence of record or specifically supported by his own references.[16] (Ex. A, p. 6; *see* Liu et al., *supra,* at Ex. C; Yamaguchi et al., *supra,* at Ex. D; Yip et al., *supra,* at Ex. E.) Dr. Ring provides no support for his further contention that bursitis cannot be identified by MRI arthrogram, a point which Dr. Schwartz counters. (Ex. A, p. 4; Ex. 32.) In any event, as the treating physician, Dr. Schwartz's assessment of bursitis was not limited to interpreting petitioner's MRI. He also conducted a physical exam, and considered the course of her condition, including her response to treatment, most notably steroid injection. (Exs. 12, 16.) Given his in-person treatment of petitioner and first-hand observation of her shoulder, he is better positioned than Dr. Ring to make judgments as to the clinical significance of his own findings. *E.g*., *Capizzano*, 440 F.3d at 1326 ("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'"); *accord Lang v. Sec' of Health & Human Servs.,* 2020 WL 7873272 (Fed. Cl. Spec. Mstr. Dec. 11, 2020); *see contra Schmidt v. Sec'y of Health & Human Servs.,* 17-1530V, 2021 WL 5226494 (Fed. Cl. Spec. Mstr. Oct. 7, 2021)(Chief special master finding treating physician's affidavit was inconsistent with his own operative report showing no rotator cuff tear and MRI showing no bursal fluid). Dr. Schwartz's bursitis assessment and reliance on MRI arthrogram is further supported by the separate interpretation of the reviewing radiologist. (Ex. 12, p. 13.)

Although petitioner had an extended course of treatment before receiving an orthopedic diagnosis, the record indicates that petitioner presented with rapid onset left

[16] Atanasoff et al. also explain that "[i]n general, chronic shoulder pain with or without shoulder joint function can be caused by a number of common conditions including impingement, syndrome, rotator cuff tear, biceps tendonitis, osteoarthritis, and adhesive capsulitis." (Atanasoff et al., *supra,* at Ex. 26.) Impingement syndrome is an "overuse injury with progressive pathologic changes resulting from mechanical impingement by the acromion, coracoacromial ligament, coracoid process, or acromioclavicular joint against the rotator cuff[.]" *Impingement syndrome,* DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=110796 (last accessed May 16, 2022). Impingement syndrome may cause reversible edema and hemorrhage, fibrosis, tendinitis, pain, bone spur formation, and tendon rupture. (*Id.*) Bursitis is inflammation of the bursa, most commonly in the subdeltoid. *Bursitis,* DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=7315&searchterm=bursitis (last accessed May 16, 2022). Therefore, while impingement syndrome may implicate other underlying mechanical causes of shoulder pain, it does not suggest that these diagnoses are all indistinguishable. *Lang v. Sec' of Health & Human Servs.,* 2020 WL 7873272 (Fed. Cl. Spec. Mstr. Dec. 11, 2020) (citing literature showing impingement syndrome encompasses multiple etiologies).

shoulder pain and subsequent reduced range of motion post-vaccination, and was later diagnosed with impingement, bursitis, and tendinopathy. Therefore, I find that petitioner has satisfied her burden under *Althen* prong 2.

iii. Proximate temporal relationship between vaccination and injury (*Althen* prong 3)

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008).

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. 32, 55.) Nor does Respondent contest that the medically accepted timeframe for the onset of a shoulder injury caused-in-fact by vaccination is within 48 hours of vaccination. (*Id.*) My own review of petitioner's medical records confirms that her symptoms began within 48 hours of vaccination.

Dr. Schwartz opines that the timing of petitioner's shoulder injury is consistent with what has been reported in the literature. (Ex. 17, p. 7.) He notes that SIRVA is expected to present as pain and/or limited range of motion within the first 48 hours post-vaccination. (*Id.* (citing Bancsi et al., *supra,* at Ex. 19).) Accordingly, petitioner reported worsening pain over 48-hours following vaccination. (Ex. 17, pp. 7-8 (citing Ex. 1, ¶ 4.)) Petitioner also reported experiencing more discomfort post-vaccination that in prior vaccinations and noted that her vaccination was administered high on the shoulder. (Ex. 17, p. 7 (citing Ex. 1, ¶ 4.)) During her first visit eighteen days post-vaccination with PA-C Wilson, petitioner reported that her "pain [has been] since shot." (Ex. 17, pp. 7-8 (citing Ex. 6, p. 1.)) Similarly, petitioner presented to NP Gagnon on March 2, 2015, reporting "left arm pain since getting TD shot." (Ex. 2, pp. 13-15.)) These statements are consistent with petitioner's sworn statement. (Ex. 1.) Likewise, Dr. Schwartz found no evidence suggesting that petitioner's pain did not begin within 48-hours post-vaccination. (*Id.*)

Accordingly, petitioner has preponderantly demonstrated that the onset of her left shoulder symptoms occurred within a time frame for which, given the medical understanding of shoulder dysfunction, it is medically acceptable to infer causation-in-fact.

iv. Factors Unrelated

Once a petitioner has established their *prima facie* case, the burden then shifts to respondent to prove, also by preponderant evidence, that the alleged injury was caused by a factor unrelated to vaccination. *Althen,* 418 F.3d at 1278 (citations omitted); §300aa-13 (a)(1)(B). In this case, respondent "does not dispute the possibility of co-existing conditions" in petitioner's case, however, "respondent's position is that petitioner's multiple co-existing cervical conditions *are* the more likely cause of her symptoms than the vaccination. (ECF No. 55, p. 10.)

As respondent indicates, in January and February of 2016, petitioner had neuro-diagnostic testing in the form of NCV and EMG studies, as well as a cervical spine MRI. (Ex. 7, p. 4; Ex. 8, pp. 16-17.) That testing revealed a C5-C6 radiculopathy and arthritis in petitioner's cervical spine. (Ex. 8, p. 16.) Dr. Ring opines that these findings represent a clear, long-standing pathophysiology that accounts for many of petitioner's symptoms. (Ex. A, pp. 3-4.) According to Dr. Carl's interpretation of petitioner's January 2016 testing, with respect to the timing of petitioner's peripheral nerve injury, she opined "I can state only that it began or occurred at least 3 months ago." (Ex. 7, p. 4.) Dr. Carl's opinion also corroborates petitioner's description of her onset of numbness and tingling. Petitioner declares, and her medical records demonstrate, that her numbness and tingling began in November 2015. (Ex. 1, p. 3 ("on November 5, 2015, I began to experience a sudden and acute onset of numbness and tingling in my left arm which I had never before experienced); Ex. 11, p. 20 ("new history" indicates "pines & needles and numbness in various points and down L arm into hand").) Therefore, Dr. Ring's statement that the cervical findings were a clear, *long-standing* pathophysiology is not clearly supported. As Dr. Schwartz explains, "simply identifying degenerative conditions on a radiological study is an insufficient and ineffective method of diagnosing a patient with upper extremity dysfunction." (Ex. 17, p. 4.) Clinical correlation, Dr. Schwartz stresses, is imperative to developing a proper diagnosis.[17]

Next, respondent argues that petitioner's treating physicians, apart from Dr. Schwartz, agree that her symptoms were caused by her cervical condition(s). (ECF No. 55, p. 11.) Respondent relies on the records from petitioner's neurologist Dr. Erlich and her first orthopedist Dr. Osland. Petitioner presented to Dr. Erlich on February 22, 2017, and again on April 25, 2017. (Ex. 13.) Based on petitioner's symptoms and history, his examination of petitioner, and the results of her EMG and MRI, Dr. Erlich assessed petitioner with a "left C6 radiculopathy" and referred petitioner to a neurosurgeon. (*Id.* at 14.) Respondent stresses that "Dr. Erlich *did not* opine that the vaccine was the cause of any of her symptoms." (ECF No. 55, p. 11 (emphasis in original).) It is true, Dr. Erlich did not positively attribute the cause of petitioner's symptoms or radiculopathy to the vaccine. (Ex. 13, p. 14.) Dr. Erlich did not offer any opinion on the cause of petitioner's onset of symptoms beyond diagnosing petitioner with cervical radiculopathy. (*See id.*) Next, respondent highlights petitioner's visit with

[17] A key point here is the distinction between the mere "evidence" of cervical radiculopathy that is enough to deprive petitioner of a causal presumption under the specific language of the SIRVA QAI and respondent's own preponderant burden of proof under a factor unrelated analysis to demonstrate that the cervical radiculopathy wholly explains petitioner's presentation to the exclusion of any vaccine-related injury.

Dr. Osland on August 26, 2016. (Ex. 15, p. 148.) In that visit Dr. Osland noted that he was "not sure or why [petitioner] has on and off numbness and tingling in different nerve distributions in her upper extremity. It fits more with her cervical problem." (*Id.*) He concluded, "I'm not sure the injection caused all this in fact they [*sic*] does not fit with anatomic distributions w[h]ere she got injection and lateral aspect of her arm." (*Id.*) Notably, however, petitioner did not undergo an MRI on her left shoulder until after this visit with Dr. Osland. Dr. Schwartz ordered an MRI on petitioner's shoulder on November 14, 2016. (Ex. 12, pp. 4, 10-13.) The radiologist's findings on MRI were mild subacromial / subdeltoid bursitis, partial tearing of the superior labrum, and mild subscapularis tendinosis. (*Id.* at 13.) Thus, Dr. Osland's opinion that preceded petitioner's left shoulder MRI and subsequent left shoulder diagnoses is less persuasive. The opinions of Drs. Erlich and Osland are both skeptical and equivocal at best. In the vaccine program, equivocal testimony alone cannot establish causation. *Paterek v. Sec'y of Health & Human Servs.*, 527 F. App'x 875, 883 (Fed. Cir. 2013) (citing *Andreu,* 569 F.3d 1375-76). Most importantly, respondent's own expert expressly contradicts respondent's theory that her symptoms were entirely caused by her cervical condition. (ECF No. 55, p. 11.) Dr. Ring opines that the primary symptoms of radiculopathy, numbness, came on 8 months after the vaccination and "[t]he symptoms from the radiculopathy are likely a completely separate process from the shoulder soreness…." (Ex. A, p. 4.) Therefore neither Dr. Erlich or Dr. Osland, nor Dr. Ring, preponderantly prove that petitioner's shoulder pain and dysfunction were more likely than not caused by her co-existing cervical radiculopathy.

Lastly, respondent argues that petitioner's shoulder pain and reduced range of motion were caused by normal, age-related changes. (ECF No. 55, p. 12.) As mentioned above, Dr. Ring opines that petitioner's MRI results demonstrate mild labral changes and mild subscapularis tendinosis which are "age appropriate and unlikely to be related to vaccination." (Ex. A, p. 4 (citing Ex. 12, pp. 12-13.) It is true that Dr. Schwartz opined that petitioner's MRI showed "signs of bursitis, probable pre-existing labral tear – d/w [discussed with] her how common labral tears are in the general population especially with age above 40, likely observe for now[.]" (Ex. 12, p. 17.) Despite petitioner's probable pre-existing labral tear, Dr. Schwartz stresses that petitioner suffered from "chemical bursitis," more likely than not caused by her Tdap vaccination. (Ex. 12, pp. 3, 12, 17, 21; Ex. 17, pp. 7-8.) Dr. Schwartz stresses that prior to her Tdap vaccination on February 2, 2015, petitioner had no prior history of injury or trauma to her left shoulder or upper arm. (*See generally,* Ex. 3; Ex. 4, pp. 1-68; Ex. 5; Ex. 7, p. 2.) The Atanasoff study, as discussed above, purported to link vaccination and injury on the basis that the lack of prior shoulder symptoms, along with the rapid onset of post-vaccination pain, allowed for the suspicion of an immune-mediate inflammatory state that provoked the symptoms. (Atanasoff et al., *supra,* at Ex. 26, p. 3.) Meanwhile, the authors explained 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 findings 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.

(*Id.* (emphasis added).) When arguing that a factor unrelated actually caused the injury alleged, the factor unrelated must be the "sole substantial factor" that caused the injury. *de Bazan,* 539 F.3d at 1354. In that regard, the possibility that some of petitioner's MRI findings could be pre-existing does not wholly distinguish petitioner's case from Atanasoff's theory, which included patients who presented with MRI findings that may have been present prior to vaccination and "became symptomatic as a result of vaccination association synovial inflammation." (Atanasoff et al., *supra,* at Ex. 26, p. 3.) Moreover, the SIRVA medical literature as a whole found significance in the presence of bursitis among subjects. (*Id.*; Arias et al., *supra,* at Ex. 29; Bodor & Montalvo, *supra,* at Ex. 25; Salmon et al., *supra,* at Ex. 31.) Additionally, to the extent Dr. Ring challenged Dr. Schwartz regarding the correct diagnosis for petitioner's shoulder pathology, I find Dr. Schwartz more persuasive for the reasons discussed above.

Therefore, I find that petitioner's cervical spine injury is a separate condition from her left shoulder injury associated with the Tdap vaccination, that it does not explain the entirety of her presentation, and that petitioner's left shoulder symptoms are not otherwise wholly explained by degenerative changes. Accordingly, respondent has not met his preponderant burden of proof with respect to demonstration petitioner's injury was caused by a factor unrelated to vaccination.

VII. 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 impingement, subacromial / subdeltoid bursitis, and subscapularis tendinosis caused-in-fact by her February 2, 2015, Tdap vaccination. A separate damages order will be issued.

IT IS SO ORDERED.

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