In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 19-1525V
Filed: August 26, 2025

ELIZABETH LUCAS,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Master Horner

Courtney Christine Jorgenson, Siri & Glimstad, LLP, Phoenix, AZ, for petitioner.
Rachelle Bishop, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT[1]

On October 2, 2019, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa, *et seq.* (2012) ("Vaccine Act"),[2] alleging that she suffered a right shoulder injury as a result of a tetanus-diphtheria-acellular pertussis ("Tdap") vaccination she received on July 11, 2018. (ECF No. 1.) For the reasons set forth below, I conclude that petitioner is entitled to compensation.

I. Applicable Statutory Scheme

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute;

[1] Because this document contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the document will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

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

AUTHENTICATED U.S. GOVERNMENT INFORMATION GPO

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

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

> SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis . . . A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time-frame;
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

(iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, and any other neuropathy).

42 C.F.R. § 100.3(c)(10).

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

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

The Vaccine Act also permits petitioners to recover damages for any vaccine-caused "significant aggravation" of a pre-existing condition. The act defines significant aggravation as "any change for the worse in a pre-existing condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." § 300aa-33(4). Where a petitioner in an off-Table case is seeking to prove that a vaccination aggravated a pre-existing injury, petitioners must establish three additional factors. *See Loving v. Sec'y of Health & Human Servs.*, 86 Fed. Cl. 135, 144 (Fed. Cl. 2009) (combining the first three *Whitecotton* factors for claims regarding aggravation of a Table injury with the three *Althen* factors for off table injury claims to create a six-part test for off-Table aggravation claims); *see also W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1357 (Fed. Cir. 2013) (applying the six-part *Loving*

test.). The additional *Loving* factors require petitioners to demonstrate aggravation by showing: (1) the vaccinee's condition prior to the administration of the vaccine, (2) the vaccinee's current condition, and (3) whether the vaccinee's current condition constitutes a "significant aggravation" of the condition prior to the vaccination. *Id*.

Cases in the Vaccine Program are assigned to special masters who are responsible for "conducting all proceedings, including taking such evidence as may be appropriate, making the requisite findings of fact and conclusions of law, preparing a decision, and determining the amount of compensation, if any, to be awarded." Vaccine Rule 3(b)(1). Special masters must ensure each party has had a "full and fair opportunity" to develop the record. Vaccine Rule 3(b)(2). However, special masters are empowered to determine the format for taking evidence based on the circumstances of each case. Vaccine Rule 8(a); Vaccine Rule 8(d). Special masters are not bound by common law or statutory rules of evidence but must consider all relevant and reliable evidence in keeping with fundamental fairness to both parties. Vaccine Rule 8(b)(1). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." § 300aa-13(b)(1)(A). The special master is required to consider all the relevant evidence of record, draw plausible inferences, and articulate a rational basis for the decision. *Winkler v. Sec'y of Health & Human Servs.*, 88 F.4th 958, 963 (Fed. Cir. 2023) (citing *Hines ex rel. Sevier v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991)).

II. Procedural History

The case was initially assigned to the Special Processing Unit ("SPU") based on the allegations of the petition (ECF Nos. 17-18). Petitioner filed an affidavit and medical records marked as Exhibits 1-12 and then filed her initial Statement of Completion on March of 2020. However, she later filed additional records marked as Exhibits 13-16, including records related to a workers' compensation claim, between June of 2020 and January of 2023. Respondent filed his Rule 4 Report in August of 2021, recommending against compensation. (ECF No. 29.) The case was reassigned to the undersigned in June of 2023 once it was determined the parties would not resolve the case via settlement. (ECF Nos. 45-46.)

Petitioner filed an expert report by orthopedic surgeon Jerome G. Piontek, M.D., in August of 2023. (ECF Nos. 49-50; Exs. 17-23.) Respondent then filed an expert report by orthopedic surgeon Geoffrey Abrams, M.D., in December of 2023. (ECF Nos. 53, 59; Exs. A-B.) The parties also exchanged expert rebuttals. (ECF Nos. 56-57, 60; Exs. 24-28, C.) Thereafter, petitioner requested an entitlement hearing. However, after considering petitioner's arguments in favor of a hearing, I concluded that it is appropriate to resolve entitlement based on the written record pursuant to Vaccine Rule 8(d). (ECF Nos. 61-63; Order (Non-PDF), 6/13/2024.) However, I advised that, "[i]f

upon review of the parties' motion practice I determine that issues have been raised that warrant an entitlement hearing, I will then set an entitlement hearing and the parties' motion papers will constitute prehearing briefs."

Petitioner filed a motion for a ruling on the written record on August 12, 2024. (ECF No. 64.) Respondent filed his response on September 30, 2024, and petitioner filed her reply on October 15, 2024. (ECF Nos. 66-67). Based on all of the above, and following review of the parties' briefing, I have determined that the parties have had a full and fair opportunity to present their cases and that it is appropriate to resolve entitlement on the existing record. *See* Vaccine Rule 8(d); Vaccine Rule 3(b)(2); *see also Kreizenbeck v. Sec'y of Health & Human Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020) (noting that "special masters must determine that the record is comprehensive and fully developed before ruling on the record").

III. Factual History

a. Pre-vaccination

Petitioner presented to a physician's assistant at Webster Orthopedics for right shoulder pain on August 11, 2015. (Ex. 3, p. 33.) She reported a prior history of a grade 2 acromioclavicular ("AC") joint separation occurring five years prior. (*Id.*) In a deposition taken as part of a workers' compensation claim, petitioner explained that she suffered that injury playing softball when she dove for a high ball. (Ex. 14, p. 2322.) Regarding her prior injury, petitioner explained that she was treated with conservative measures only (a sling and anti-inflammatory medication) and that she "had no sustained pain over the last 5 years."[3] (Ex. 3, p. 33.) However, as of her August 2015 encounter, she reported progressively worsening pain over the course of several months. (*Id.*) She noted having difficulty with reaching overhead and sleeping at night. (*Id*.) Petitioner described her new onset of shoulder pain as "different" and "deeper within the shoulder" as compared to her prior shoulder pain, but she did not identify any specific accident or trauma as a trigger for the pain. (*Id.*) Although she did not identify any specific accident or trauma as a trigger for the pain during her August 11, 2015 encounter (*Id.*), in her workers' compensation deposition, petitioner explained that she attributed her pain to carrying heavy boxes (Ex. 14, p. 2326). She indicated that on August 3, 2015, she started feeling neck pain, like a neck strain, while she was out inspecting poles, but that she attributed it to carrying heavy boxes a few days prior. (*Id.* at 2326, 2331.) After that, she indicated that "over the next month, it progressed from my neck to my chest, down my whole right side, upper extremity." (*Id*. at 2327.) This incident formed the initial basis for the workers' compensation claim.

As of her August 11, 2015 physical exam, petitioner's range of motion included 165 degrees flexion, 160 degrees abduction, 80 degrees of external rotation, and internal rotation to T10. (Ex. 3, p. 33.) She had positive impingement signs and pain

[3] Although petitioner's 2009-2015 records are not available in the evidentiary record of this case, they were apparently reviewed as part of petitioner's workers' compensation claim. (Ex. 14, pp. 694-705.) I have reviewed the description of those records, but do not find them necessary to resolution of this case.

with O'Brien testing. (*Id*.) Tenderness at the AC joint and bicipital groove was also noted. (*Id.*) An x-ray showed a "superior displacement of the clavicle in regard to the acromion." (*Id*. at 32.) She was diagnosed with "right shoulder pain" with a "prior grade 2 AC separation." (*Id*. at 33.) About ten days later, on August 21, 2015, petitioner followed up with a different orthopedic practice. (Ex. 2, p. 9.) She reported being in worse pain. (*Id*.) An MRI of the right shoulder showed "a moderate rotator cuff tenodesis with a small 4mm x 4mm bursal surface partial tear of the supraspinatus tendon" with no other significant findings. (*Id*.) An MRI of the cervical spine showed "mild annular bulge at C3-C4 with no central canal stenosis or impingement on exiting nerve roots." (*Id*.) She was diagnosed with a cervical strain and a thoracic strain. (*Id*.) Given the finding on the shoulder MRI, petitioner received a subacromial cortisone injection. (*Id*.) However, given the cervical/thoracic diagnoses, she was also referred for further evaluation of those conditions. (*Id.*)

Petitioner presented for her annual physical exam on November 5, 2016. (Ex. 5, p. 20.) Cervical radiculopathy was listed among her active problems (*Id*.); however, petitioner did not seek further treatment or examination of her neck and shoulder complaints until February 23, 2017, when she presented to chiropractor and Qualified Medical Examiner ("QME") Manuel M. Fonseca, D.C., relative to her workers' compensation claim. (Ex. 14, pp. 693-740.) Petitioner reported that her cortisone injection had not helped and that she had not pursued recommendations for physical therapy and for evaluation by a physiatrist, though she did pursue regular massage therapy, acupuncture, and chiropractic treatment beginning in September of 2015. (*Id*. at 706.) Her chiropractor took her off of work for about two months. (*Id*.) She did not seek treatment after returning to work in November of 2015 and reported that her symptoms "gradually got better" even without continued treatment. (*Id*. at 707.)

However, as of her February 23, 2017 evaluation, petitioner reported constant, dull pain rated at 3 out of 10 on a pain scale, worsened with repetitive activity and overhead lifting, affecting her "neck, right shoulder, arm, and forearm" and associated with numbness in her right hand. (Ex. 14, p. 709.) She described her pain as radiating from the neck to her right breast, axilla, scapula, arm, and posterolateral forearm. (*Id*.) On physical exam, petitioner demonstrated mild to moderate pain with cervical flexion, extension, lateral flexion, and rotation as well as right shoulder external rotation, which also increased her neck pain. (*Id*. at 728, 730.) Petitioner's right shoulder range of motion was measured at 165 degrees flexion, 40 degrees extension, 85 degrees external rotation, and 55 degrees internal rotation. (*Id.* at 732.) She had no signs of shoulder impingement. (*Id*. at 733.) Petitioner was assessed as having the following condlitions: myofascial pain syndrome, chronic cervical strain, right-side thoracic outlet syndrome, bicipital tendinitis, elbow lateral epicondyle, and right-hand numbness/tingling. (*Id*. at 737.) However, either ulnar neuropathy at the elbow or cervical radiculopathy still needed to be ruled out. (*Id.*) MRI of the cervical spine, right shoulder, and right thoracic outlet, as well as EMG/NCS studies, were recommended. (*Id*. at 738, 2377.) Dr. Fonseca opined that there was "a causal relationship between the occupational injury that occurred on 08/03/2015 and her current condition," but

deferred on apportionment as between her neck, shoulder, and extremity complaints, until she reached maximum medical improvement. (*Id.* at 2376-77.)

On March 16, 2017, petitioner underwent a cervical spine MRI. (Ex. 14, p. 1733.) It showed mild to moderate foraminal stenosis at C3-C4, C4-C5, C5-C6, and C6-C7 with "probability of irritation of exiting nerve roots" over C3-C4, C4-C5, and C6-C7, as well as "probability of impingement of the exiting left nerve root" at C5-C6. (*Id.* at 1734.) An EMG conducted two days later was normal. (*Id.* at 1755.) A right shoulder MRI of March 21, 2017, showed mild acromioclavicular joint arthrosis and diffuse supraspinatus-infraspinatus tendinosis. (Ex. 3, pp. 48-49.) Additionally, it was noted that there was "a moderate-sized full-thickness bursal sided tear of the supraspinatus tendon footprint anteriorly and a small linear interstitial tear of the tendon more posterior." (*Id.* at 49.)

Petitioner presented to Eduardo Lin, M.D., on April 20, 2017, for an initial pain management evaluation in connection with her workplace injury. (Ex. 14, p. 1745.) Physical examination revealed reduced range of motion in her shoulder, and positive Tinel's Sign test in her right elbow. (*Id.* at 1747.) Petitioner was diagnosed with myofascial pain syndrome, right shoulder rotator cuff injury, right elbow lateral epicondylitis, right cubital tunnel syndromes, right shoulder and elbow sprain/strain, and cervical disc displacement, pain, and sprain/strain. (*Id.*) An EMG of the upper extremity was ordered, and physical therapy was recommended. (*Id.*) Petitioner was evaluated for physical therapy on May 31, 2017. (*Id.* at 900.) She reported her pain as 8 out of 10 in her right shoulder, and she had reduced range of motion in several planes: active forward flexion was 150 degrees and abduction was 145 degrees, and her passive forward flexion was 165 degrees and abduction was 160 degrees. (*Id*.) Her functional impairment included difficulty with overhead activities, lifting, pushing, pulling, and carrying, and she had tenderness "all around" her right shoulder. (*Id*.) Petitioner was reluctant to try physical therapy because she stated that any movement in her right shoulder increased her pain. (*Id*.)

On June 21, 2017, petitioner presented to orthopedist (QME) Donald Pang, M.D., in connection with her workers' compensation claim. (Ex. 14, pp 902-03.) She reported "pain with diffuse trigger points from the right scapular region to the entire right shoulder, forearm, and wrist region" that was at times associated with tingling and numbness in her fingers. (*Id.* at 903.) On examination, petitioner exhibited full passive range of motion but reduced active range of motion: her abduction was 150 degrees, flexion was 150 degrees, internal rotation was 50 degrees, and external rotation was 50 degrees. (*Id.*) Petitioner was assessed with diffuse myofascial pain, cervical spine degenerative disc changes, thoracic spine degenerative disc bulging, and right shoulder rotator cuff tear with full thickness bursal sided rotator cuff tear. (*Id.* at 904.) It was noted that structured therapy had led to flare ups in the past and that prior steroid injections had not alleviated her symptoms. (*Id.*) Because petitioner "was still functioning at a fairly high level and living with her discomfort," Dr. Pang recommended "observation only" with the option for "more aggressive treatment" if her symptoms progress. (*Id.*) During an October 19, 2017 follow up appointment, Dr. Pang assessed

rotator cuff tear and C3-C4, C4-C5, and C6-C7 foraminal stenosis. (*Id.* at 907-08.) He recommended physical therapy and cervical traction. (*Id.*)

Petitioner had an initial physical therapy evaluation on January 23, 2018. (Ex. 14, p. 911.) She reported a three-year history of neck pain that radiated down her right arm to her fingers and was associated with numbness and tingling. (*Id.*) After four physical therapy sessions with mechanical traction, petitioner reported no improvement in her symptoms. (Ex. 4, pp. 5-6.) Dr. Pang agreed to discontinue cervical traction on February 8, 2018. (Ex. 14, p. 918.) He suggested that a multiple level cervical fusion could be necessary if her symptoms continue to progress. (Id.)

Petitioner testified that she was in an automobile accident in April of 2018 that aggravated her prior injuries to her neck, upper back, and both shoulders. (Ex. 14, p. 2324; *see also id.* at 924 (encounter with Dr. Pang).) She indicated that she treated those injuries for about three months, until about July of 2018. (*Id*. at 2325.) Prior to the accident, she was experiencing pain that she rated 8 out of 10. The accident exacerbated her pain to a 10 out of 10, but then it returned to the baseline of 8 out of 10. (*Id*. at 2331.) In particular, she saw Dr. Pang on June 12, 2018, about one month prior to the vaccination at issue. (Ex. 14, p. 926.) Petitioner had been receiving chiropractic treatment for her cervical spine, and reported tenderness over the right shoulder. (*Id.*) Dr. Pang noted that her symptoms were "in the same distribution" as before the automobile accident. (*Id.*) Dr. Pang opined, "I am now declaring her permanent and stationary and I have recommended a provision for her to seek out medical attention for flare-ups." (*Id.*)

On July 11, 2018, petitioner received the Tdap vaccination at issue in her right deltoid following a cat bite. (Ex. 1, p. 2; Ex. 6, p. 3.)

b. Post-vaccination

Petitioner presented to orthopedist Nic Gay, M.D., on July 20, 2018, with a complaint of right shoulder pain. (Ex. 2, p. 11.) In connection with this encounter, petitioner filled out a "new condition form" by hand. In it, she was prompted to identify the date of her injury. She wrote "7/11/18." (*Id.* at 13.) She described her symptoms as consisting of "extreme pain in arm w/ movement and without" and indicated that she had no prior treatment for her condition. (*Id*.) She was also prompted to identify "when and what were the first symptoms." She wrote "7/11/18 – tetanus shot." (*Id*.) However, Dr. Gay recorded the following history as part of his medical record:

> The patient is a 52 year old female with a multiple month history of insidious onset of right shoulder pain. The patient notes pain that is dull, intermittently sharp pain localizing to the posterolateral aspect of the shoulder of insidious onset, exacerbated by overhead activity and lifting and partially relieved by rest. This limits the patient's daily functional activity and they present today for subspeciality evaluation and treatment options.

(*Id*. at 11.)

On physical exam, petitioner had external rotation of 45 degrees and internal rotation to T7. (Ex. 2, p. 11.) Her forward flexion was 130 degrees, and her abduction was 130 degrees. (*Id.*) She had positive Neer's, Hawkin's, and Empty can tests but a negative Spurling's test. (*Id.* at 11-12.) She was diagnosed with "right shoulder pain consistent with external impingement, possible rotator cuff tendinopathy versus tear." (*Id.* at 12.) Dr. Gay provided a recommendation as follows:

> Given that the patient has not had significant relief from conservative measures over a protracted period of time and still has pain on a daily basis limiting their functional ability an MRI of the right shoulder is medically indicated in order to rule out significant pathology which is causing proacted [sic] and refractory pain.

(*Id*.)

Petitioner had a right shoulder MRI the same day. (Ex. 2, pp. 22-23.) It was compared to her prior study of August 17, 2015. (*Id*. at 22.) The impression was as follows:

1. Partial-thickness bursal surface tear of the anterior supraspinatus tendon centered at the greater tuberosity and superimposed upon moderate tendinosis. This has slightly progressed. No muscle atrophy.
2. Mild infraspinatus tendinosis; no tear. This is similar to previous exam.
3. Amorphous edema with the teres minor muscle could represent strain or denervation change. The axillary nerve and quadrilateral space are normal. This is new from prior exam.
4. Fraying of a diminutive glenoid labrum; no tear. The glenohumeral joint cartilage and capsule are normal. There is physiologic joint fluid. These findings are similar to previous exam.
5. Mild acromioclavicular joint osteoarthritis. This is similar to previous exam.
6. Mild subacromial subdeltoid bursitis.

(*Id*. at 23.)

Three days later, petitioner presented to orthopedist Hany Elrashidy, M.D. (Ex. 3, p. 26.) Her chief complaint was right shoulder pain, and she provided the following history:

> The symptoms began on 7/11/2018 after a tetanus shot. She was previously diagnosed with grade 2 AC joint separation of the right shoulder rotator cuff 10 years ago. Today, the patient reports worsening constant sharp and aching 10/10 right shoulder pain. Associated symptoms include

> joint locking, loss of motion and popping. Of note, she denies neck pain, numbness, tingling, previous physical therapy and previous injections. Her symptoms are exacerbated by any movement, overhead activities and lifting, and treatments thus far include current shoulder sling use, tramadol and Percocet.

(*Id*.)

On physical exam, petitioner and significant tenderness over the proximal bicipital groove. (Ex. 3, p. 26.) Her active range of motion was "170 with pain/160/50/T10" and her passive range of motion was "170/170/60." (*Id.*) The following tests were positive: O'Brien's, Yergason's, Hawkin's, and Neer's.[4] (*Id.* at 27.) Dr. Elrashidy also reviewed petitioner's MRIs from July 20, 2018 and March 21, 2017, as well as her x-rays from August 11, 2015. (*Id*.) Petitioner was diagnosed with a partial thickness rotator cuff tear, SLAP tear with biceps instability, subacromial impingement, and AC joint osteoarthritis. (*Id*.) She received a cortisone injection and was advised to continue Tramadol and start Mobic. (*Id*. at 28.) Physical therapy and a repeat MRI were recommended. (*Id.*)

On August 1, 2018, petitioner returned to Dr. Pang, who she had last seen about one month prior to the vaccination at issue. (Ex. 14, p. 928.) During this encounter, petitioner noted that her pain was most notable in her head and neck. (*Id.*) A physical examination showed extension at 30 degrees, flexion at 140 degrees, and internal and external rotation at 80 degrees. (*Id.*) Dr. Pang assessed petitioner as being "maximally medically improved," though she remained "permanent and stationary." (*Id.* at 929.)

Dr. Pang performed a QME report in connection with petitioner's workplace injury on August 20, 2018. (Ex. 14, p. 903, 932.) Petitioner reported pain that radiated into her shoulder girdle and paracervical musculature, as well as weakness in her right shoulder. (*Id.* at 932.) She stated that her pain was "moderate at the moment and fairly severe most of the time." (*Id.*) She decreased active range of motion in her shoulder: extension was "40/42/40 degrees," abduction was "140/138/140 degrees," flexion was "138/140/141 degrees," internal rotation was "80/78/79 degrees," external rotation was "75/79/78 degrees," and adduction was "50/49/50 degrees." (*Id.* at 933.) She also had positive signs of impingement in the right shoulder. (*Id.*) She was diagnosed, in pertinent part, with right shoulder rotator cuff tear and assessed with a 6% upper extremity impairment that translated to a 4% whole person impairment. (*Id.*) For her ongoing right shoulder pain, Dr. Pang assessed a 2% whole person impairment. (*Id.* at 934.) Dr. Pang concluded that petitioner's cervical spine and shoulder symptoms were likely unrelated to the automobile accident. (*Id.*) Notably, Dr. Pang's report did not mention petitioner's vaccination.

[4] The record includes conflicting notations with respect to whether a Speed's test was positive or negative. (Ex. 3, p. 27.)

Petitioner underwent an MRI of the right shoulder on August 29, 2018. (Ex. 3, p. 45.) The study's results showed "moderate grade partial thickness bursal surface rim rent type tear through the leading edge of the supraspinatus extending into the distal superior subscapular tendon fibers, superimposed upon tendinosis," but no full thickness tear; "low-grade undersurface tearing of the distal infraspinatus superimposed on mild tendinosis"; and "moderate intra-articular biceps tendinosis." (*Id.*) She also underwent an MRI of the right elbow on August 31, 2018, which showed "intact biceps tendon" and "findings compatible with mild distal bicipitoradial bursitis." (*Id.* at 44.) This latter finding was believed to explain her symptoms. (*Id.*)

Petitioner returned to Dr. Elrashidy on September 12, 2018. (Ex. 3, p. 21.) In the history of present illness, Dr. Elrashidy recorded:

> The symptoms began on 7/11/2018 following a tetanus shot. She was previously diagnosed with grade 2 AC joint separation of right shoulder 10 years ago and right shoulder rotator cuff tear 10 years ago. Today, the patient reports aching 10/10 posterior right shoulder pain and occasional lateral shoulder pain during overhead activities. Associated symptoms include right elbow pain, joint locking, loss of motion and popping. Of note, she denied neck pain and numbness.

(*Id.*) On examination, there was tenderness over the AC joint and proximal bicipital groove. (*Id.* at 22.) Petitioner's active range of motion was recorded as "170/160/50/T10," and she had positive O'Brien's, Yergason's, and Hawkin's tests and a positive Neer sign. (*Id.*) Dr. Elrashidy's assessment included right shoulder partial thickness rotator cuff tear, SLAP tear with biceps instability, subacromial impingement, and AC joint osteoarthritis. (*Id.* at 23.) Petitioner was referred for further evaluation to rule out a neck and spine pathology for her shoulder condition. (*Id.*)

On October 2, 2018, petitioner underwent an MRI of the right shoulder with contrast. (Ex. 3, p. 43.) The study's results showed "no full-thickness rotator or labral tear"; "moderate grade partial tear spanning the anterior supraspinatus and superior subscapularis tendon fibers, both superimposed on tendinosis," that was unchanged since the August 2018 study; and "mild to moderate subacromial/subdeltoid bursitis" that had increased slightly since the last study. (*Id.*)

Petitioner followed up with Dr. Elrashidy on November 5, 2018, with reports of dull and aching right shoulder pain at a 4 out of 10. (Ex. 3, p. 16.) A physical examination again revealed tenderness over the AC joint and proximal bicipital groove, as well as active range of motion recorded as "170/160/50/T10." (*Id.*) She also again had positive O'Brien's, Yergason's, and Hawkin's tests and a positive Neer sign. (*Id.* at 17.) Dr. Elrashidy noted that "conservative treatment alone is unlikely to provide maximal improvement" and petitioner elected to pursue surgery. (*Id.* at 18.)

On November 20, 2018, petitioner underwent a right shoulder arthroscopy with subacromial decompression, distal clavicle excision, and double row rotator cuff repair.

(Ex. 3, pp. 38-40.) During her post-operative encounter with Dr. Elrashidy the following day, petitioner reported constant dull pain at a 3 out of 10 that worsened with movement. (*Id.* at 13-14.) She was instructed to return in two weeks if her symptoms progressed. (*Id.*) On December 3, 2018, petitioner presented for a two-week post-operative evaluation. (*Id.* at 4.) She reported no shoulder pain at rest and sharp pain with movement. (*Id.*) Petitioner was cleared to begin physical therapy focused on right shoulder rehabilitation and adhesive capsulitis the following day. (*Id.* at 5.) However, during her eight-week post-operative evaluation, petitioner reported constant aching, burning, and throbbing right shoulder pain at an 8 out of 10. (*Id.* at 8.) She indicated that she could not afford physical therapy and that she was on workers' compensation for her bilateral upper extremities. (*Id.*) On examination, petitioner's forward flexion was measured at 100 degrees, but she otherwise had full range of motion at the elbow, wrists, and digits. (*Id.* at 9.) A January 9, 2019 MRI of petitioner right shoulder following her surgery showed a "thinning of the supraspinatus tendon along the tuberosity attachment and anterior half around the critical zone with indistinct margins" but the supraspinatus repair was intact; "[e]vidence of adhesive capsulitis"; "[a]nteroinferior labral degeneration and very small glenohumeral joint effusion"; and "[a]cromioclavicular joint arthrosis." (*Id.* at 9, 36-37.) There was also a new, "[v]ery small partial-thickness bursal sided subscapularis tendon tear laterally." (*Id.*) Dr. Elrashidy suggested that petitioner take oral anti-inflammatories as needed and continue in-home exercises. (*Id.* at 9.)

On January 23, 2019, petitioner presented for an initial evaluation by orthopedist Kerisimasi Reynolds, D.O., for a second opinion regarding potential recurrent tears. (Ex. 2, pp. 4-5.) Petitioner complained of worsening pain of her right shoulder, which she rated as a 10 out of 10 at worst, and reduced range of motion, including difficulty with forward elevation and external rotation. (*Id.* at 4.) On examination, petitioner's abduction was 80 degrees, forward elevation was 110 degrees, and external rotation was 15 degrees. (*Id.*) There was tenderness over the AC joint, globally. (*Id.*) Dr. Reynolds noted that petitioner's post-operative MRI showed new tears but that the MRI was "potentially not representative of the actual rotator cuff" as it was "really early in the rehab and recovery process at that time." (*Id.*) Petitioner was diagnosed with recurrent right shoulder pain, bursitis, and pain status post right shoulder arthroscopy and rotator cuff repair. (*Id.*) She received a cortisone injection and a prescription for Prednisone. (*Id.* at 4-5.)

In March of 2019, Dr. Fonseca was deposed in connection with petitioner's workers' compensation claim. (Ex. 14, p. 7.) Dr. Fonseca averred that he was still in the process of determining the cause of petitioner's right shoulder symptoms. (*Id.* at 12-14.) Petitioner's vaccination was not mentioned during this deposition. On September 10, 2019, Dr. Fonseca performed a Panel Qualified Medical Re-Evaluation in connection with petitioner's worker's compensation claim. (*Id.* at 133.) He noted an increase in petitioner's range of motion since the January 26, 2017 evaluation; however, petitioner did have a positive Neer's sign. (*Id.* at 176-77.) Dr. Fonseca determined that petitioner's current right shoulder condition was "40% related to the 08/03/2015 [workplace] injury and 60% related to other causes." (*Id.* at 190.) Dr. Fonseca opined

that "there is a direct relationship between [petitioner's] current complaints to the neck, left and right upper extremity [that] occurred on 08/03/2015 and her current condition." (*Id.* at 186.) He explained that petitioner's "bilateral upper extremity symptoms are related to the cervical spine and thoracic outlet region" and her "upper extremity industrial complaints are not related to any orthopedic injury to the shoulder, elbow, wrist or hands." (*Id.*) However, although petitioner's Tdap vaccination was listed in passing in her medical history, her vaccination was not considered in Dr. Fonseca's ultimate causal analysis. (*Id.* at 150, 186.) This is likely due to the fact that, during a deposition taken as part of her worker's compensation proceeding on February 12, 2019, petitioner did not state that she had been injured by the Tdap vaccine, despite being asked to identify all injuries she had sustained to her right shoulder since August of 2015, specifically identifying a cat bite in 2018, and referencing treatment with Dr. Elrashidy. (*Id*. at 2322-29.) This deposition occurred about six months following her alleged vaccine-related shoulder injury. However, petitioner subsequently filed an affidavit in this case, dated September 25, 2019. (Ex. 8.) Within the affidavit, petitioner averred under oath that "I sustained right shoulder injuries caused by the administration of the Tdap vaccine on July 11, 2018." (*Id*.)

In December of 2019, petitioner presented for an initial evaluation with physical medicine and rehabilitation specialist Allen Kaisler-Meza, M.D. in connection with her workers' compensation claim. (Ex. 14, p. 2637.) Petitioner had positive Hawkin's, Yergason's, Jobe's, and shoulder crossover tests. (*Id.* at 2641.) There was tenderness to palpation over the AC joint, periscapular muscle, rhomboids, trapezius, and subdeltoid bursa. (*Id.*) Petitioner was diagnosed with cervicalgia, bursitis in both shoulders, impingement syndrome in the right shoulder, cervical disc disorder with radiculopathy, and lateral epicondylitis of the right elbow. (*Id.*) Later that same month, petitioner returned to Dr. Reynolds with complaints of, *inter alia*, right shoulder pain that radiated down the lateral aspect of her arm. (Ex. 13, p. 15.) On examination, petitioner's range of motion was slightly decreased: forward flexion was 160 degrees, abduction was 160 degrees, and external rotation was 40 degrees and symmetric. (*Id.* at 16-17.) There was no tenderness to palpation, and petitioner had negative rotator cuff, impingement, stability, biceps, and SLAP/Labral testing. (*Id.* at 17.) Dr. Reynold's assessment included "[p]ersistent pain status post right shoulder arthroscopy." (*Id.*) An MRI of the right shoulder was ordered to rule out significant pathology that could explain petitioner's protracted and refractory pain. (*Id.*)

Petitioner returned to Dr. Reynold's on January 6, 2020. (Ex. 13, p. 18.) Her physical examination and testing were consistent with her prior evaluation. (*Id.* at 18-19.) Dr. Reynold's noted that her right shoulder MRI showed "a significant amount of subacromial fluid" and suggested that she continue treating with at-home exercises and anti-inflammatory pain medication as needed. (*Id.* at 19.) During a follow up encounter with Dr. Reynolds on January 27, 2020, petitioner reported increased shoulder pain. (*Id.* at 20.) Petitioner's range of motion remained consistent, but she now had positive signs of impingement. (*Id.*) Dr. Reynolds assessed "[r]etear of rotator cuff with failure of internal hardware" and recommended a right shoulder arthroscopy with removal of a foreign body and revision rotator cuff repair. (*Id.* at 21.)

On February 21, 2020, petitioner underwent a right shoulder arthroscopy with revision rotator cuff repair, removal of foreign body, labral debridement, and subacromial decompression with coracoacromial ligament release. (Ex. 13, pp. 30-31.) Her post-operative diagnoses included right shoulder rotator cuff retear, intraarticular foreign body, subacromial impingement, and labral tearing. (*Id.* at 31.) During her post-operative encounters in March of 2020, petitioner reported that she was doing well and her pain was controlled. (*Id.* at 24, 26.) However, in June of 2020, petitioner presented to Dr. Fonseca with reports of pain over the anterior and posterior of her bilateral shoulder region and localized to the base of her neck. (Ex. 14, p. 36.) Dr. Fonseca's assessment included myofascial pain syndrome, chronic cervical sprain, bilateral cervical radiculopathy, and bilateral thoracic outlet syndrome. (*Id.* at 59.) Bilateral rotator cuff impingement, right full thickness of the supraspinatus tendon, and bilateral subacromial bursitis are listed under non-industrial conditions. (*Id.*)

IV. Expert Opinions

a. Jerome Piontek, M.D., for petitioner[5]

Dr. Piontek opines that petitioner's history meets all four of the QAI criteria for a Table SIRVA.[6] (Ex. 17, p. 4.) Based on his review, Dr. Piontek opines that petitioner's history demonstrates an abrupt onset of new severe shoulder pain within 24 hours of her Tdap vaccination.[7] (*Id*.) He acknowledges that petitioner had a prior work-related injury affecting her neck, right shoulder, and arm, but contends that she was released to return to work in September of 2017 and was confirmed as having reached maximal medical improvement by August of 2018. (*Id*.) Although he notes that her July 2018 MRI showed slight progression of chronic bursal tears, it also showed new findings of

[5] Dr. Piontek received his medical degree from St. Louis University Medical School in 1979, before going on to complete an internship at United States Public Health Service Hospital in San Francisco in 1980 and an orthopedic surgery residency at Washington University Department of Orthopedic Surgery in 1985. (Ex. 18, pp. 1-2.) From there, Dr. Piontek maintained a clinical practice in orthopedic surgery with a special concentration in disorders and injuries of the hips, knees, and shoulders for over 35 years. (Ex. 17, p. 1.) He is a board-certified orthopedic surgeon, and he maintains an active medical license in Missouri. (Ex. 18, p. 2; Ex. 17, p. 1.) Although Dr. Piontek has retired from clinical practice, he maintains a position as a medical consultant to the Disability Determination Section of Social Security for the State of Missouri. (Ex. 17, p. 1.)

[6] In response to Dr. Abrams's contention that suffered no reduced range of motion, Dr. Piontek asserted only that a finding of reduced range of motion is not a requirement for a Table SIRVA. (Ex. 24, pp. 7-8.) However, this is a legal conclusion beyond Dr. Piontek's purview as an expert witness. Contrary to Dr. Piontek's assumption, the Chief Special Master has previously concluded that a demonstrated reduction in motion is a requirement under the third QAI criterion for SIRVA. *Bolick v. Sec'y of Health & Human Servs*., No. 20-893V, 2023 WL 8187307, at *6-8 (Fed. Cl. Spec. Mstr. Oct. 19, 2023). I agree with the Chief Special Master's analysis in *Bolick* and adopt the same understanding herein.

[7] Regarding onset, Dr. Piontek credits the history petitioner provided on her new condition form, as well as the history recorded by Dr. Elrashidy on July 23, 2018, over the history of an "insidious onset" recorded by Dr. Gay on July 20, 2018. (Ex. 24, p. 7.)

edema within the infraspinatus tendon, as well as subacromial and subdeltoid bursitis. (*Id*. at 3-4; *see also* Ex. 24, p. 8 (citing Elisabeth M. Hesse et al., *Shoulder Injury Related to Vaccine Administration (SIRVA): Petitioner Claims to the National Vaccine Injury Compensation Program, 2010-2016*, 38 VACCINE 1076 (2020) (Ex. 19); Ken Yamaguchi et al., *The Demographic and Morphological Features of Rotator Cuff Disease: A Comparison of Asymptomatic and Symptomatic Shoulders*, 88 J. BONE & JOINT SURGERY 1699 (2006) (Ex. 27)).)

Dr. Piontek acknowledged that "SIRVA is a clinical diagnosis"; however, he also set forth a causal opinion. He indicated that vaccines can cause shoulder injuries as a consequence of inflammation when incorrect administration results in an injection into the subacromial or subdeltoid space. However, these injuries are "not the result of a needle penetration alone." Instead, the "common denominator" is "inflammation secondary to antigen related complexes." (Ex. 17, p. 4 (citing T. Derek Cooke & Hugo E. Jasin, *The Pathogenesis of Chronic Inflammation in Experimental Antigen-Induced Arthritis: I. The Role of Antigen on the Local Immune Response*, 15 ARTHRITIS & RHEUMATISM 327 (1972) (Ex. 21); T. Derek Cooke et al., *The Pathogenesis of Chronic Inflammation in Experimental Antigen-Induced Arthritis: II. Preferential Localization of Antigen-Antibody Complexes to Collagenous Tissues*, 135 J. EXPERIMENTAL MED. 323 (1972) (Ex. 22)).) Thus, noting an onset of shoulder pain "within hours" of vaccination, he opines that petitioner "suffered a localized inflammatory event causally related to the vaccination received on 7/11/2018." (*Id*.) He further opines that "[t]he bursitis and edema, seen on the MRI of 7/20/18, though nonspecific, are consistent with this inflammation, and were not noted previously." (*Id*.)

Dr. Piontek disagrees with Dr. Abrams's opinion that petitioner's overall clinical symptomology was the same before and after vaccination. (Ex. 24, p. 7.) He suggests that, prior to vaccination she experienced primarily neck pain, with pain, numbness, and tingling radiating into her right shoulder, forearm and hand. This pain was aggravated primarily by rotation, flexion, and extension of her neck. (*Id*.) After vaccination, by contrast, he contends that she had an abrupt onset of shoulder pain with and without movement and her complaints referred primarily to the shoulder, rather than the neck. (*Id*.) However, Dr. Piontek agrees that differentiating shoulder symptoms from cervical spinal symptoms "can prove to be a diagnostic dilemma." (*Id*. at 8.)

Finally, Dr. Piontek disagrees with Dr. Abrams's assertion that petitioner's lack of significant relief from a corticosteroid injection and surgery argue against a SIRVA. (Ex. 24, p. 8.) He notes two studies that showed only a minority of SIRVA subjects demonstrated relief from such treatments. (*Id.* (citing Hesse et al., *supra*, at Ex. 19; S. Atanasoff et al., *Shoulder Injury Related to Vaccine Administration*, 28 VACCINE 8049 (2010) (Ex. 28)).)

b. Geoffrey Abrams, M.D., for respondent[8]

Dr. Abrams opines that "petitioner has a long history of pre-vaccination shoulder pain and symptoms – as well as other musculoskeletal complaints such as neck pain" and that "the clinical presentation, description of her shoulder pain, physical examinations, and advanced imaging findings, are all similar both before and after the July 2018 vaccination, strongly arguing against SIRVA." (Ex. A, p. 8.) He concludes that "if you consider her right shoulder area and neck pain a continuation of her prior pathology and symptoms, she does not meet any of the QAI or formal Table criteria for SIRVA, including decreased range of motion requirements for SIRVA diagnosis following the vaccination." (*Id*.) Moreover, Dr. Abrams expressed doubt with respect to petitioner's initial post-vaccination presentation. (*Id*. at 14.) He notes that "during her first medical visit with Dr. Gay on July 20, 2018, she reported [a] 'multiple month history of insidious onset of right shoulder pain. The patient notes pain that is dull, intermittently sharp pain localizing to the posterolateral aspect of the shoulder of insidious onset' (Ex. 2, p. 11). This is contrary to what would be expected in cases of SIRVA and directly suggests chronic shoulder symptomatology." (Ex. A, p. 14.)

Following a detailed review of petitioner's medical encounters between 2015 and 2018, Dr. Abrams noted that petitioner's 2017 records demonstrate that, prior to vaccination, she was complaining of progressively worsening right shoulder pain as of April 2017 and that, by June of 2017, she had "right upper extremity and neck discomfort," which is similar to her August of 2018 reports of pain affecting her "neck and shoulder" and "right shoulder and upper back region." (Ex. A, p. 10.) Additionally, petitioner was consistent, both before and after vaccination, in reporting that her symptoms were aggravated by overhead activities and made sleeping more difficult. (*Id.*)

Dr. Abrams stresses petitioner's physical exam findings pre- and post-vaccination. In particular, he describes loss of external rotation, forward elevation, and abduction as "universally accepted" findings in SIRVA. (Ex. A, p. 10 (citing Gail B. Cross et al., *Don't Aim Too High: Avoiding Shoulder Injury Related to Vaccine*

[8] Dr. Abrams received his medical degree from the University of California, San Diego, in 2007, before going on to complete a surgical internship and residency at Stanford University Hospital and Clinics in 2008 and 2012, respectively, followed by a fellowship in orthopedic sports medicine at Rush University Medical Center in 2013. (Ex. B, pp. 1-2.) During his fellowship, Dr. Abrams worked as a clinical instructor at Rush University Medical Center. (*Id.* at 1.) In 2013, he returned to Stanford University School of Medicine to accept a position as an assistant professor. (*Id.*) He was eventually promoted to associate professor of orthopedic surgery in 2021. (*Id.*; Ex. A, p. 1.) During that time, Dr. Abrams also worked as an attending physician at Veterans Administration Hospital, Palo Alto, and he maintains positions as Director of Sports Medicine for Varsity Athletics and Director of the Lacob Family Sports Medicine Center at Stanford University. (Ex. B, p. 1; Ex. A, p. 1.) Dr. Abrams is board certified in orthopedic surgery with a subspecialty in orthopedic sports medicine, and he maintains a medical license in California. (Ex. B, p. 2; Ex. A, p. 1.) In his research capacity, Dr. Abrams has published, *inter alia*, nearly 150 peer-reviewed publications, 4 peer-reviewed short communications, 37 book chapters, and 97 abstracts focused on orthopedic conditions of the shoulder, as well as on shoulder and other musculoskeletal pathology. (Ex. B, pp. 2-32; Ex. A, p. 1.)

Administration, 45 AUSTRALIAN FAM. PHYSICIAN 303 (2016) (Ex. A-1); Christopher V. Macomb et al., *Treating SIRVA Early with Corticosteroid Injection: A Case* Series, 185 MIL. MED. e298 (2020) (Ex. A-2); Michael Shahbaz et al., *Shoulder Injury Related to Vaccine Administration (SIRVA): An Occupational Case Report*, 67 WORKPLACE HEALTH & SAFETY 501 (2019) (Ex. A-3)).) He observes that, prior to vaccination, petitioner had documented forward flexion of between 150 to 165 degrees and, post-vaccination, her documented flexion was to 130 degrees. (*Id*.) Prior to vaccination, her abduction was between 145 to 150 degrees, and after vaccination, it was 130 degrees. (*Id*.) Prior to vaccination, petitioner's external rotation was measured at 50 degrees. Following vaccination, it was 45 degrees. (*Id.*) Dr. Abrams characterizes all of these findings as "extremely similar." (*Id*. at 10-11.) If anything, he suggests that petitioner's earliest post-vaccination encounters reflect "essentially normal" and "symmetric" range of motion. (*Id*. at 11.) Furthermore, petitioner had documented signs of impingement both pre- and post-vaccination. (*Id*. at 10-11.) Specifically, petitioner had a positive Hawkins sign on August 11, 2015, as well as July 20, 2018, and July 23, 2018. (*Id*. at 11.) Petitioner's records also reflect paracervical and parascapular tenderness in April and June of 2017, while post-vaccination, she had documented pain in the neck, shoulder, and upper back that was noted to radiate into the paracervical musculature. (*Id*.)

Dr. Abrams also opines that petitioner's March 21, 2017 MRI was "nearly identical" to her post-vaccination MRI of July 20, 2018. (Ex. A, pp. 11-12.) Both showed infraspinatus tendinosis, bursal surface tearing of the supraspinatus tendon, and mild acromioclavicular osteoarthritis. (*Id*.) While the tearing was noted to have progressed slightly, the other findings were noted to be similar on both MRIs. (*Id.*) Dr. Abrams opines that there are "chronic shoulder related dysfunction rather than SIRVA." (*Id*. at 12.) Dr. Abrams did not initially comment on the mild subacromial subdeltoid bursitis he additionally noted to be among the findings of the July 20, 2018 MRI. (*Id.*) In his supplemental report, he stated that "[a]ny new findings on the 2018 MRI are minor and could simply be related to normal expected physiologic fluid (such as mild bursitis) or from a shoulder muscle strain or nerve irritation – as proposed by the interpreting radiologist (Ex 2, p. 23)." (Ex. C, p. 2.)

Dr. Abrams opines that petitioner's symptoms are more likely explained not only by her pre-existing shoulder pathology, but also by cervical spinal pathology and a myofascial pain syndrome. (Ex. A, p. 12.) He stresses that it is not unusual for people to have chronic degenerative changes affecting both the shoulder and cervical spine and that distinguishing the source of the resulting pain "presents a diagnostic dilemma for clinicians." (*Id.*) Moreover, petitioner was diagnosed by Dr. Lin as suffering myofascial pain syndrome on April 20, 2017, which is known to lead to chronic shoulder and neck pain. (*Id*. at 13.) In petitioner's case, he explains:

> In support of cervical spine mediated symptoms, petitioner reported "neck, right shoulder, arm, and forearm pain that radiates into the right breast, axilla, scapula, arm, and posterolateral forearm" during her February 23, 2017 visit with Dr. Fo[n]seca (Ex 14, p. 709). She also reported "pain…from the right scapular region to the entire right shoulder, forearm, and wrist

> region" with "tingling and numbness in the ring and small fingers" with Dr. Pang on June 21, 2017 (Ex 14, p.902). Post-vaccination, she complained that "pain is most notable to her with head and neck motions" during her August 1, 2018 visit less than one month after vaccination (Ex 14, p. 928). All of these symptoms are consistent with cervical spine pathology and are present and similar both before and after the vaccination.

(*Id*. at 13 (alteration in original).) Furthermore, Dr. Abrams notes that petitioner's March 2017 cervical spinal MRI showed mild to moderate foraminal stenosis with a probability of nerve root irritation. (*Id*. (citing Ex. 14, p. 1734).)

Dr. Abrams further notes that petitioner experienced only temporary relief from a cortisone injection administered in September of 2018 and from her arthroscopic surgery in November of 2018. (Ex. A, pp. 13-14 (citing Ex. 3, pp. 21, 38).) This suggests that her primary source of pain is not her shoulder pathology. (*Id*.) Moreover, because SIRVA is an inflammatory condition, if petitioner's pain were due to SIRVA she likely would have experienced significant relief from the corticosteroid injection. (*Id*. at 14.)

Dr. Abrams provided a supplemental report responding to Dr. Piontek's rebuttal of his initial report. (Ex. C.) That report elaborated on some of the above points, but did not introduce any new lines of reasoning. (*Id*.)

V. Party Contentions

a. Table Injury

In her motion for a ruling on the record, petitioner initially paid little attention to her allegation of a Table injury of SIRVA. (ECF No. 64, pp. 16-17.) Citing to Dr. Piontek's opinion, she simply asserts that the history she provided at her July 20, 2018 medical encounter "is clearly describing development of a new injury," that this new injury occurred within 48 hours of her vaccination, was limited to her right shoulder, and that no other condition would explain "her nearly immediate development of symptoms." (*Id*. at 17.) Instead, petitioner mostly focuses on why she believes she has met her burden of proof to demonstrate causation-in-fact under the *Althen* test.

In response, respondent challenged petitioner's showing with respect to all four of the SIRVA QAI criteria. (ECF No. 66, pp. 15-26.) With regard to the first criterion, respondent argued that "[t]he similarity between petitioner's pre- and post-vaccination symptomology, clinical presentation, imaging, diagnoses, response to treatment, and pre-vaccination prognosis more likely reflects a continuation of the same condition than a SIRVA." (*Id*. at 16.) Regarding the second criterion, respondent argues that, because her post-vaccination condition is merely a continuation of her prior condition, she "has not established that she suffered a new, acute shoulder injury within forty-eight hours of vaccination." (*Id*. at 22.) Moreover, at her first post-vaccination encounter, just nine days post-vaccination, she described her condition to Dr. Gay as a "multiple month

history of insidious onset." (*Id*.) Regarding the third criterion, respondent argues that petitioner's clinical presentation included reports of pain extending to her neck and upper back, consistent with cervical spinal involvement in her condition. (*Id.* at 22-23.) Finally, regarding the fourth criterion, respondent argues that Dr. Abrams's opinion that petitioner's condition is explained as a combination of pre-existing shoulder and cervical pathology, as well as myofascial pain syndrome, should control. (*Id.* at 23-26.)

In reply, petitioner argues that she has demonstrated her post-vaccination condition to be "new and distinct" from her prior symptomology, such that her prior symptomology was "unrelated" and would not prevent her from experiencing a SIRVA. (ECF No. 67, pp. 2-3.) She disputes the accuracy of Dr. Gay's notation regarding the onset of her condition. (*Id*. at 4.)

b. Causation-in-fact

Regarding *Althen* prong one, petitioner argues that "Health and Human Services did not magically invent the acronym SIRVA for use on the Vaccine Injury Table in 2017." (ECF No. 64, p. 17.) Instead, the term derives from medical literature as a way of describing vaccine adverse events including deltoid bursitis, tenonitis, rotator cuff tears, frozen shoulder, impingement syndrome, and adhesive capsulitis. (*Id*. at 17-18 (citing Atanasoff et al., *supra*, at Ex. 28; Marko Bodor & Enoch Montalvo, *Vaccination-Related Shoulder Dysfunction*, 25 VACCINE 585 (2007) (Ex. 23; *see also* Ex. A-5)).) Petitioner argues that "[t]he concept of a vaccine-induced shoulder injury, or "SIRVA," whether Table or not, is now a widely accepted medical diagnosis." (*Id*. at 17-18.) In that regard, she stresses that her expert, Dr. Piontek, has set forth an opinion, based in the relevant medical literature, that administration of a vaccine into the subacromial space can lead to an inflammatory response within the shoulder capsule resulting in a rapid onset of pain and limited range of motion. (*Id*. at 18-20.)

In response, respondent argues that petitioner must present a theory pertaining to a defined and recognized injury. (ECF No. 66, pp. 29-30.) He argues that "SIRVA is an injury as a matter of law defined only by administration rule making, *see* 42 C.F.R § 100.3(c)(10), and petitioner may not pursue a causation-in-fact SIRVA claim because SIRVA is not an injury that exists outside of the regulatory framework." (*Id*. at 29.) Although petitioner argues that "SIRVA" is a "widely accepted medical diagnosis," respondent counters that none of petitioner's treating physicians used the term SIRVA and that "where petitioner has numerous pre-existing and co-morbid findings related to her right arm, cervical spine, and thoracic spine, identification of a specific shoulder injury is critical – and critically missing – to evaluate causation." (*Id*. at 29-30.) Respondent contends that petitioner's reliance on penetration into the subacromial space "is an impermissible attempt to circumvent *Althen* by expanding a Table claim." (*Id*. at 30.)

Regarding *Althen* prong two, petitioner argues that the logical sequence of cause and effect is clear, because she reported experiencing symptoms of her alleged injury "as of the date of the vaccination" and her diagnostic imaging confirmed the presence of

bursitis and edema as of July 20, 2018. These findings were not present before and are consistent with the type of localized inflammatory event that Dr. Piontek hypothesized. (ECF No. 64, pp. 21-22.) Quoting a lengthy portion of Dr. Piontek's report, petitioner seems to implicitly argue that, because her prior shoulder condition had reached maximum medical improvement and had been stationary, her prior condition cannot explain her post-vaccination presentation. (*Id*. at 22-23.)

Regarding *Althen* prong two, respondent argues that petitioner's proffered evidence "amount to petitioner's word that she suffered a new and abrupt injury on the date of her vaccination, that her July 20, 2018 right shoulder MRI study showed edema and bursitis, and her expert's endorsement of these two facts." (ECF No. 66, p. 31.) On these points, respondent reiterates his argument that Dr. Gay's record indicated an insidious onset of shoulder pain and further stresses Dr. Abrams' supplemental report that indicated that petitioner's new MRI findings were "minor and could simply be related to normal expected physiologic fluid (such as mild bursitis) or from a shoulder muscle strain or nerve irritation – as proposed by the interpreting radiologist." (*Id*. at 31 (quoting Ex. C, p. 2).)

Regarding *Althen* prong three, petitioner argues that she experienced new pain complaints "within hours" of her vaccination. (ECF No. 64, p. 23.) In particular, she stressed that on July 20, 2018, she filled out a "New Condition Form" in which she identified her date of vaccination as the date of her first symptoms and attributed those symptoms to the vaccination. (*Id*. (citing Ex. 2, p. 13).) She further noted that she first presented for care nine days post-vaccination, which is close to the median time of 15 days for post-vaccination shoulder pain. (*Id*. at 24 (citing Hesse et al., *supra*, at Ex. 19).)

As with petitioner's alleged Table injury, respondent contends that petitioner's post-vaccination condition is merely a continuation of her pre-vaccination condition. (ECF No. 66, p. 32.) Thus, he contends that she cannot satisfy the third *Althen* prong. (*Id*.)

c. Significant aggravation and factor unrelated to vaccination

Although Dr. Abrams presented the opinion that petitioner's condition was a continuation of her prior, chronic pathology, petitioner asserts that Dr. Piontek rebutted this conclusion, noting especially Dr. Piontek's disagreement as to petitioner's reduced range of motion and MRI findings. (ECF No. 64, pp. 24-25.) Thus, petitioner contends that respondent has not demonstrated her condition to be due to a factor unrelated to vaccination. (*Id*.) Petitioner argues that, at a minimum, her post-vaccination condition represents a significant aggravation of her condition consistent with the *Loving* test. (*Id*. at 26.) However, respondent stresses with respect to *Loving* prong one that petitioner has not demonstrated her condition to have been asymptomatic pre-vaccination. (ECF

No. 66, p. 33.) He also incorporates his arguments relative to *Althen* as additional reasons why petitioner cannot satisfy *Loving*.[9] (*Id*.)

VI. Analysis

After consideration of the parties' arguments as well as the record as a whole, I have concluded that petitioner's entitlement to compensation must be resolved as a question of whether her July 11, 2018 Tdap vaccination significantly aggravated her pre-existing right shoulder condition. Thus, the analysis that follows addresses the six-part *Loving* test for significant aggravation. Although the parties extensively briefed petitioner's potential claims relative to either a Table SIRVA or a shoulder injury initially caused-in-fact by her vaccination, separate analyses of these claims is not necessary given that petitioner has demonstrated she is entitled to compensation based on significant aggravation. In any event, the analysis with respect to *Loving* prong three suffices to explain why petitioner's history is incompatible with either the first QAI criterion for a Table SIRVA or a logical sequence of cause and effect under *Althen* prong two relative to a de novo injury.

a. *Loving* prong one

The first *Loving* prong involves an examination of petitioner's pre-vaccination condition. *Loving*, 88 Fed. Cl. at 144. Prior to vaccination, petitioner had an ongoing history of neck and right shoulder pain beginning in 2015. In June of 2018, just one month prior to vaccination, Dr. Pang declared that petitioner's injury is permanent and at maximum medical improvement. (Ex. 14, p. 926-27.) In a more detailed follow up report dated August 20, 2018, Dr. Pang explained that, at maximum medical improvement, petitioner still carried diagnoses of a right rotator cuff tear, multi-level cervical spinal degenerative changes with foraminal stenosis, and thoracic spine strain. (*Id.* at 933.) She had ongoing tenderness over her right shoulder, demonstrated reduced range of motion, and positive impingement testing. (*Id.*)

Although Dr. Abrams notes that differentiating cervical spinal pain from shoulder pain is challenging, the evidence does not preponderate in favor of a finding that petitioner's pre-vaccination condition is wholly explained by her cervical spinal issue.

---

[9] Of note, the parties paid relatively little attention to the question of significant aggravation in their briefing. However, in my prior Rule 5 order, I specifically noted the fact of petitioner's pre-existing shoulder dysfunction and directed the parties to review two prior cases in which I found that pre-existing shoulder injuries had been significantly aggravated by vaccination. (ECF No. 47, p. 2 (citing *Kelly v. Sec'y of Health & Human Servs.*, No. 17-1918V, 2022 WL 1144997 (Fed. Cl. Spec. Mstr. Mar. 24, 2022); *Forrest v. Sec'y of Health & Human Servs.*, No. 17-1905V, 2023 WL 2493263 (Fed. Cl. Spec. Mstr. Feb. 15, 2023)).) I further advised the parties that, "[i]n the undersigned's view, regardless of whether Table SIRVA is recognized by judicial notice, the particulars of petitioner's theory under *Althen* prong one/*Loving* prong four are critical to evaluating *Althen* prong two/*Loving* prong five." (*Id*.) Accordingly, the parties were on notice with regard to the likelihood that I would resolve this case based on significant aggravation. *See Sword v. U.S.*, 44 Fed. Cl. 183, 187 (1999) (explaining that "[n]o judge or jury can be forced to accept or reject an expert's opinion or a party's theory at face value. To require such a choice in this context is to neglect the Special Master's duty to 'vigorously and diligently investigate the factual elements' underlying the petition.").

There is no dispute that petitioner suffered a right-sided grade 2 AC joint separation in 2009 that caused pain and reduced range of motion, though she denied sustaining any rotator cuff or labrum injury at that time. (Ex. 14, p. 2322.) Following a flare in shoulder pain related to a workplace injury in 2015, a right shoulder MRI showed "a moderate rotator cuff tenodesis with a small 4mm x 4mm bursal surface panel tear of the supraspinatus tendon," while a cervical spine MRI showed "mild annular bulge at C3-C4." (Ex. 2, p. 9.)

Reimaging of petitioner's right shoulder in March of 2017 showed a full-thickness bursal sided tear of the supraspinatus tendon anteriorly and a small linear tear of the tendon posteriorly, as well as diffuse supraspinatus-infraspinatus tendinosis. (Ex. 3, p. 49.) Reimaging of the cervical spine showed mild to moderate foraminal compromise over C3-C4, C4-C5, C5-C6, and C6-C7, as well as annular bulging over those same regions. (Ex. 14, pp. 1734-35.) Dr. Abrams emphasizes the cervical MRI findings with regard to irritation of the C5 nerve root, which he submits is "a classic cause of shoulder area pain." (Ex. C, p. 1 (citing Ruth Jackson, *The Classic: The Cervical Syndrome*, 468 CLINICAL ORTHOPAEDICS & RELATED RES. 1739 (2010) (Ex. C-1)).) However, Jackson explained that "irritation of a single nerve root occurs in only a small percentage of cases, and that this accounts for the multiplicity of symptoms and clinical findings." (Jackson, *supra*, at Ex. C-1, p. 4.) Additionally, "many of the findings are difficult to understand on the basis of an exact anatomical explanation." (Jackson, *supra*, at Ex. C-1, p. 4.) Literature cited by respondent's expert also cautions against overreliance on pain maps as "areas of pain are not diagnostic of a particular source." (Grant Cooper et al., *Cervical Zygapophysial Joint Pain Maps*, 8 PAIN MED. 344 (2007) (Ex. A-8, p. 9).) On the contrary, in a deposition taken on March 5, 2019, as part of petitioner's workers' compensation claim, Dr. Fonseca opined that a comparison of petitioner's March 2017 cervical spine MRI and subsequent reimaging led him to believe that "the symptoms are all coming from somewhere else, other than the cervical spine, especially the new symptoms for the new injuries she reported." (Ex. 14, p. 430.) Although Dr. Abrams opines that petitioner's diagnosis of myofascial pain syndrome is a well-known cause of shoulder area pain (Ex. A, p. 8), he also cites literature emphasizing that myofascial pain syndrome (and bursitis, for that matter) should not be diagnosed unless "cervical nerve root irritation has been ruled out entirely." (Jackson, *supra*, at Ex. C-1, p. 6.)

In June of 2017, orthopedist Dr. Pang reviewed petitioner's imaging and assessed, in pertinent part, cervical spine degenerative changes, as well as diffuse myofascial pain and right shoulder rotator cuff tear with full thickness bursal sided rotator cuff tear. (Ex. 14, p. 904.) Dr. Pang noted that an automobile accident in the early months of 2018 caused a flare in petitioner's symptoms, but her pain was "in the same distribution" as before the accident with tenderness over the right shoulder. (*Id.* at 924, 926.) Notably, not only did cervical traction not relieve petitioner's symptoms but it seemed to make her symptoms worse. (*Id.* at 918, 2327.) Dr. Pang noted during a follow up that petitioner's chiropractors, who were treating her cervical issues, were "having some difficulty coping with her overlapping" shoulder injury. (*Id.* at 924.) As recent as 2019, Dr. Fonseca indicated that he was struggling to determine the cause of petitioner's respective shoulder and cervical issues; however, he determined that at

least some portion of petitioner's right shoulder pain was attributable to the 2009 injury to her AC joint. (*Id.* at 434.) Indeed, although Dr. Abrams opined that petitioner's own cervical spinal findings are capable of causing shoulder pain, he further opined that "[p]etitioner's shoulder pain, of course, is likely also due to her preexisting shoulder pathology that was present both before and after the vaccination." (Ex. C, p. 1.)

As recent as June 12, 2018, just one month prior to vaccination, Dr. Pang diagnosed C4-C7 foraminal stenosis, as well as rotator cuff tear. (Ex. 14, p. 926.) Also as of June 2018, petitioner's shoulder and cervical injuries resulting from her 2015 workplace injury were determined to be permanent. (*Id.* at 926.) Dr. Piontek opines on petitioner's behalf that her MRI, which showed evidence of tear as early as 2015, indicate that her shoulder condition was chronic. (Ex. 17, p. 4.) Dr. Abrams similarly acknowledges that petitioner's MRI support "chronic shoulder related dysfunction." (Ex. A, p. 12.) In his response to petitioner's motion for ruling on the record, respondent acknowledges that the "available medical records indisputably document shoulder pain and dysfunction from three years up until one month prior to her Tdap vaccination." (ECF No. 66, p. 15.)

Accordingly, there is preponderant evidence that petitioner suffered shoulder pain and reduced range of motion up to the time of vaccination.

b. *Loving* prong two

The second *Loving* prong examines petitioner's post-vaccination condition. *Loving*, 88 Fed. Cl. at 144. There is no evidence that petitioner's chronic shoulder symptoms had fully resolved at the time of vaccination. However, following vaccination, Dr. Piontek opines that petitioner experienced "an abrupt onset of right shoulder pain with and without motion" and that her complaints referred primarily to her right shoulder, rather than cervical spine. (Ex. 24, p. 7.)

Petitioner's first post-vaccination encounter was with orthopedist Dr. Gay on July 20, 2018, approximately 9 days after the subject vaccination. (Ex. 2, p. 11.) The record for this encounter includes conflicting information with regard to onset and the severity of petitioner's condition. Dr. Gay recorded "a multiple month history of insidious onset of right shoulder pain . . . . that is dull, intermittently sharp pain" (*Id.* at 11), while a handwritten new condition form indicates that petitioner's symptoms began on July 11, 2018, after receipt of the Tdap vaccine, and manifested as "extreme pain in arm" (*Id.* at 13). These notations may be harmonized by the understanding that petitioner was experiencing a significant aggravation, with petitioner's own intake report reflecting the exacerbation of her symptoms and Dr. Gay's notation attempting to place those symptoms in the broader context of her pre-existing condition. But in any event, even to the extent they cannot be harmonized, petitioner's handwritten intake form carries greater weight. *Demitor v. Sec'y of Health & Human Servs.*, No. 17-564V, 2019 WL 5688822, at *10 (Fed. Cl. Spec. Mstr. Oct. 9, 2019) (giving weight to a handwritten intake form because it was petitioner's "own report verbatim" and "cannot be said to reflect any transcription mistake or miscommunication"); *Gairdo v. Sec'y of Health &*

Human Servs., No. 18-929V, 2024 WL 4262961, at * (Fed. Cl. Spec. Mst. Aug. 22, 2024) (indicating that a handwritten intake form "is strong evidence in itself"). Following a physical examination, Dr. Gay determined that petitioner's right shoulder pain was consistent with external impingement with possible rotator cuff tendinopathy or tear. (Ex. 2, p. 12.) A right shoulder MRI performed on the same day showed new evidence of subacromial and subdeltoid bursitis, as well as amorphous edema within the teres minor muscle. (*Id.* at 23.)

After reviewing petitioner's July 20, 2018 right shoulder MRI, another orthopedist, Dr. Elrashidy, diagnosed partial thickness rotator cuff tear, SLAP tear with biceps instability, subacromial impingement, and AC joint osteoarthritis. (Ex. 3, p. 27.) Although these diagnoses do not readily distinguish petitioner's complaints from her pre-vaccination condition, Dr. Elrashidy consistently reported petitioner's symptoms as beginning after her July 11, 2018 Tdap vaccination. (*Id.* at 16, 21, 26.) In that regard, petitioner's initial encounter with Dr. Gay and her MRI of the same date evidence that she experienced increased pain and new onset of subacromial bursitis shortly after her vaccination.

Petitioner underwent further MRI in August of 2018, which showed "moderate grade partial thickness bursal surface rim rent type tear through the leading edge of the supraspinatus extending into the distal superior subscapular tendon fibers, superimposed on tendinosis," high-grade bursal and articular tearing of the distal infraspinatus superimposed on mild tendinosis, and moderate intra-articular biceps tendinosis, as well as evidence consistent with mild distal bicipitoradial bursitis. (Ex. 3, pp. 44-45.) Dr. Elrashidy noted reduced range of motion and positive signs of impingement during a September 2018 encounter and maintained his prior assessment. (*Id.* at 22.) However, an October 2018 MRI with contrast showed progression of the bursitis seen on the last study. (*Id.* at 43.) In November of 2018, petitioner underwent a right shoulder arthroscopy with subacromial decompression, distal clavicle excision, debridement, and rotator cuff repair. (*Id.* at 18, 38-40.)

Following the surgery, a January 2019 MRI showed new evidence of thinning of the supraspinatus tendon, adhesive capsulitis, labral degeneration with glenohumeral joint effusion, acromioclavicular joint arthrosis, and a small, partial-thickness bursal sided subscapularis tendon tear. (Ex. 3, pp. 9, 36-37.) Another orthopedist, Dr. Reynolds, opined that petitioner's most recent MRI showed evidence of new tears and assessed, in pertinent part, bursitis. (Ex. 2, p. 4.) Petitioner had reduced range of motion, and she reported her pain as being a 10 out of 10. (*Id.* at 4.) In December of 2019, petitioner presented to physical medicine and rehabilitation specialist, Dr. Kaisler-Meza, who diagnosed petitioner with cervicalgia, bursitis in both shoulders, impingement syndrome in the right shoulder, cervical disc disorder with radiculopathy, and lateral epicondylitis of the right elbow. (Ex. 14, p. 2641.) Petitioner continued to experience pain, reduced range of motion, and impingement. (Ex. 13, pp. 15-21.) She underwent a further arthroscopy with revision of rotator cuff repair, removal of foreign body, labral debridement, and subacromial decompression. (*Id.* at 30-31.) As of March 2020, petitioner reported that she was doing well and her pain was under control;

however, in June of 2020, petitioner reported pain over the bilateral shoulder region and neck. (*Id.* at 24, 26, 36.)

Accordingly, there is preponderant evidence that petitioner experienced new onset of bursitis and edema, as well as a progression of her pre-existing rotator cuff tear following vaccination.

c. *Loving* prong three

Under *Loving* prong three, a comparison of the pre- and post-vaccination conditions examined under the first two prongs must indicate that petitioner has experienced "a change for the worse" in her pre-existing condition, "which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." § 300aa-33(4); *Loving*, 88 Fed. Cl. at 143-44. This aspect of the analysis does not reach the question of vaccine-causation and petitioner is not obligated to show that her outcome is worse than the expected outcome for a person with her condition. *Sharpe v. Sec'y of Health & Human Servs*., 964 F.3d 1072, 1081-82 (Fed Cir. 2020).

In the instant case, the medical records show that petitioner's post-vaccination condition reflects a change for the worse in petitioner's pre-vaccination condition. As discussed above, petitioner experienced new onset of bursitis and rapid progression of her pre-existing condition. Although petitioner experienced a flare in her symptoms following an automobile accident prior to vaccination, the flare primarily affected her cervical issues (Ex. 14, p. 911), and she was noted to be functioning at "a fairly high level" despite her shoulder symptoms (*Id.* at 904). However, MRI following vaccination evidence a clinical progression of petitioner's right shoulder condition with new evidence of bursitis and, within approximately four months of her vaccination, petitioner underwent a right shoulder arthroscopy whereas, prior to vaccination, her condition was considered to be stable and at maximum medical improvement, with no recommendation for surgery.

Respondent contends that petitioner's post-vaccination physical examinations do not evidence a significant aggravation of her pre-vaccination shoulder dysfunction. (ECF No. 66, pp. 17-19.) As respondent points out, petitioner experienced reduced range of motion prior to vaccination. (Ex. 14, p. 903 (June 2017 encounter, during which petitioner's range of motion was measured at 150 degrees flexion, 150 degrees abduction, 50 degrees external rotation, and 50 degrees internal rotation); Ex. 4, p. 10 (initial physical therapy encounter in January of 2018, during which petitioner's range of motion was measured at 180 degrees flexion, 180 degrees abduction, 60 degrees extension, 90 degrees external rotation, and 70 degrees internal rotation).) Respondent also asserts that there were positive signs of impingement on physical examination both prior to and following petitioner's vaccination. (ECF No. 66, pp. 18-19.) As respondent's correctly notes, petitioner displayed a "mildly positive" impingement sign during an August 2015 encounter. (Ex. 3, p. 33.) Thus, respondent contends that petitioner's post-vaccination condition amounts to a mere "continuation" of her prior condition based on "similarity between petitioner's pre- and post-vaccination

symptomatology, clinical presentation, imaging, diagnoses, response to treatment, and pre-vaccination prognosis." (ECF No. 66, p. 16.) On respondent's behalf, Dr. Abrams argues that petitioner's descriptions of her pain and aggravating factors, as well as her physical examinations, were similar both before and after vaccination. (Ex. A, p. 12.) For example, respondent cites several records containing petitioner's reports of pain as being aggravated by overhead activity, lifting, and repeated movements. (ECF No. 66, p. 16 (citing Ex. 2, p. 11; Ex. 3, pp. 21, 26, 33; Ex. 14, pp. 709-10, 900).) Finally, respondent argues that petitioner's right shoulder diagnoses remained constant following vaccination. (*Id.* at 20-21.)

I have considered the arguments raised by respondent, but do not find that they are dispositive of whether a significant aggravation occurred. The fact that petitioner had pre-existing difficulties with range of motion and impingement and reported similar aggravating factors both before and after vaccination is not necessarily surprising where the same underlying shoulder pathology is at issue. Petitioner's subjective reports of pain, which increased in severity in July of 2018 following her vaccination,[10] and new onset of bursitis indicate a marked change in her condition. Although respondent argues that petitioner's "pre- and post-vaccination right shoulder MRI document a continuation of the same underlying shoulder pathology" (ECF No. 66, pp. 19-20), petitioner's July 2018 MRI included new findings not seen on prior imaging, particularly subacromial/subdeltoid bursitis. (Ex. 17, p. 4.) Progression of petitioner's bursitis was observed on MRI in August and October of 2018. (Ex. 3, p. 43.) By September, petitioner was still reporting "aching 10/10 posterior right shoulder pain" that was now associated with "right elbow pain, joint locking, loss of motion and popping." (Ex. 3, p. 21.) And, whereas her pre-vaccination condition had been determined to be stable and at maximum medical improvement, her post-vaccination symptoms were severe enough to warrant several steroid injections and two shoulder surgeries. (Ex. 3, pp. 27, 38-40; Ex. 2, pp. 4-5; Ex. 13, p. 30; *see also* Ex. 3, p. 18 (Dr. Elrashidy noting that continued conservative treatment measures were unlikely to resolve petitioner's symptoms)). Looking at the totality of the evidence, while respondent is correct that some aspects of her condition remained substantially the same, there is nonetheless preponderant evidence that petitioner experienced a new onset of bursitis accompanied by a worsening of her pain and resulting in a change in the trajectory of her condition that necessitated additional treatment. This represents a change for the worse and a deterioration in her health. § 300aa-33(4).

Accordingly, there is preponderant evidence that petitioner experienced a significant aggravation in her pre-existing shoulder condition following vaccination.

d. *Althen* prong one / *Loving* prong four

[10] There is no specific information regarding petitioner's subjective shoulder pain during her last encounter prior to vaccination; however, Dr. Pang noted that petitioner reported improvement. (Ex. 14, p. 926.) Petitioner also subsequently averred that her symptoms were at baseline prior to vaccination. (*Id.* at 2331.) And, as noted in the preceding section, her initial encounter with Dr. Gay also evidences that her pain had worsened post-vaccination. (Ex. 2, p. 13.) Three days later, petitioner described her pain as "worsening constant sharp and aching 10/10." (Ex. 3, p. 26.)

Petitioner's burden under the first *Althen* prong/fourth *Loving* prong is to provide, by preponderant evidence, "a medical theory causally connecting the vaccination and the injury." *Althen*, 418 F.3d at 1278; *Loving*, 88 Fed. Cl. at 144. Such a theory must only be "legally probable, not medically or scientifically certain." *Knudsen v. Sec'y of Human & Health Servs.*, 35 F.3d 543, 548-49 (Fed. Cir. 1994). Moreover, scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Andreu v. Sec'y of Health & Human Servs*., 569 F.3d 1367, 1380 (Fed. Cir. 2009). However, to satisfy this prong, petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen*, 35 F.3d at 548; *Boatmon*, 941 F.3d at 1359. Petitioner's burden under *Loving* prong four varies from her burden under *Althen* prong one in that a significant aggravation claim requires petitioner only to show that the vaccine at issue can worsen the condition at issue rather than being its cause. *Sharpe*, 964 F.3d at 1083 (explaining that "[u]nder *Loving* prong 4, a petitioner need only provide 'a medical theory causally connecting [petitioner]'s significantly worsened condition to the vaccination.' In other words, Petitioner was required to present a medically plausible theory demonstrating that a vaccine 'can' cause a significant worsening of [petitioner's injury].")

In this case, the parties differ on the extent to which the concept of "SIRVA" can assist petitioner in meeting her burden of proof relative to her theory of causation. Consistent with respondent's view, I have previously explained:

> [W]here a petitioner alleges both an on-Table SIRVA and off-Table shoulder injury, she must set forth a theory of causation to meet her burden for the off-Table claim. *Grant v. Sec'y of Health & Human Servs*., 956 F.2d 1144, 1147-48 (Fed. Cir. 1992) (explaining with respect to cause-in-fact claims that "[s]imple similarity to conditions or time periods listed in the Table is not sufficient evidence of causation; evidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation for such a petitioner."). "The Act relaxes proof of causation for injuries satisfying the Table in § 300aa–14, but does not relax proof of causation in fact for non-Table injuries." *Id.* at 1148. The government's recognition of "SIRVA" as a vaccine-caused injury was limited by the accompanying QAI criteria and for the reasons discussed above, I have already concluded that petitioner has not met those criteria.

Layne v. Sec'y of Health & Human Servs., No. 18-57V, 2022 WL 3225437, at *18 (Fed. Cl. Spec. Mstr. July 12, 2022) (second alteration in original). To permit a petitioner to simply present the fact of the Table Injury of SIRVA as a theory of causation where that petitioner cannot meet the accompanying QAI criteria "would be to expand the causal presumption afforded by the Vaccine Injury Table." *Kelly v. Sec'y of Health & Human Servs*., No. 17-1918V, 2022 WL 1144997, at *21 (Fed. Cl. Spec. Mstr. Mar. 24, 2022).

However, consistent with petitioner's view, special masters have also observed that "the very decision to add a claim [to the Vaccine Injury Table] reflects Respondent's

determination that valid science supports revising the Table." *E.g.*, *L.J. v. Sec'y of Health & Human Servs.*, No. 17-59V, 2021 WL 6845593, at *14 (Fed. Cl. Spec. Mstr. Dec. 2, 2021). In that regard, while a petitioner must specify her injury and shoulder the burden of proving causation, *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1346 (Fed. Cir. 2010), I have previously found respondent unpersuasive in seeking to entirely block petitioners from invoking the concept of SIRVA in the cause-in-fact context. Specifically, I have explained that

> [r]egardless of respondent's argument that the broader SIRVA concept is a creature of his own rulemaking, respondent cannot reasonably argue that these studies [referring to the Atanasoff and Bodor studies cited in respondent's proposed rulemaking] which he had already himself specifically endorsed are not persuasive as support for a medical theory of causation.

Morris v. Sec'y of Health & Human Servs., No. 19-1570V, 2023 WL 5092691, at *6 (Fed. Cl. Spec. Mstr. July 11, 2023).

Here, Dr. Piontek has reasonably theorized that vaccines can cause shoulder injuries as a consequence of inflammation when incorrect administration results in an injection into the subacromial or subdeltoid space. (Ex. 17, p. 4.) Moreover, he additionally cited to the above-referenced Atanasoff study, which 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.

(Atanasoff et al., *supra*, at Ex. 28, p. 3.) This is further supported by the Bodor and Montalvo case studies, also cited by Dr. Piontek, that specifically concluded that injection into the subdeltoid bursa likely caused "a robust local immune and inflammatory response" and that, "[g]iven that the subdeltoid bursa is contiguous with the subacromial bursa, this led to a subacromial bursitis, bicipital tenonitis, and inflammation of the shoulder capsule." (Bodor & Montalvo, *supra*, at Ex. 23, p. 3.)

Thus, although Dr. Piontek's theory is only succinctly stated, it is sufficient to preponderantly demonstrate a theory of causation whereby a vaccine can cause subacromial/subdeltoid bursitis that significantly aggravates pre-existing shoulder pathology. This is also consistent with prior cases. *See Kelly*, 2022 WL 1144997;

Layne, 2022 WL 3225437; *Colbert v. Sec'y of Health & Human Servs.*, No. 18-166V, 2022 WL 2232210 (Fed. Cl. Spec. Mstr. May 27, 2022).

e. *Althen* prong two / *Loving* prong five

The second *Althen* prong/fifth *Loving* 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; *Loving*, 88 Fed. Cl. at 144; *Andreu*, 569 F.3d at 1375-77; *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* § 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) (stating that "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").

In this case, the records lack any explicit medical opinion addressing whether petitioner's vaccination exacerbated her condition. However, while the opinions of treating physicians are often favored, *Capizzano*, 440 F.3d at 1326, a petitioner may support a cause-in-fact claim through presentation of either medical records or an expert medical opinion. *See* § 300aa-13(a). Absent any explicit opinion in the medical records either for or against vaccine causation, analysis of *Althen* prong two/*Loving* prong five becomes a weighing of the competing expert opinions. And, given the analyses under the other five *Loving* prongs – finding petitioner's condition worsened post-vaccination as evidenced by a new finding of bursitis, that petitioner's expert presented a theory of causation implicating post-vaccinal bursitis as a potential cause of that worsening, and that an appropriate temporal relationship exists to support a causal inference – the primary question to be resolved under *Loving* prong five is whether Dr. Piontek is persuasive in attributing petitioner's bursitis to her vaccination or whether Dr. Abrams is instead persuasive in suggesting that bursitis can be otherwise explained.[11] Dr. Abrams raises two primary points.

[11] Even where *Althen* prongs one and three have been satisfied, the Federal Circuit has cautioned that *Althen* prong two "is not without meaning." *Capizzano*, 440 F.3d at 1327. Indeed, the *Althen* court held that "neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation." 418 F.3d at 1278. Ultimately, a petitioner bears an affirmative burden of proof to establish that the vaccine did cause the injury at issue. *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1358 (Fed. Cir. 2006). However, the Federal Circuit has also explained that satisfaction of *Althen* prongs one and three is probative regarding the presence of a logical sequence of cause and effect. *Capizzano*, 440 F.3d at 1326. The Court described the circumstances in which *Althen* prong two may be a stumbling block as follows:

> There may well be a circumstance where it is found that a vaccine *can* cause the injury at issue and where the injury was temporally proximate to the vaccination, but it is illogical to conclude that the injury was actually caused by the vaccine. A claimant could satisfy the

First, Dr. Abrams contends that petitioner's July 20, 2018 MRI was "nearly identical" to her prior MRIs and that all of the MRI findings "are expected age-related changes and not associated with SIRVA or vaccine administration." (Ex. A, p. 12 (citing Sarah K. Eustace et al., *MRI Findings in Atraumatic Shoulder Pain – Patterns of Disease Correlated with Age and Gender*, 192 IRISH J. MED. SCI. 847 (2023) (Ex. A-6)).) With specific regard to the mild bursitis documented on the MRI, he indicates that this "could simply be related to normal expected physiologic fluid" or "from a shoulder muscle strain or nerve irritation," which he indicated had been proposed by the reviewing radiologist. (Ex. C, p. 2 (citing Ex. 2, p. 23).)

Eustace et al., as cited by Dr. Abrams, did show that shoulder dysfunction is more common with aging and that bursitis is commonly present in such cases. (Eustace et al., *supra*, at Ex. A-6, p. 4.) As Dr. Abrams noted, it also suggested that in some cases "fluid within the bursa may have been within normal range, physiological rather than pathological." (*Id.* at 4.) The authors observed that "the exact cause of symptoms becomes harder to define with multiple pathologies at play simultaneously." (*Id*.) However, all of the subjects in the Eustace study were experiencing shoulder pain and nothing in the study doubts the pain-generating potential of bursitis. Moreover, examining their findings among younger patients, they observed that "generally subacromial bursitis precedes the development of supraspinatus tendinopathy" while only a minority have tendinopathy that precedes the development of bursitis. (*Id*.)

Here, as discussed in the preceding analysis, petitioner had a history of right shoulder pain dating back to 2015 with a documented diagnosis of rotator cuff dysfunction as recent as 2017. And, although Dr. Abrams opines that petitioner's cervical spinal condition also contributed to her symptoms, he opined that her presentation was at least partly explained by her shoulder pathology. (Ex. C, p. 1.) However, petitioner had MRI studies of her right shoulder conducted on August 21, 2015, and March 21, 2017, both of which confirmed the presence of rotator cuff dysfunction without any evidence of bursitis. (Ex. 2, p. 9; Ex. 3, p. 49.) It was only in the MRI study of July 20, 2018, just a little over a week post-vaccination, that any bursitis was detected in petitioner's right shoulder. (Ex. 2, pp. 22-23.) Nonetheless, Dr. Abrams cites the treating radiologist as opining this finding may be due to muscle strain or nerve irritation. However, the reviewing radiologist indicated that a finding of "amorphous edema within the teres minor" might be explained by muscle strain or denervation. (*Id.* at 23.) The finding of mild subacromial subdeltoid is recorded as a separate and distinct finding with no such commentary. (*Id*.)

The second point raised by Dr. Abrams is that if what petitioner were experiencing were an inflammatory bursitis, then her treatment with a cortisone

---

> first and third prongs without satisfying the second prong when medical records and medical opinions do not suggest that the vaccine caused the injury, or where the probability of coincidence or another cause prevents the claimant from proving the vaccine caused the injury by preponderant evidence.

Id. at 1327.

injection, which is an anti-inflammatory medication, should have abated that process. (Ex. A, p. 14 (citing Bodor & Montalvo, *supra*, at Ex. A-5; Atanasoff et al., *supra*, at Ex. A-10).). Similarly, he suggested that, because petitioner had surgery "directly targeting her shoulder pathology (and any inflammation that would have been present in a suspected SIRVA injury)," the fact that her surgery did not provide significant relief counsels against her shoulder being her actual pain generator. (Ex. C, p. 2.) This is not persuasive because the citations provided by Dr. Abrams would not support the proposition that either therapeutic injections or surgery necessarily provide complete relief and Dr. Abrams otherwise acknowledges that petitioner experienced at least temporary relief following her injection. (*Id.*) Indeed, the literature Dr. Abrams cited indicates that many subjects required multiple therapeutic injections. Atanasoff et al. indicated that while more than half of their subjects had corticosteroid injections and 31% had surgical intervention, "[l]ess than one third of patients had complete recovery while the majority of patients in this series had continuing symptoms." (Atanasoff et al., *supra*, at Ex. A-10, p. 2.) Of the 31% of Atanasoff subjects who had surgery, half of those subjects required a second surgery. (*Id*.)

Finally, Dr. Abrams's opinion is based at least in part on his understanding that petitioner's clinical course did not change post-vaccination. However, Dr. Piontek reasonably credited petitioner's medical records as reflecting a distinct change in petitioner's pain presentation following vaccination. Petitioner described a change in her pain symptoms to both Drs. Gay and Elrashidy, and to Dr. Elrashidy, she specifically attributed the change to her vaccination. Moreover, even setting aside her specific attribution, the medical records otherwise show that her pain increased post-vaccination. While she had experienced an exacerbation of pain following her April 2018 automobile accident, she had returned to her baseline. (Ex. 14, p. 2332.) However, following her vaccination, the pain she described was "extreme" and a 10 out of 10. (Ex. 2, p. 13; Ex. 3, p. 26.) Although many of the objective findings were substantially the same pre- and post-vaccination, this is less significant in the context of significant aggravation. The fact that objective findings apart from the post-vaccination bursitis would be similar is unsurprising in that I have concluded that petitioner's post-vaccination condition is simply an exacerbation of her prior condition and not a new or separate injury. As discussed under *Loving* prongs one through three, just prior to vaccination, petitioner was suffering a combination of neck and shoulder conditions, which remained symptomatic, but she was stable and had reached maximum medical improvement. After vaccination, however, she began reporting significantly increased right shoulder pain that ultimately resulted in a recommendation for surgery, which had not been an anticipated part of her treatment plan prior to vaccination. Thus, on the whole, Dr. Piontek's opinion attributing petitioner's painful bursitis to her vaccination is more credible in the context of her overall clinical course.

For all these reasons, I find that petitioner has established by a preponderance of the evidence that there is a logical sequence of cause and effect whereby her vaccination likely induced painful subacromial/subdeltoid bursitis that significantly aggravated her pre-existing shoulder pathology.

f. *Althen* prong three / *Loving* prong six

The third *Althen* prong/sixth *Loving* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281; *Loving*, 88 Fed. Cl. at 144. That term has been equated to the phrase "medically-acceptable temporal relationship." *Althen*, 418 F.3d at 1281. 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). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury. *Id.*; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand*, 105 Fed. Cl. 353 (2012), *aff'd per curiam*, 503 F. App'x 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877, at *26 (Fed. Cl. Spec. Mstr. May 30, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

Onset of shoulder pain within 48 hours of vaccination has been well accepted in the Program as an appropriate timeframe for a shoulder injury caused-in-fact by vaccination. *Kelly*, 2022 WL 1144997, at *25 (citing cases). Atanasoff et al. noted that "[o]nset of pain was reported as occurring less than 24 [hours] after vaccination in 93% and occurred immediately following injection in 54% of our cases." (Atanasoff et al., *supra*, at Ex. 28, p. 2.) The authors explained that "rapid onset of pain with limited range of motion following vaccination in our series of patients is consistent with a robust and prolonged immune response within already-sensitized shoulder structures following the injection of antigenic substances into the subacromial bursa or the area around the rotator cuff tendon." (Atanasoff et al., *supra*, at Ex. 28, p. 3.) Although Hesse et al. made similar observations, with 68.7% of cases reporting onset on the day of vaccination, the authors also noted that the "[m]edian time from vaccination to seeking healthcare was 15 days." (Hesse et al., *supra*, at Ex. 19, p. 5.)

Respondent does not provide any evidence in dispute of the medical acceptability of a 48-hour onset or to suggest an alternative medically acceptable timeframe. Instead, respondent's sole argument against petitioner's *Althen* prong 3/*Loving* prong 6 showing is a reiteration of his primary contention that petitioner's post-vaccination condition is a continuation of her pre-vaccination condition and can otherwise be explained by her pre-existing non-shoulder pathologies. (ECF No. 66, p. 32.) However, for the reasons discussed above, I find that petitioner has preponderantly established that her post-vaccination condition was a significant aggravation of her pre-vaccination condition and that the significant aggravation was vaccine-caused.

Petitioner first presented for treatment of her post-vaccination shoulder pain roughly 9 days after vaccination. (Ex. 2, p. 11.) In a handwritten new condition form associated with her initial presentation, petitioner alleged onset of "extreme pain" beginning on July 11, 2018, the date of vaccination. (Ex. 2, p. 13.) In follow up

encounters with Dr. Elrashidy, petitioner consistently related her symptoms to her Tdap vaccination. (Ex. 3, pp. 16, 21, 26.) Accordingly, there is preponderant evidence that petitioner's significantly aggravated shoulder pain began within a medically accepted timeframe following vaccination to infer causation.

g. Factor unrelated

Once a petitioner has presented a prima facia showing that her pre-existing condition was significantly aggravated by the subject vaccination, the burden shifts to respondent to demonstrate, by a preponderance of the evidence, that the significant aggravation was caused by some factor other than the vaccination. *Loving*, 88 Fed. Cl. at 144. Respondent may alternatively show that the pre-existing condition was, in fact, the but for cause of petitioner's post-vaccination condition. *Id.* In the instant case, respondent has not offered any evidence to support that another factor could have significantly aggravated petitioner's pre-vaccination condition. To the extent that respondent has argued that petitioner's pre-existing condition was the but for cause of her post-vaccination condition, as discussed previously, I find that petitioner has preponderantly demonstrated that her post-vaccination condition is a significant aggravation of her prior condition that was caused-in-fact by the vaccine.

VII. Conclusion

After weighing the evidence of record, I find by preponderant evidence that petitioner's pre-vaccination shoulder pain and dysfunction was significantly aggravated by her July 11, 2018 Tdap vaccination. Accordingly, petitioner is entitled to compensation. A separate damages order will be issued.

IT IS SO ORDERED.

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